

AN INTERVIEW WITH...

Subhash Banerjee, MD

Dr. Banerjee discusses the CPRS-CKD study, PREMIER phase 2 trial, the Cardiovascular Innovations meeting, and more.



What are the background and aims of the recently initiated CPRS-CKD study, for which you are the Principal Investigator? What led to your interest in studying this hypothesis (ie, that dual antiplatelet therapy with ticagrelor will lead to better outcomes)?

The CPRS-CKD pilot study has a main emphasis of studying various forms of antiplatelet regimens. It is being conducted completely through the Veterans Affairs' (VA) electronic medical record system (called the computerized patient records system [CPRS]). At our center, the programmers at the VA have designed a way to identify, screen, randomize, and follow patients for events within the next 12 months completely through the electronic medical record system, which is completely integrated with the patient care record management system.

This study then becomes a hybrid of testing multiple ideas, one of which is the clinical question of studying the use of clopidogrel or ticagrelor in acute coronary syndrome (ACS) patients with chronic kidney disease (CKD), defined as having a glomerular filtration rate of < 60 mL/min/1.73 m². This hypothesis arose from the published data showing a potential benefit of ticagrelor over clopidogrel in the subgroup analysis of the PLATO study for CKD patients.

We are also expanding to five other sites. At this point, the sample size is very small (400 patients), which is why it is being advertised as a pilot study to test both the clinical hypothesis and point-of-care randomization and data collection scheme through the electronic medical record.

What is the current status and latest information on the PREMIER phase 2 trial, and what was learned in phase 1? What are the unique opportunities and/or challenges that come with performing this research in the VA health care system?

The PREMIER trial's focus is on plaque progression and endothelial progenitor cell mobilization with intensive lipid elimination. The idea was to assess whether aggressive low-density lipoprotein (LDL) cholesterol-lowering immediately

after percutaneous coronary intervention (PCI) in patients with ACSs but without familial hyperlipidemia would reduce or change the progression of coronary atheroma detected by intravascular ultrasound (IVUS).

We randomized patients with ACS who underwent PCI. If they had an uneventful course 24 hours after PCI, they were randomized to intensive statin therapy. The other arm had intensive statin therapy plus a single LDL apheresis to bring their LDL levels close to zero or in the single digits. This was performed acutely during hospitalization.

The patients also underwent IVUS of a target coronary segment, and the same segment of the coronary artery was interrogated with IVUS again at 90 days.

LDL apheresis selectively removes LDL from the peripheral blood and has never been performed in nonfamilial hyperlipidemic patients, although it is an approved treatment for patients with familial hyperlipidemia and those with very high (> 200 mg/dL) LDL levels after myocardial infarction. The second novelty of this is that this was the most aggressive lowering of LDL in the peri-ACS period.

The second phase of the study was completed in July 2017, and we are going to complete the follow-up of the study in early January 2018. The analysis will probably take a few months, and then we are planning to submit the results to one of the major national meetings in the United States or Europe.

With your extensive work and research on the treatment of chronic total occlusions (CTOs) in the coronary arteries, what would you say is the latest in treatment techniques in 2017? What are you most excited to see happen next, and how do you see therapies evolving over the next 10 years?

Performing a CTO procedure, both for treating coronary and peripheral artery disease, is no longer viewed as something out of contemporary practice. The reality is that if there are rigorously tested clinical indications, CTO procedures in patients can be performed extremely safely. If people dedicate themselves to these procedures, the complication and success rates can be dramatically improved over

(Continued on page 96)

(Continued from page 98)

a relatively short period of time. Therefore, the development of this technology and honing of skills has a direct effect on improving patient safety and clinical outcomes.

It is becoming fairly widespread and acceptable for fellows in training to either go to courses or practicing interventionalists to develop CTO programs at their centers. There are a lot more CTO programs today than there were 5 years ago.

This clinical success would not have happened had there not been a focus on developing coronary CTO guidewires, balloons, specialized balloons, and devices, along with low-profile catheters. Our center is involved in testing these devices and conducting comparative effectiveness research.

The PROGRESS CTO Registry is a large registry that accumulates patient data from more than 11 centers and is led by my ex-partner and friend, Dr. Emmanouil E. Brilakis, as the Principal Investigator. Patients have been enrolled in close to 2,500 coronary CTO procedures, which has provided cues as to where the areas of maximum impact can be in terms of recognizing potential problems or developing new technologies. This has been the source of a large number of publications. I encourage more CTO operators to come and become a part of this movement and join the registry.

On the peripheral side, I am the Principal Investigator of the XLPAD registry that currently collects infrainguinal peripheral interventional procedural data and outcomes from 15 United States centers that are independently adjudicated by our core lab. The registry has more than 3,300 patient procedures (approximately 56% are CTOs). The XLPAD registry has become a recognized source of peripheral intervention publications and presentations in the United States and around the world.

In which patients do you consider a full metal jacket (FMJ) to be a reasonable approach to treating CTOs? What concerns, if any, do you have about using this approach?

It is extremely important to say that a FMJ is defined as coronary stenting that is continuous and extends beyond 60 mm in length. Such interventions, if performed in the territory of the left anterior descending artery, could deprive the patient of the option to undergo coronary artery bypass surgery. Therefore, in most clinical studies, FMJ stenting is mainly performed in the right coronary artery for the treatment of CTOs or severely diseased vessels.

In terms of their outcomes, it is undoubtedly true that the overall patency is lower and the need for repeat intervention could actually be higher. Apart from the length of the stent placed, in the study I reviewed, it was surprising that one of the important predictors of patency of these long-stented segments was the caliber of the distal vessel.

If the outflow of the stents is compromised and the distal vessels are diffusely diseased, or if the flow is compromised or there were dissections, outcomes are generally worse. The health of the distal vessel and distal flow is an important predictor of clinical outcomes.

One of the main reasons why long stents are often placed in a CTO with diffuse disease is because sometimes there are no normal or near-normal landing zones for stents. So, operators keep extending the stented segment. There are initial case reports that discuss how practitioners are revascularizing a CTO with a distal small vessel outflow by not extending the stents far into the distal vessel. These vessels then actually grow over time at follow-up angiography.

As a member of the Board of Directors for the Cardiovascular Innovations meeting, which was held in Denver, Colorado, what were some of the highlights from this past year, and what do you hope to replicate or do even better for this coming year?

Along with three of my codirectors, we were on a mission to create a meeting with features that would help fill an important void. We always felt that when interventional clinical studies are presented and data are reviewed at large medical meetings, there is often a learning gap regarding how to execute and reproduce the study results for their own patients. For interventional cardiology, this relates to specific skills, techniques, strategies, and competent handling of various devices.

We felt there was a gap in terms of providing more hands-on and in-depth technical education. Our first mission was to fill this gap and make our meeting more about technical skills and technical aspects of coronary, peripheral artery, and structural heart interventional procedures and focus on problem solving and tackling complications.

Another emphasis of our meeting is to support and energize medical students, residents, fellows, and early career faculty interested in interventional cardiology practice and research. We accomplished this goal by fully supporting access to the meeting for 150 fellows and residents; that benefit was also extended to early career faculty who were within the first 3 years of their clinical practice. The Cardiovascular Innovations meeting in 2018 is again going to be in Denver at the Grand Hyatt Hotel between July 26 and 28. Information is also available at www.cvinnovations.org.

What made you decide to focus your expertise in high-risk PCIs with hemodynamic support devices?

One group of patients who somehow do not always get revascularized, but who are most likely to benefit,

includes those who have ischemic cardiomyopathy, diffuse and multivessel coronary disease, and extremely challenging coronary anatomy, but with severely reduced left ventricular ejection fraction and compelling symptoms. These patients often have advanced angina, large areas of ischemia, or heart failure. Unfortunately, coronary artery bypass surgery is not always a viable option for these patients. Therefore, performing high-risk PCI in this group of patients requires advanced skills and a team approach. Our team at the VA North Texas and University of Texas Southwestern Medical Center is invested in developing a highly successful high-risk PCI program.

Hemodynamic support devices are an important component of high-risk PCI programs that allow us to successfully and safely accomplish these high-risk procedures. These devices, especially the Impella device (Abiomed, Inc.), have undergone a series of technological advancements that have made the delivery and removal of the device very safe and easy to accomplish with some training. Currently, these devices allow more complete revascularization in a cost-effective manner by reducing the length of hospital stay.

We read that you enjoy the strategy of chess and at one time even considered it as a professional career. Can you describe how the strategy/experience with chess has influenced your approach to interventional cardiology?

I have always enjoyed chess since my middle school days, but I didn't realize thinking and planning far ahead had become a part of my lifestyle. This is something that I carry with me, not just during procedures, but also in real life; I always try to weigh a situation and thoughtfully interpret available options and gain perspectives of those around me before acting or responding. It's a rigorous sport like any other, requiring continuous training, honing of skills, and above all, it fosters discipline. I simply wish I had a few extra hours a week to devote to this life-long passion and play with my son who also has a keen interest in the game. ■

Subhash Banerjee, MD

Professor of Internal Medicine
University of Texas Southwestern
Dallas, Texas
subhash.banerjee@utsouthwestern.edu
Disclosures: None.
