Ajay J. Kirtane, MD, SM

Ajay J. Kirtane, MD, SM, talks about TCT's 2009 move to the West Coast, challenges in interpreting clinical trial designs and data, and one of the most rewarding moments in his practice this year.

What led to the decision to move the Transcatheter Cardiovascular Therapeutics (TCT) meeting to the West Coast, with this year's session being held in San Francisco?

This was actually an idea proposed by Gregg W. Stone, MD (one of my colleagues and partners and Director of TCT along with Martin B. Leon, MD). As you may know, Dr. Stone spent a fair amount of time in practice on the West Coast, and he believed this would be a way to appeal to West Coast physicians who might have a difficult time coming to DC for TCT. That was the initial inception of the idea; after we thought about it a bit more, it seemed to be a great way to change the vibe of the meeting and increase exposure to some of our colleagues in the Asia-Pacific region, for whom the West Coast would be a much shorter trip. San Francisco is a fantastic city, and, not to detract from the value of DC, but we believed it would be an interesting breath of fresh air. For me personally, San Francisco is a fantastic location because I spent 4 years there during my Internal Medicine residency at the University of California San Francisco, and I am looking forward to getting back.

What are some of the more pervasive questions that the TCT scientific committee hoped to address when inviting the presentations for this year's peripheral vascular sessions?

TCT is a very broad meeting, and there are many goals we try to accomplish each year. My colleague and partner, William A. Gray, MD, directs the endovascular portion of TCT, and from an endovascular standpoint, we first try to increase overall exposure for the types of cases that are currently being performed in the periphery. As a result, there are a fair number of case-review sessions with expert discussants from around the world. There is also a series of how-to sessions, which are great for those who are just trying to get started in peripheral interventions or need a refresher course. And of course, there are updates and discussion/controversy sessions, where data, as well as the need for data, are discussed.

The endovascular sessions at TCT are difficult to organize because TCT is not a niche peripheral meeting, and people who attend the peripheral sessions come from a broad variety of backgrounds. We always hope to have something that appeals to everybody and are very excited about the evolution of the program this year.

At TCT 2009, you will be a lecturer and panelist in a session discussing clinical trial design and interpretation, a very important topic in the current practice of medicine. What are some of the reasons why not all trials are created equally?

This is a complicated issue. Some trial investigators do not have the resources—either financial or a fund of knowledge—to be able to create well-designed trials in the increasingly sophisticated environment in which we live. On the other hand, there are certain trials that are under regulatory auspices—for example, of the US Food and Drug Administration (FDA); these are often of the highest quality overall but are very expensive and complex to run. The majority of clinical trials are not conducted under regulatory auspices, and perhaps (although not necessarily) may not be executed as rigorously. The bottom line is that if careful attention is paid up front—before the trial is conducted—to rigorous study design attributes including inclusion/exclusion criteria, sample size, and power, following a frank assessment of the trial's overall goals and objectives, good clinical science can result.

What about studies conducted outside the United States?

There are certainly many good trials that are conducted outside of the United States. However, one of the issues that often comes up is that regulatory requirements outside the Unites States are typically more lax than those of the US FDA, and devices can enter non-United States markets much sooner. There are often no requirements, therefore, to do a randomized, controlled

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study of a device in order to receive approval outside the United States. It is to some of our non-United States colleagues' credit, in fact, that these trials do actually get performed despite the fact that they are not required by any regulatory body. However, I think that because the United States requirements are so stringent and are required for approval here in the States, many United States physicians often wait for the large, FDA trial to come out before really passing judgment on whether or not a device or drug is truly beneficial.

When interpreting published or presented data, how can physicians be sure whether or not the data truly support the stated conclusions?

I think this is the perhaps the most difficult aspect of clinical trial interpretation because it can be so nuanced. It takes time and a certain degree of familiarity with statistical methodology to read and understand a study's methods/design, and sometimes it is actually quite difficult to find detailed information regarding a trial's design. Particularly with limited time and limited resources, it is often easier to listen to "expert opinion" or media sound bites rather than to perform a detailed study of a trial's inclusion/exclusion criteria and design. I do think, though, that it behooves us to do so, particularly given that so much often rides on these trials in terms of our interpretation of them and what this means for our patients.

Based on the collective experiences in the coronary arteries, as well as previous and ongoing peripheral studies, what potential do you see for drug-eluting stents (DES) in the periphery?

There are data that suggest that coronary DES-type stents can work well in focal infrapopliteal lesions. The superficial femoral artery is always a difficult area for stenting because of all the motion and the greater plaque burden that is there, and there are some conflicting data for DES use in that area. I think there is obviously some excitement over the use of drug-eluting balloons in the superficial femoral artery, but we need larger and additional corroborative studies to sort that out. Overall, we know that DES do reduce late lumen loss and can reduce restenosis in the coronary bed, and there is always hope that they will do the same in the periphery if some of the biomechanical issues can be sorted out.

What are your thoughts on when and how stenting should be used in patients with renal artery stenosis?

The key issue with renal artery stenosis and stenting is patient selection. It is difficult in an all-comers study to show a benefit of stenting, particularly given that selection bias can greatly affect enrollment in randomized clinical trials. Many nonrandomized experiences show that there can be significant benefits in selected patients with regard to hypertension control and slowing the progression of renal disease. Obviously, not every patient with hypertension and renal artery stenosis should have a renal stent, and not every patient with progressive renal disease should have a stent, but there clearly are patients with either or both of those conditions who could benefit from a stent.

My typical criteria for renal artery stenting are patients with renal artery stenosis who have severe refractory hypertension despite multiple medications or patients with bilateral disease and renal insufficiency. Overall, I try to stick to guideline-based recommendations, but I think that even within the scope of guidelines, there will be nuances that dictate that good clinical judgment gets used.

What do you consider to be the most rewarding procedures you perform?

I perform both coronary and peripheral interventions, and I would say that the reward is not limited to one particular vascular bed. I think in general for a proceduralist, the greatest reward occurs with procedures that are performed on the most symptomatic patients—for instance, patients with critical limb ischemia or with severe disabling angina or ST-elevation myocardial infarction. Revascularization of these patients is potentially life-saving and can really affect patients' quality of life.

In terms of clinical "bang for your buck," though, I believe the most impressive cases often occur in the periphery because vascular disease is so often underdiagnosed and because the disease can sometimes be so extensive. I recently treated a patient with bilateral iliac disease and severe claudication. His physicians had managed him medically for years (never diagnosing vascular disease). His iliac arteries were occluded bilaterally with fairly complex disease, but I was able to revascularize him percutaneously with iliac stents. His referring physician just called me last week (about 10 days after the procedure) and made a point of telling me that the patient wanted to be sure to send his thanks because he was able to go for a walk outside for the first time in 10 years. That was pretty nice to hear. ■

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