

Society for Cardiac Angiography and Interventions

Steven R. Bailey, MD, FACC, FSCAI, President-elect (2009–2010) of the SCAI, discusses the results of SYNTAX and HORIZONS AMI, the society's plans for 2009, and his thoughts on future studies.

Cardiac Interventions Today: SYNTAX and HORIZONS AMI seemed to be the big topics at TCT this year. What is your take on them?

Dr. Bailey: SYNTAX provides two important lessons. The first, and possibly the more enduring, is a better method of communicating about patients among the entire cardiovascular care group. We have recognized for a long time that three-vessel/left main disease is actually a constellation of disease processes that range from relatively low-impact/low-risk to high-impact/high-impact patients. When you discuss a three-vessel/left main patient with a colleague, the term *three-vessel/left main* is insufficient to convey the details that affect your clinical choices. SYNTAX has given us a way to look at left main disease and quantitate in an ordinal scale what that vessel disease actually is. We are then able to think in a more critical fashion about how we should begin to approach patient care for this degree of atherosclerotic burden.

Second, because we now have a way to think about and stratify patients, we can begin to ask the important questions about comparison of care. So, when we talk about studies that allow us to think about medicines versus CABG versus PCI, we can be better at asking and answering questions about what that means in patient groups and matching those more specifically. We have been very good at the demographic matching (ie, how many patients have diabetes, how many have hypertension, how many smoke, how many have had previous heart attacks). But, we have not been able to accurately look at the actual ischemic burden. I think COURAGE is a great example: in COURAGE, what we are now post hoc is that ischemic burden clearly identifies individuals who are at risk and

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may well separate out the benefits of treatment much better than this global demographic matching.

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HORIZONS AMI is a trial that gave us a lot of insight into a question that arose in 2006 about how we should be using drug-eluting stents (DES) and if we are putting our patients at increased risk by using DES in the most complex lesions compared to using bare-metal stents (BMS). We need to look back to the 1993 to 1995 period when we asked that same question about BMS compared to angioplasty because we were concerned then that putting BMS in this very acute milieu may predispose patients to increased problems compared to just performing balloon angioplasty. I think HORIZONS answered that question very specifically and with a reasonably sized database to give us statistically valid numbers that say the following: yes, patients with acute MI who are treated have different outcomes than those with chronic stable angina. Those outcomes include subacute stent thrombosis, which is increased at the same level in both groups. But, if you compare DES to BMS, at least as employed in the HORIZONS trial, there was no penalty paid with respect to acute complications by using DES and, if we factor into that how patients fared subsequently in their clinical course, DES in

this patient population continued to convey benefit with regard to not having to undergo subsequent lesion revascularizations. I think there is no doubt about the acute safety. I think that HORIZONS, because it only carried out to 1 year and questions have been raised about late events, will have to be followed longer.

Cardiac Interventions Today: How are plans progressing regarding the SCAI meeting in 2009?

Dr. Bailey: Planning for the meeting is proceeding spectacularly. The organizing committee is doing a great job, and the program and educational content are exactly those that our members have expressed a desire to be included. The meeting continues to address the educational needs, both didactic and practical, that the interventionists working every day in the cath lab need. It will include cutting-edge research and practice, the incorporation of simulators into practice, live cases, and all of the components that will help our members practice better interventional cardiology.

Cardiac Interventions Today: What else is SCAI planning for 2009?

Dr. Bailey: The Society continues to focus on two fronts. The educational efforts remain paramount for us, and those efforts are at all levels. The Society is appropriately proud of having been at the forefront of helping to fund the interventional cardiology fellowships. There are no funds for subspecialty fellows through the current pathways; all the funds that are available are used for residents and interns and for general cardiology fellows. The Society has been instrumental in identifying funding sources. Those funds are dispersed in a competitive evidence-based fashion. We have a Fellows course that is the foundation of interventional cardiology, both in the educational content and the tactile/hands-on component, and we are beginning to marry those early on in the training of fellows to ensure that they have a common basic level throughout the US and North America. That really helps to move the field along when all of the Fellows start out with these great basic concepts of what interventional cardiology entails.

The Society continues to support the credentialing process by having the SCAI/ACC review course. Now, with the need for those of us who took the first course needing to begin the maintenance of the certification (MOC) process, we have been very active in developing and helping people understand how those MOCs proceed.

Beyond that, if you look at the courses in the US and, in fact, throughout the world, that address interventional cardiology, the SCAI has been an important part of partnering in all of those courses.

Also incredibly important is advocacy. The SCAI has been a strong voice in advocating quality of care, measuring quality of care, and appropriate compensation for ongoing care. It is important for our members and the cardiology community as a whole to understand that.

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Another initiative that is just as important is the establishment of a patient and primary-care physician education resource. Secondscount.org is an initiative that allows individuals to access information about their care, and it has grown very rapidly. We are proud of the fact that we received a grant from Google. It is a statement about the impact that has been seen on the Web from this site. The SCAI is not only focused on our own interventional cardiology colleagues. We are making sincere efforts to improve the delivery of care for everyone.

Cardiac Interventions Today: How did the Cardiology Fiesta meeting go?

Dr. Bailey: Cardiology Fiesta was extraordinarily successful this past year. It is also part of the partnership organization associated with SCAI. I think it illustrates that SCAI's commitment is not just about interventions—it is also about the spectrum of cardiovascular care. We were very excited about the success of Cardiology Fiesta because it brought the spectrum of cardiology, including newer interventional technologies, into a regional format, which made it more accessible. I think that has become increasingly important: the opportunity for individuals to not have to take so much time off from their practice to attend the large meetings. Having the chance to interact with national and international experts in these areas, in a smaller and more intimate environment has been very well received.

I think this has been part of the SCAI forum for a long time; the mentored, one-on-one approach in which you can actually have a discussion with the experts and get your specific question answered rather than in a large forum, which may not result in a lot of interaction.

Cardiac Interventions Today: Last year, we interviewed Dr. Bonnie H. Weiner about COURAGE. Has the message about COURAGE been delivered to physicians?

Dr. Bailey: All of these messages are continuing processes. People are now beginning to understand that COURAGE is a very focused evaluation of a very narrowly defined population that had extraordinary care. The challenge that we have is the American perspective of only looking at headlines. The main problem that remains with COURAGE is that entire datasets are encapsulated into an editorial headline. How do you discuss data that are presented as only 60 characters of type?

Having said that, yes. From the SCAI perspective, people are becoming much more understanding of the difficulties in generalizing these very narrowly focused studies to everyday care.

Cardiac Interventions Today: The original release of the SCAAR data in 2007, resulted in a dramatic decrease in DES usage due to concerns about in-stent thrombosis. Have misperceptions regarding the original SCAAR data publication been rectified?

Dr. Bailey: As often happens, when these initial data were reanalyzed, there clearly was a change in their conclusions. People have come to understand that the problem with data is that the smaller the dataset, the less scrubbed the data are and the more difficult it is to draw meaningful conclusions from it. In small datasets, it is not hard at all for the original conclusions to change.

Cardiac Interventions Today: What studies and new technology are most needed in the cardiology space?

Dr. Bailey: We continue to move into, not only coronary studies, but also endovascular studies, as well as structural heart studies. I think that the carotid stenting and stroke areas are examples of where we continue to look for new data. Of course, the conflict is always how to define a study that has appropriate endpoints in a dataset that is accomplishable. It is increasingly difficult to design an accomplishable, fiscally possible trial. I think that the percutaneous valves are a good example of this question about how to understand the outcomes, how to compare between outcomes, and how to appropriately weight events. Going back to SYNTAX, the inclusion of stroke clearly was one of those endpoints not previously considered that had an important impact on numerical outcomes. We probably need to ask about a weighting scale. That is, if a patient has a creatine phosphokinase (CPK) rise that is twofold greater than normal, it would count as an event. A stroke would also count as an event. But clinically, the impact of a 2.2-fold CPK elevation is extraordinarily less than that of a stroke. As we design studies, we need to think more about how we weigh events.

In terms of new technology, things have been pretty static with endovascular devices. We have developed better polymers and the next generation of drugs, but I think the concept of vascular healing remains paramount. Therefore, technology that will allow us to achieve appropriate healing of an artery is clearly an area people are beginning to look at. As we have gotten better at treating heart attacks, we need to be aggressively pursuing what we should do about that damaged heart muscle. There is a whole arena regarding therapies for regeneration of cardiac muscle that is not moving ahead as rapidly as any of us would like.

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Cardiac Interventions Today: CMS recently announced their decision regarding carotid artery stenting? How has that decision been received by the SCAI, and what will be the impact on physicians and patients?

Dr. Bailey: We understand, as has been presented both in the vascular literature and from data developed looking at carotid stenting, that the majority of individuals who are candidates for the opening of blocked carotid arteries are actually asymptomatic—the risks are significant enough in the asymptomatic population that they should be treated, the FDA agreed with that in their labeling, and typically, eight out of 10 patients are affected. The fact that the CMS is requiring symptoms in order to reimburse for a procedure that is already FDA approved, and for which the data demonstrate that this is true in asymptomatic patients, seems not to be in the best interest of patients. That is the SCAI's position. Given the data, including the recent long-term reviews of the data, the patients clearly benefit from these procedures. Also, this is concordant with what the surgical literature has shown for a long period of time. The SCAI remains in support of improved patient outcomes, and the current data would seem to support both symptomatic and asymptomatic patients receiving these procedures. ■

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