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The President of the SCAI discusses society goals, details this year's annual meeting, and provides insights into the COURAGE trial.

There have been some changes at the Society for Cardiovascular Angiography and Interventions (SCAI) with respect to the annual meeting. Please tell us about those changes.

This year, our annual meeting is being co-located with the American College of Cardiology (ACC) in Chicago, as opposed to our usual May meeting. The reasons for this change are multiple, but the goal is to ultimately develop a single, spring interventional meeting with all of the stakeholders in interventional cardiology. Given the timing of when our meeting was supposed to have taken place this year, we felt it was to the interventional community's advantage to move the meeting to earlier in the season. This move will allow us to take advantage of some of the science that will be available at ACC earlier in the spring.

Do you mean science relating to data from trials that will be presented at ACC? That is part of it. But because it is a larger venue, we will also be able to add some of the characteristics of a larger meeting, which is the direction we want to go in terms of live cases and a larger international presence.

What is the current size of the society? We have approximately 4,000 members, most of whom are North America or US based, and close to 10% are internationally based.

Are there other societies that incorporate the same membership? Most of our US and Canadian members are also members of the ACC because to get to interventional training in the US, you have to go through conventional cardiology training. Therefore, most of us are also ACC members. However, there is no other organization totally focused on invasive and interventional cardiovascular diseases.

Is TCT the co-host of the interventional component of this year's ACC meeting? They are not this year. Although

many of the Cardiovascular Research Foundation members are members of the SCAI, and as part of their role of Society members, they are participating in the planning and development of the meeting but not as a separate organization.

Is the combined meeting part of the i2 summit this year? It is not. This is the SCAI's annual scientific session in partnership with the ACC i2 session. Because our meeting and i2 were each partially planned before we jointly came to this understanding, it was decided that we would try to blend the different components. The

only two formal organizations that are actually planning this merger are the ACC and SCAI. The dates are not coextensive. We are actually starting 1 day (Saturday) before the main ACC sessions begin. What we are looking forward to in the future is engaging all of the other organizations in a meaningful way so they can be part of this larger meeting.

What is the SCAI's position on the results of the COURAGE trial? I think there are a couple of things to discuss about

COURAGE. First is the medicine versus percutaneous coronary intervention (PCI) conflict, in which the kinds of medicines we are talking about are part of normal management of patients with coronary disease even if they receive a stent. It has never been one treatment or the other. The issue really is whether PCI in conjunction with optimal medical therapy offers benefit in terms of death and myocardial infarction (MI) to these very select, stable patients who do not have a lot of angina. Keep in mind is that interventional cardiology has never professed that any revascularization strategy, particularly PCI, in the type of patients we are talking about, reduces mortality or incidence of MI. The premise of the COURAGE trial was to answer a question that we were never asking. We knew that was never the intent.

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If you look at symptom relief and quality of life, which is what PCI and other revascularization strategies seek to provide, it is really a different story. In terms of improving quality of life and providing symptom relief, it is clear that PCI is effective. In particular, in the current era of drug-eluting stents, in which restenosis is less of a problem, there is clearly longevity to that reduction in symptoms that was not manifest in COURAGE because only approximately 30 patients received drug-eluting stents.

One of the banes of large randomized trials, which are incredibly valuable, is that they frequently test technologies that have been surpassed by newer technologies by the time the results are actually presented. That is simply the nature of the beast and should always be kept in mind when interpreting the results. If we look at drug-eluting stents as one thing that could have potentially had an impact on the results of COURAGE, not in terms of death and MI, but in terms of symptom relief and the maintenance of symptom relief, then the 20% of patients who had repeat revascularization in COURAGE would probably be much smaller with drug-eluting stents. Therefore, the symptom relief observed would have been more dramatic.

One of the other messages about COURAGE that patients, their primary physicians, and general cardiologists need to understand is that COURAGE addresses only stable angina. When we talk about unstable angina, acute coronary syndrome, and acute MI, there is no question that PCI saves lives and improves quality of life. We do not want patients and physicians to take home from COURAGE the belief that those patient populations should not be sent on for revascularization.

Do the results of COURAGE create a change in practice patterns? Not really. Frankly, the results of COURAGE are actually in line with what the guidelines currently state. If we have been practicing by the guidelines, there should be no change in practice.

Was the COURAGE trial the first study to come to this conclusion? No. If you look at all of the trials comparing revascularization versus medical therapy, going back to the original surgery study (CASS), which showed that in left main and multivessel disease, as well as impaired left ventricular function, it has been definitely shown that revascularization does save lives. All the other trials of PCI versus medicine show the same thing: no difference in death or MI. Yes, there was symptom relief but at a cost of repeat procedure before drug-eluting stents. Now there is a significantly

reduced need for repeat revascularization events by retarding restenosis. When we look at the current trials, including COURAGE, it is still the same message. It was never a question that any of us were particularly concerned about asking because we already had the answers.

What percentage of PCI patients are represented in the COURAGE study? Overall, if you look at the current number of patients with coronary disease, approximately 90% are currently being treated medically, and the other 10% are receiving some sort of revascularization strategy. In fact, these are the same numbers seen in COURAGE in terms of the number of patients actually randomized. In round numbers, 35,000 patients were screened, 3,000 were actually eligible for the trial, and the other 32,000 were excluded, mostly because they were too unstable, had complex disease, or had some other indication that necessitated revascularization based on clinical presentation. It is also important to realize that in COURAGE the patients were not enrolled until after angiography, the results of which would have dictated an invasive strategy in many of these patients. A small group of patients actually end up being in that revascularization group for stable angina, given the overall number of patients who have coronary disease.

One of the interpretations of COURAGE was that there are many unnecessary interventions being performed. This just is not the case, and never was. The interventions performed are based on quality of life, intolerance to medication, and symptom relief in appropriate patients.

What effect does the patient's willingness to partake in best medical therapy affect treatment decisions? It affects it a lot. If you look at the COURAGE patients, they had optimal risk factor interventions. They were very good to start with (they improved over the course of the trial) in terms of lipids, control of diabetes, weight control, and so forth. That is another element to COURAGE that must be considered. The COURAGE study population comprised half from the Veterans Affairs system and half from Canada, meaning most of the COURAGE sample received their medications essentially for free, so their ability to afford medications was not an issue. This is rarely the case with insured or uninsured patients in the US. Some of the data, in economic terms, suggest that patients who have to pay for a significant part of the cost of their medication are less likely to take all of the medications prescribed.

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Also, COURAGE does not deal with the patient population that is intolerant of some of these medicines. Medicines are great and do not have a lot of side effects; however, they do have some side effects—some patients cannot take them. We are also talking about a medical regimen that is very complicated.

It was at the European Society of Cardiology meeting last year that we first heard the bombshell that drug-eluting stents were going to kill more patients than bare-metal stents. Where does this controversy stand now? We have a plethora of information, including a reversal from the original trial at this year's ESC, that demonstrates there is no disadvantage of drug-eluting stents over bare-metal stents, particularly in patients in whom optimal stent deployment and experience is involved. Operator experience has been shown to be a significant factor. Early in the drug-eluting stent experience, there was a sense that they were just another stent, and you could place them the same way you place bare-metal stents. We now know that is not entirely true due to factors such as the polymer and other characteristics specific to drug-eluting stents. With each subsequent year of data collected regarding drug-eluting stents, the results become better and better, suggesting that there is a learning curve, either in terms of the way we place these stents, experience in general, patient selection, the use of dual antiplatelet agents, or a combination of some or all of these factors.

In addition, we are seeing more and more evidence that drug-eluting stents are safe and outperform a medications-only regimen. At the AHA meeting, the MASS Stent trial showed drug-eluting stents are not only safe but also have a mortality benefit over bare-metal stents. This study is very important for a number of reasons. First, it was a very large trial, containing more than 20,000 patients conducted over 2 years. Second, I think of it as a real-world study because the patients were not carefully selected, as you find in randomized clinical trials, and the hospitals were representative of how interventional cardiology is really practiced in the US.

And then there was the nuclear substudy of COURAGE, also presented at AHA, which used SPECT imaging to show that patients with moderate-to-severe but stable ischemia do, despite earlier pronouncements from COURAGE, benefit from having their clogged arteries opened up by PCI. This substudy found that 33% of patients who underwent PCI and took medications had their ischemia, which carries risk

even in stable patients, reduced by 5% or more. This was in clear contrast to the medications-only patients, only 19% of whom experienced such reduced ischemia.

There is a clear difference between the mechanics of drug-eluting and bare-metal stents. There is no question that drug-eluting stents, because of their design, may not expand as well their bare-metal counterparts. I do not think we realized that early on. I think there was a different sense as to how meticulous you needed to be in placing drug-eluting stents because we were used to dealing with restenosis. Now, with drug-eluting stents and the fact that we do not have the same endothelialization on drug-eluting stent struts, the presentation is no longer restenosis to the same degree, but late thrombosis. It is evident now that there are technological differences that we did not appreciate, which was part of the learning curve.

The original study report sent shockwaves through the industry and physician community. Has the revised message resonated in the community as loudly as the original message? It has not—at least not so far. That is exactly the problem, and we are trying to change it. The initial, alarming data made headlines, but the recent, reassuring data are buried on page 20. It's not newsworthy any more. Part of our goal and responsibility as the professional community is to clarify these facts for our referring physicians, our members, and our patients. We do not want patients to be unnecessarily concerned about this. Yes, there are some risks, as there are in all medical procedures. Yes, they do need to take dual-antiplatelet agents for a year or more. But, the fact is there should not be fear of getting a drug-eluting stent. Putting it into perspective, a 50% reduction in restenosis is a real phenomenon; it is not subtle. Compare that to a .5% per-year incidence of late thrombosis. The orders of magnitude are so dramatically different that now, with all of the data available, we can be very confident in saying that, although late thrombosis occurs and is a problem when it occurs, the major predictor is premature cessation of dual-antiplatelet agents. If we do a good job placing stents and selecting patients, and our patients are compliant with drug therapy, they will do very well with drug-eluting stents.

At AHA this year, SCAI launched www.Seconds-Count.org, a new Web site aimed at providing accurate, balanced education for patients and noninterventional healthcare professionals. Seconds-Count.org will

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address some of the issues and misconceptions that we have discussed here. SCAI's goal is to disseminate the kind of balanced, responsible information that is useful to patients, their families, and referring physicians.

We understand our noninterventional colleagues do not read the cardiology literature. They see the same headlines that patients do and are not receiving the follow-up data that show how many of the findings about drug-eluting stents have been reversed in just 1 year.

Is there any subset of patients for whom bare-metal stents are the recommended therapy? Certainly bare-metal stents are recommended in patients who are intolerant of dual-antiplatelet agents, as well as patients in whom it is known that a surgical procedure is going to be necessary in the short term, which would require removal from dual-antiplatelet therapy before the recommended year.

A common placement for bare-metal stents is in the acute MI situation. Because of our goal of rapidly reopening those arteries, we do not have the time to have the dual-antiplatelet compliance discussion with patients and their families. There have been data presented that show drug-eluting stents to be safe in such situations, but when we cannot have that discussion and we think that the bare-metal stent is a reasonable option, it is common to go with placement of a bare-metal stent, at least in the US.

What future drug-eluting stent technologies need to be developed to address lesions that currently cannot be treated? Currently, the only lesions that may not be best treated with drug-eluting stents are some of the distal left main or bifurcation lesions. In general, for both drug-eluting and bare-metal stent designs, we do not yet have good bifurcation stent technology.

Perhaps bioabsorbable stents will come into play in the future because a potential safety benefit could be the result of no foreign body left in the vessel to cause late thrombosis. Development of new polymers could also play an important part in reducing vessel reaction. I think there is a whole host of technologies that will be available in the future that will not only be as effective but also safer than what we are currently using. This is the extraordinary thing about the history of interventional cardiology. Since Andreas Grüntzig performed the first coronary angioplasty 30 years ago, the specialty's pioneers have continued to innovate, developing more effective technologies for every challenge we have encountered. ■

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