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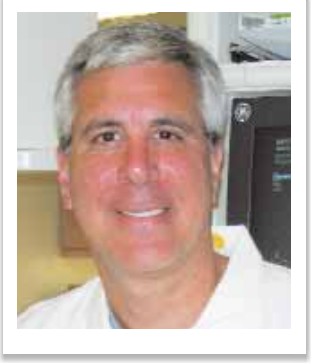
Cardiac Interventions Today talks with one of today's leading interventional cardiologists about his recent work, the future of coronary interventions, and his personal experience as a principal investigator.

Please tell us about your program at Washington Adventist Hospital.

When we first started the program at Washington Adventist Hospital, we wanted to be as inclusive as possible, so we tried to work very closely with almost all of the physicians that use the cardiac catheterization lab. Although we have certain site principal investigators and sub-investigators, we do try to get everyone involved in the newer technologies, which has led to some of the successes that we have had in enrolling patients into trials. We have one head research administrator who oversees the department and two regulatory experts who help us with our institutional review board submissions and other regulatory issues. We also have four accomplished research coordinators who work hard at looking for patients for our clinical trial program. Each of the research coordinators is assigned a certain number of trials so that they are focusing their efforts on particular areas. On any given day, our institution will have upward of 20 to 25 active registries or clinical trials. It is a very robust program, and its breadth is very broad.



What is the current focus of your research energy?

We continue to have a broad scope of research efforts. Certainly, we continue to look at drug-eluting stents (DESs) and try to improve and move forward with regard to DES technology. We are involved in SPIRIT IV, which is evaluating the Xience V (Abbott Vascular, Santa Clara, CA) stent versus the Taxus Express stent (Boston Scientific Corporation, Natick, MA); this trial is coming near completion. We are also working on many of the postmarket registries and will be involved in the Xience V USA Registry.

Another area that we are focusing on is heart failure management. We are involved in the CHAMPION trial, which is assessing the use of a monitoring device (CardioMems, Atlanta, GA) that sits within the pulmonary artery to help sense changes in pressures within the heart. We are very involved with Abiomed, Inc. (Danvers, MA), which is evaluating its Impella 2.5 catheter for the high-risk percutaneous coronary intervention (PCI) indication, as well as acute myocardial infarction patients. I think this will provide some answers to its benefits over intra-aortic balloon pumps and help with left ventricular salvage.

We are also working on some pharmacology trials, mainly evaluating clopidogrel duration, the issue of clopidogrel nonresponders, and some of the new thrombin-receptor antagonists. We also have some site-specific protocols looking at the issue of vulnerable plaque, and we are working with some companies to evaluate technologies to identify vulnerable plaque.

What is your take on the debate between medical therapies versus PCI in stable coronary artery disease?

In my mind, not now or ever, was there much of a debate. First, it has never really been about medical therapy versus angioplasty. In our catheterization lab, no one places a stent and then says that medical therapy is not necessary. It is not one or the other; it is a combination of both. We need to be aggressive with our PCI patients with regard to medical therapy, and we need to refer medical therapy patients to PCI when indicated. There has been such mass misinformation about trials such as COURAGE that it has been very difficult to glean an accurate take on the facts.

The issue with COURAGE that we need to keep in mind and keep explaining to primary care referring physicians and the public is that patients were randomized after angiography. Because patients were randomized after angiography, COURAGE looked at a very select patient population that actually received med-

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ical therapy. You can see from the start how many patients overall were excluded after angiography to find the number of patients who were ultimately enrolled into COURAGE. We should have never seen, in the US, a decline in the number of coronary angiographies performed, as we did when the data from COURAGE were reported. We have missed out on many patients, and I would bet that we have lost some lives of patients with unrecognized left main disease who were being treated with medical therapy who would have been better evaluated by undergoing diagnostic catheterization. I would raise the case of one particular patient of late who has been highly publicized, that is Tim Russert. I think his death is a real example in which possibly an earlier move to diagnostic cardiac catheterization might have aided Mr. Russert in his medical care. That is not to say that the care he received was not optimal or not the best possible care; it just raises the issue of when and who should receive cardiac catheterization and how aggressive we should be. These are questions that are still poorly understood by many patients and by their referring primary care physicians.

What do you think will be the next big development in interventional cardiology in the next 5 to 10 years?

We still have a lot of work to do in finding the next generation of DESs. Unfortunately, we are going to experience a waiting period before any new DES comes to market. I think we need to continue to find newer devices that will reduce clopidogrel duration and enhance safety. I am not quite sure that we will be able to do much better regarding the efficacy of DESs, at least in their current iterations.

Another area of development is structural heart disease. We are moving slowly but are certainly moving toward percutaneous valvular therapies. We have a long way to go regarding newer-generation devices that are retrievable, are smaller in

size, and which will allow more than just high-surgical-risk patients to undergo the benefits of these treatment modalities. We also need to look into new technologies for other areas of structural heart disease, such as patent foramen ovale, atrial septal defect, and ventricular septal defect closure.

Lastly, we need to focus on the peripheral vasculature. We still do not have the perfect tools for treating the superficial femoral artery given its restenotic mechanisms. We also need to have better modalities for treating disease below the knee. I think some of the things coming down the pike may help; for instance, if we can ever get DES technology to work in the superficial femoral artery or below the knee, and certainly some of the early drug-coated balloon data seem to suggest future benefits.

What areas of cardiology need the most attention from physicians and industry in the next several years?

It is a very difficult time for both the major cardiovascular device companies and for new start-up companies. The regulatory pathways for new device development are very arduous and lengthy. Additionally, they are very costly. We need to find a way in this country to streamline the regulatory process so that we maintain the safety aspects of our devices that come to market without hobbling new product development that might be beneficial to our patients. We cannot fall behind our colleagues outside of the US.

We need to deal with the issue of clopidogrel. What is the duration of clopidogrel for DESs? How do we approach patients who need to have early surgical procedures and have received a DES? Hopefully, many of the ongoing trials will answer these questions, but my guess is that we will have to await newer technologies to resolve these issues.

We still do not have answers about bifurcation disease. We need to learn what is the best treatment modality and technique for bifurcations in coronary arteries, and we need dedicated platforms to treat them.

I also think that we must work harder to increase awareness of what we can do in this field. There is so much press coverage focusing on the overutilization of some of our technologies that the public is unaware that, in many cases, we may be underutilizing some of the technology. We need to find ways of increasing awareness of signs and symptoms of disease. We need to continue striving to improve presentation times for patients with acute coronary syndromes. We are working very closely with the SCAI in advocacy efforts.

There is much anticipation about the next-generation DESs. What do we have to look forward to?

I think the idea is to continue improving on efficacy and—most importantly—on safety. Looking forward, we are going to be in a situation in which there is nothing new on the market for at least the next 3 to 5 years.

Obviously, companies will continue to look at thinner strut designs that may improve deliverability, conformability, and late loss. Companies will try to improve their delivery systems by focusing on the delivery balloon and the coatings on the shaft of the balloons to allow us to treat even more diffuse and distal disease. New polymers and drugs will also be evaluated. The issue of resorbable or errodable technology is currently being evaluated.

Please tell us about your experience as principal investigator of a trial with respect to trial design and coordinating all of the various elements that go into the planning, conducting, and ultimately collection, of the results in such trials.

These have been some of the most rewarding experiences that I have had the pleasure to be involved in. I have had the privilege of working as a principal investigator in several trials, most recently, the Taxus Liberté trial with Boston Scientific. It is a very gratifying experience to take a protocol from its inception, go through the regulatory processes, and then work with each of the sites and each of the very talented physician/investigators at those sites to come up with a body of evidence so that we can then prepare a manuscript and move forward with publication, and ultimately develop a commercial device.

I have learned a lot in the process of being a principal investigator. One thing I have learned is that any trial is only going to be successful if the enrollment rate in that trial is fairly rapid and if the nursing and physician teams involved at each of the various hospitals are excited about the technology and are very active. Further, the data collection and case selection must be superior. I have also learned that if we regionalize our experiences, we can help with trial enrollment. Within regions in the country, we will elect certain site-specific or region-specific investigators who help propel the enrollment in those particular regions. As a principal investigator, my role is to be the bandleader and keep the momentum and excitement of the trial going. When all of these things come together, and we are able to stand up at a major meeting to present the data, it is a tremendous experience. I have enjoyed my time working with both industry colleagues, as well as with my professional colleagues and professional organizations. ■