AN INTERVIEW WITH...

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A leading interventional expert discusses the state of CAS and CMS, as well as TCT 2008 and 2009.

Several years after gaining FDA approval, carotid artery stenting (CAS) continues to be under scrutiny, perhaps more than ever. What do you think is the biggest reason CAS has yet to gain greater acceptance?

There are multiple reasons. The first has to do with the data that were published from Europe, specifically the EVA-3S data published in 2006, which, even though it was highly problematic on multiple fronts from a trial conduct perspective, had a significant impact on both the referring physicians as well as the reimbursement agencies in the US. The second reason has to do with a lack of Medicare coverage for the asymptomatic, high-risk population, which is the major population at high risk. And these factors interact in a circular fashion—one feeds the other. Centers for Medicare & Medicaid Services (CMS) sends a negative message to the at-large medical community and, potentially, patients because it denies payment coverage for the asymptomatic, high-risk population.

What is not an issue are the outcomes in CAS. The most recent data sets in several thousand high-surgical risk patients clearly demonstrate continued improvement in outcomes.

What are your thoughts on the current CMS reimbursement situation? Do you think public commentary is going to have any impact, or is it going to be too difficult to sway CMS on its decision?

The draft decision not to cover anatomic high-risk, asymptomatic patients is disappointing but not yet final. The data set for the entire asymptomatic population at high risk for surgery has been increasingly robust and compelling. The postmarket studies now demonstrate a low stroke and death rate for several thousand high-surgical-risk asymptomatic patients, and these data are of high quality: multicenter, prospective, neurologically audited, and independent Clinical Events Committee adjudication. These data are fulfilling the standards the American Heart Association set forth 10 years ago to achieve the asymptomatic 3% stroke and death rate in the population undergoing carotid endarterectomy (CEA), although it is something that has never been achieved in a prospective multicenter CEA survey. To the extent that this same landmark achievement has not been demonstrated in a similar CEA cohort, I believe that stenting has fairly firm legs to stand on when it comes to requesting coverage.

In addition, there is the issue of individualized patient care; specifically, not all asymptomatic, high-surgical-risk patients are the same. Some have more prohibitive surgical risks than others, such as a patient with previous extensive radiation, tracheostomy stoma, contralateral laryngeal nerve palsy, etc. The CMS prior coverage restriction effectively took individual decision making out of the hands of the patient and physician and basically made a blanket statement as to the access to this technology.

One of the significant things not really discussed when this kind of artificial limitation to FDA-approved technologies is in place is the larger public health issue. When devices are shown to be safe and effective and achieve FDA approval, patients denied access to these devices are forced to choose potentially higher-risk medical or surgical care. It is therefore possible that there is an excess of stroke and death in these patients as a result of this lack of access. Moreover, an inequality in Medicare has been established when one beneficiary can pay out of pocket for an approved device, and others cannot avail themselves of the same opportunity.

Additionally, we have static CAS volumes in this country, which means that there are the same or more operators performing the same or fewer procedures. And as a result of a lack of reimbursement, device iteration has largely ground to a halt. This creates a kind of a self-fulfilling prophecy—outcomes that we can only hope to improve modestly—based on the current technology and volumes. If we are, on the other hand, allowed to more naturally roll this procedure out, there will be volumes enough to maintain expertise and have technologic improvements, which reduce stroke and death rates, and ultimately translate into improved patient outcomes. These are two significant issues that have to do with the larger patient populations subjected to restricted technology.

Is it at all known what it would take to get clinicians, who feel coverage should be expanded, and CMS on the same page? If the data continue to show clinicians that this is a compelling argument, what is it going to take for CMS to see the same thing?

There are elements of this decision that are not data-sensitive. One of the reasons CMS is citing for not extending coverage is a lack of consensus. Although consensus is not a typical mandate driving these decisions, achieving it among the various physician communities would certainly be compelling for a broader coverage decision.

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How has TCT changed in the 20 years since it was first held?

It has changed dramatically for the better. I have not been involved with TCT for the entire 20 years, but when I was an attendee as far back as 1993, it was a very small meeting, held at the Renaissance Hotel in Washington. It was one of the first meetings to put on live cases, invite people into the workshop of the experienced operator, and really highlight the advancing and expanding technology in this field. Since that time, it has gone from a primarily coronary-based meeting to one that has grown into the subspecialties of peripheral, structural, neurovascular, and surgical intervention, and has brought in faculty of more than 800 people to share their expertise from all over the world. TCT touches every continent, and it has become the real mainstay of the interventional community's mode of communication, data development, education, and demonstration about and of novel therapies.

Which presentations are you most looking forward to this year? Which data might we expect to see at TCT this year?

The late-breaking trial data from the SYNTAX trial of left main and triple-vessel disease and the HORIZONS trial examining the use of drug-eluting stents in the acute coronary syndrome patient will be, I believe, two trials that have the potential to significantly influence several aspects of interventional medicine.

How will the peripheral component of the meeting differentiate itself from previous years?

TCT has moved from having a cardiology focus to more diverse topics attempting to expand the horizon of the participant, whatever their background may be. Over the years, we have evolved to have an increasingly inclusive and multispecialty approach to the endovascular portion of this meeting, with a broad-based faculty sharing their expertise. The meeting runs 5 days and weaves throughout the entire TCT program, with multiple parallel/concurrent meetings going on throughout. This year, aortic therapies, including stent grafting for thoracic and abdominal disease, will be a highlighted session, and that really is a significant evolution of what was previously primarily a cardiology-based meeting.

What can you tell us about the venue change in 2009?

The Moscone Center in San Francisco is going to be a very interesting place to have the meeting. San Francisco is a wonderful city; it really brings into play a lot of the Australasian and Pacific Rim partnerships that are starting to develop and allows them to engage more directly, for both potential live case sites, as well as hopefully at presentations at the meeting, while maintaining US and European access. It should be a very exciting change of venue. ■