



## **SCAI President's Page**

### **The DES Debate: Staying Focused on Our Patients**

**Bonnie H. Weiner, MD, MSEC, MBA, FSCAI**  
Professor of Medicine  
Interim Chair of Cardiovascular Medicine  
St. Vincent Hospital at Worcester Medical Center  
Worcester, Massachusetts  
President  
Society for Cardiovascular  
Angiography and Interventions



As I begin my term as President of the Society for Cardiovascular Angiography and Interventions, the issue of drug-eluting stent (DES) safety recently has been one of the most widely discussed topics in health care. More than a year after data were released associating the devices with rare cases of late stent thrombosis [1,2] and following recommendations issued by the Food and Drug Administration (FDA) that largely supported their ongoing use while calling for additional research [3], both physicians and patients remain concerned about the degree to which DES should continue to be part of the interventionalist's armamentarium for treating coronary artery disease. These concerns are largely due to the many dramatized headlines we have seen in the mainstream media. It is understandable for patients and their families to become deeply confused when they are bombarded with headlines announcing that individuals with DES have "ticking time-bombs" in their chests.

The goal of my first President's Page is, therefore, to put the controversy into some perspective and to make some suggestions for how we, as the physicians on the front line of this debate, handle the reactions of

our patients and our colleagues in our own as well as other specialties.

#### **What We Know and What We Do Not Know Yet**

When DES were approved for use in the United States in early 2003, they were widely lauded as revolutionary. The Society was among many organizations and individuals who praised the FDA for making these important additions to our tool box available to the thousands of patients who, if treated with bare metal stents, might very well be back in our cath labs for repeat procedures as

Correspondence to: Bonnie H. Weiner, MD, MSEC, MBA, FSCAI, Professor of Medicine, Interim Chair, Cardiovascular Medicine, St. Vincent Hospital at Worcester Medical Center, 123 Summer Street, Worcester, MA 01608. E-mail: [president@scai.org](mailto:president@scai.org)

Received 9 April 2007; Revision accepted 9 April 2007

DOI 10.1002/ccd.21226

Published online 16 May 2007 in Wiley InterScience ([www.interscience.wiley.com](http://www.interscience.wiley.com)).

restenosis developed. This advance became even more significant as it had become apparent that restenosis may not be as benign as we once thought, especially in some patient populations. The Society, under the leadership of then-SCAI President Dr. John McB. Hodgson, developed a position paper analyzing the clinical, medico-legal, and socioeconomic impact that DES would have on practice and healthcare delivery [4].

Three years later, DES were at the center of a storm of controversy: some proclaimed the devices outright dangerous and suggested they should be recalled. Others defended them as important advances in medical care. The FDA held advisory hearings in December 2006, where for 2 days experts testified on the safety, efficacy, and complications related to the devices. My predecessor as SCAI President, Dr. Greg Dehmer, was among those who testified, urging the panel and all those listening to carefully consider the risk-to-benefit ratio of the devices and to wait for findings from additional studies that determine specifically why late stent thrombosis occurs in a small percentage of patients [5]. Shortly thereafter, the Society, again under the leadership of Dr. Hodgson, issued a *Clinical Alert* with practical guidance for physicians on when, how, and in whom DES should be implanted [6]. An independent summary of the data presented at the FDA hearing has also been published to provide an overview of the available data [7].

As the Society's *Clinical Alert* states, one of the key things we currently know about DES is that they are generally safe and effective when used "on label." While the rate of late and very late stent thrombosis is slightly higher than bare metal stents, the benefit in reducing restenosis and its associated complications far outweigh these risks, thus on balance DES use remains the preferred approach.

So-called "off-label" use of DES, such as in the treatment of complex anatomy and patient subsets as well as acute myocardial infarction, represent as many as 60% of the PCIs performed in this country. The data are not as clear because the same level of randomized studies has not been performed. The ultimate answers will come from carefully constructed clinical investigations and through comparison of the risks and benefits observed. From the findings of those studies we will be able to ascertain where DES fit into our treatment options for patients with complex coronary artery disease.

Until those findings become available, the challenge facing us as interventional cardiologists is how to react to the controversy.

### Focus on the Patients

Some engaging in the heated debate about DES would like to paint the devices as either miracle treat-

ments or thoroughly dangerous. The truth likely lies somewhere in between and, until more conclusive data become available, we still have patients to treat, many of whom are ideal candidates for DES. Thus, the conundrum we as physicians face: what should we do?

First, I think we need to heed the words of Dr. Dehmer in his last President's Page. When concerns about DES arose, he wrote, "SCAI took a deep breath, gathered the best minds and available data, and examined the evidence carefully" [8]. As individual practitioners, we need to take a deep breath, try not to over-react to the headlines or our colleagues' or patients' anxieties, gather the data currently available, and look critically at those data. That way, when our patients or their family members ask or express fears about the stents already implanted or those we are recommending, we can answer calmly and from, as Dr. Dehmer wrote, "authority and credibility."

The reality is that we encounter many of our patients in acute scenarios, when pain and panic are their primary sensations. What they want (and deserve) from us in those situations is help, truthfulness, and reassurance that the patient will receive the best care we can possibly provide. Later, after the procedures are completed and they are resting comfortably, they begin to ask more questions. Perhaps they recall the headlines about "ticking time-bombs" or they hear from a relative or friend that "those stents are dangerous... they cause blood clots that can kill you." The panic may return and some may even respond to us in anger or fear or both.

In my opinion, the best approach in such situations is to stay totally focused on the individual patient (and family) and what he or she is conveying. How we handle that conversation and those that follow will go a long way in the all-important relationship- and trust-building that must be the cornerstone of our patient care. In my experience, different patients are comforted and reassured by different information. Some appreciate hearing, and perhaps even seeing, hard data and having it translated to their specific situation. For others, percentages and odds ratios are inappropriate and it is more helpful to explain that you made the best medical decision considering the patient's specific constellation of health issues.

It is critical that we maintain our patient-centered approach. Despite the importance of the many things we are increasingly scrutinized over (door-to-balloon times, pay-for-performance, and many others), we must never forget that we must maintain the patient-centered approach.

Fundamental to that approach is taking a little time to simply listen. The extra 5 min of discussion with either the patient or their family—before and after an

interventional procedure—can be the difference between long-term success or failure. For example, it is too late to discuss dual antiplatelet agents *after* DES implantation, if the patient has a recent history of gastrointestinal bleeding, is scheduled for resection of a colon cancer, or is generally noncompliant with medications. We must take the time to identify and discuss each of those situations (and many more) *before* doing a procedure, to choose the best therapy for that individual. This has always been our “must-do” process, since well before the DES debate arose, and must continue to be our process well after this immediate debate subsides.

In nonacute scenarios, during which there is more time for discussion with the patient and his or her family members who are considering the therapeutic options, we have the opportunity for detailed conversation about the risks and benefits of DES and for determining how likely it is that the patient will continue taking dual antiplatelet medications for at least 1 year. From such conversations, the patient often comes away feeling that he or she made an informed, educated decision about next steps in treating the disease. It is an excellent foundation for the doctor–patient relationship, something that is more difficult to maintain these days in an increasingly challenging (even at times adversarial) environment.

### **Stand by for Changes to Treatment Protocols**

As forthcoming investigations announce their findings, the protocol for DES, as with all medical therapies, will continue to evolve [9]. The devices themselves are likely to be refined over time. To stay up-to-date on the latest news about DES, I urge you to turn to SCAI, specifically [www.scai.org](http://www.scai.org) and this *Journal*, where we will publish the information you need for your own practice and that you might like to share with colleagues in related specialties. We are also investigating opportunities to help you increase patient awareness and compliance with the necessary drug regimens as we currently know them.

The Society will continue to participate in initiatives by government entities, such as the FDA, on DES and

other drugs, devices, and technologies relevant to the care of our patients. If you would like to share your thoughts or experiences with DES, or any other topic related to SCAI’s mission, please email me. I will gladly answer each message received.

### **REFERENCES**

1. Pfisterer M, Brunner-La Rocca HP, Buser PT, Rickenbacher P, Hunziker P, Mueller C, Jeger R, Bader F, Osswald S, Kaiser C, for the BASKET-LATE investigators. Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents. *J Am Coll Cardiol* 2006;48:2584–2591.
2. Leon MB, Stone GW. Presentation at TCT, October 25, 2006. Available at [http://www.tctmd.com/csportal/appmanager/tctmd/main?\\_nfpb=true&\\_pageLabel=TCTMDContent&hdCon=1453648](http://www.tctmd.com/csportal/appmanager/tctmd/main?_nfpb=true&_pageLabel=TCTMDContent&hdCon=1453648).
3. U.S. Food and Drug Administration Center for Devices and Radiological Health. Update to FDA statement on coronary drug-eluting stents. Available at <http://www.fda.gov/cdrh/news/010407.html> (updated Jan 4, 2007).
4. Hodgson JM, King SB, Feldman T, Cowley MJ, Klein LW, Babb JD. SCAI statement on drug-eluting stents: Practice and health-care delivery implications. *Catheter Cardiovasc Interv* 2003;58:397–399.
5. Dehmer GJ. Public statement to the FDA Circulatory System Devices Panel of the Medical Devices Advisory Panel Meeting, Washington, DC, Dec 7–8, 2006. Available at <http://www.scai.org/PDF/FDA%20Testimony.pdf>.
6. Hodgson JM, Stone GW, Lincoff AM, Klein L, Walpole H, Bottner R, Weiner BH, Leon MB, Feldman T, Babb J, Dehmer GJ. Clinical alert: Late-stent thrombosis: Considerations and practical advice for the use of drug-eluting stents: A report from the Society for Cardiovascular Angiography and Interventions Drug-eluting Stents Task Force. *Catheter Cardiovasc Interv* 2007;69:327–333.
7. Popma JJ, Weiner B, Cowley MJ, Simonton C, McCormick D, Feldman T. FDA Advisory Panel on the safety and efficacy of drug eluting stents: Summary of findings and recommendations. Available at [http://www.theheart.org/documents/satellite\\_programs/cybersessions/760859/FDA\\_Advisory\\_Panel.pdf](http://www.theheart.org/documents/satellite_programs/cybersessions/760859/FDA_Advisory_Panel.pdf).
8. Dehmer GJ. SCAI President’s Page: Passing the torch: Challenges ahead. *Catheter Cardiovasc Interv* 2007;69:929–931.
9. Grines CL, Bonow RO, Casey DE Jr, Gardner TJ, Lockhart PB, Moliterno DJ, O’Gara P, Whitlow P. Prevention of premature discontinuation of dual antiplatelet therapy in patients with coronary artery stents: A science advisory from the American Heart Association, American College of Cardiology, Society for Cardiovascular Angiography and Interventions, American College of Surgeons, and American Dental Association, with representation from the American College of Physicians. *Circulation* 2007;115:813–818.