AN INTERVIEW WITH...

Ralph G. Brindis, MD

Dr. Brindis discusses updated guidelines for DAPT, accreditation, the development of a national medical device postmarket surveillance system, and more.

As past president of the American College of Cardiology (ACC), what did you see as your primary goal to accomplish while you were in that position?

One of my major goals was partnering with the ACC staff to educate and equip our members to become more poised and ready for the existing and projected future changes occurring in health care reform affecting them and their patients. This is a key issue because our members are markedly diverse. They represent private practice, integrated health systems, academics, and more. We, as an organization, need to honor and advocate for our members in terms of their present work situations, but even more importantly, we must prepare them for the changes ahead.

I would always tell my private practice colleagues that I was there to represent their needs, and at the same time, I would work with the ACC to help set up needed education and infrastructure tools, such as appropriate use criteria and National Cardiovascular Data Registry (NCDR) registries to meet future health care reform mandates. We did this to best assess cardiovascular quality so that clinicians could prepare for dealing with the changes occurring in health care (ie, the Medicare Access and CHIP Reauthorization Act of 2015 [MACRA], heralding the movement from volume to value).

You recently coauthored an article about preventing myocardial infarction after coronary stenting in the randomized Dual-Antiplatelet Therapy (DAPT) study. Were any of those results surprising to you? Or, were the results as anticipated?

I don't think the results were particularly different than anticipated. One has to remember that these patients were selected in that if they were having significant complications related to bleeding with DAPT during the first year after percutaneous coronary intervention (PCI), then they weren't included for the long-term study. I think the most exciting thing related to the DAPT trial is its ability to help the clinical community assess when long-term DAPT is indicated, or as I would refer to it, the application of the ischemic risk versus bleeding risk equation for a given cardiovascular patient.

A clinical decision-making tool resulting from this study was recently published in the *Journal of the American Medical Association*.[1] The goal with this decision-making tool is to help clinicians and their patients decide when long-term DAPT therapy is indicated, in terms of assessing the benefit/harm issue related to ischemic risk versus bleeding risk. I hope the clinical community will find the tool valuable.

In your opinion, what is the biggest takeaway from the updated guidelines for DAPT in patients with coronary artery disease from the ACC/American Heart Association?

First, I want to acknowledge the incredible leadership of Glenn Levine, MD, as the lead author of this guidelines document. He did an absolutely stupendous job in leading this writing group. Primarily, the guidelines update the clinical recommendations related to DAPT, along with simplifying and coordinating those recommendations embedded in six relevant clinical practice guidelines: (1) coronary artery bypass surgery, (2) non–ST-elevation acute coronary syndrome, (3) PCI, (4) management of coronary artery disease for patients undergoing noncardiac surgery, (5) stable ischemic heart disease, and (6) ST-elevation myocardial infarction. One such change is simplifying the aspirin dose to 81 mg, whereas before, we had varying dosage recommendations related to aspirin among the six aforementioned guidelines.

Are there any particular ACC/NCDR initiatives and/or registries that you are excited about offering to the cardiovascular community?

One of our newer registries launched this year is a left atrial appendage occlusion registry, which will meet national coverage decision requirements from The Centers for Medicare & Medicaid Services, the goal of which is to better understand safety and efficacy of the left atrial appendage

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occlusion device as it is utilized in the general community. We have also launched an atrial fibrillation ablation registry, which I think the cardiovascular community and many stakeholders have been begging for. Again, the goal of the atrial fibrillation ablation registry is to better understand community practices, safety, and long-term efficacy.

Another advance that is very exciting is the utilization of the NCDR as the infrastructure platform for randomized clinical trials. We've already produced a randomized clinical trial called SAFE PCI in women. We're now putting together another clinical trial of safe ST-elevation myocardial infarction for seniors, to examine not only safety and efficacy, but also new stent device assessments, and drug therapy in a manner that is markedly less costly than previous models implementing standard randomized clinical trials. Additionally, utilizing the registry platforms, we're able to enroll patients representing a broader swath of the cardiovascular community at a much lower trial cost overall and in a much quicker fashion.

The NCDR also has a public reporting initiative. At present, clinicians are being publicly reported using administrative data or data from proprietary organizations typically not transparent as to their methodology. A given clinician or a hospital can be viewed in one of these public reporting efforts as being exemplar, yet in another reporting effort be viewed as deficient. This is confusing to the clinicians, but even more so to the patients. Registries, by actually using clinical data, have the opportunity to more accurately and transparently offer value to hospitals, clinicians, and most importantly, to patients, payers, and purchasers. The public is demanding it. The NCDR, with our public reporting advisory group, is moving forward cautiously, but responsibly, in these efforts to initially report processes of care and will soon take on reporting actual clinical outcomes. Again, the purchasers, the payers, and the patients are demanding this transparency in care delivery.

How does accreditation by external quality review services relate to better patient outcomes?

Outside accreditation offers an individual hospital and the practicing clinicians the ability to assess what they're doing while standardizing their systems and processes of care (in this case, for a cardiac catheterization laboratory). In addition, utilization of data from the NCDR registry (for example, the NCDR CathPCI registry) offers benchmarking related to clinical outcomes and appropriate use for clinicians and hospitals to identify opportunities for improvement. Blinded random case and cineangiography reviews allow hospitals and clinicians to have more confidence in the quality of their work, as well reassurances that proper techniques are followed during coronary angiography, and that the reading and assessment of coronary angiograms is accurate. These proactive measures will help protect both the hospitals and clinicians against accusations of fraud and abuse. I would encourage hospitals to look into the possibility of pursuing accreditation.

To what extent do you agree with shared decision making between the doctor and the patient?

There is no doubt that the term *shared decision making* has become a buzzword in the practice of medicine. The days of the paternal "Marcus Welby approach" are long gone. By having shared decision making with informed patients and families, wiser decisions are made, and the chances for medication adherence are further enhanced. I'm involved in a National Institutes of Health grant awarded to the UCSF Philip R. Lee Institute for Health Policy Studies that is developing an evaluation tool of shared decision making as performed in the management of patients with stable coronary artery disease undergoing PCI. Although we talk about shared decision making, we don't even know how well it is actually is working, nor do we have a shared decision-making evaluation tool. With such a tool, we can evaluate a patient's knowledge of the procedure itself, their own assessment of their interactions with the clinician, and, potentially, even decision regret.

Where do we stand in the development of a national medical device postmarket surveillance system?

The previous paradigm involved the hospitals or clinicians writing in or filing individual case reports related to potential adverse outcome related to a device or drug. The US Food and Drug Administration had problems with trying to fully understand correct numerators (in terms of duplicate reports) and true denominators (meaning the number of devices or patients at risk). Utilizing registries and long-term follow-up has given us an incredible opportunity to be able to assess low-frequency adverse outcomes in large patient groups.

Presently, the US Food and Drug Administration, along with visionary leaders, has been implementing what's called the Delta System or the Sentinel System. For a lot of this work, we need to acknowledge Frederic Resnic, MD, in leading this effort with the US Food and Drug Administration. With the Sentinel System, we can actually have real-time assessment related to cardiovascular devices in terms of safety and efficacy, so that when we see signals of devices with potential adverse events, they can be more fully assessed or, if necessary, more quickly removed from the marketplace.

An example Dr. Resnic gives is that of a recalled defective Sprint Fidelis (Medtronic) and Riata (St. Jude Medical)

implantable cardioverter-defibrillator leads. If we had the fully functional Sentinel System in place, we would have identified one of these leads as being at risk of being defective nearly 25 months prior to it being pulled off the market. This represents more than 70,000 patients who received the potentially defective ICD lead who would not have received it under a fully developed Sentinel System. That represents substantial morbidity and cost to the health care system, so real-time postmarket surveillance via the Delta or Sentinel system is a very exciting development.

What is the best piece of advice you'd like to share with your cardiology fellows?

I have to say that I'm jealous of my cardiovascular fellows. This is an exciting time to be in medicine. My first piece of advice would be to work hard and learn your trade. Become the best clinician that you can be in your early career. Then, I would encourage you to get involved in both your local ACC chapter and also in national ACC initiatives.

My general advice is to make sure you show up when you first get asked to be involved in a workgroup or committee. Actually come to the meeting, and when you're there, be "present." In other words, focus on the task at hand, and speak up as opposed to looking at your phone. Work hard. Be credible. Be trustworthy in meeting deadlines. Demonstrate selflessness. Choose mentors who can help facilitate your own development. Have a high emotional quotient. Every endovascular specialist is smart in terms of intelligence, but not everyone has a high emotional quotient. And finally, use humor in your interactions. If you are able to incorporate these suggestions, I think that your chances of making significant contributions to our professional societies while also offering your own legacy in the advancement of the treatment of cardiovascular disease will be markedly enhanced. ■

1. Yeh RW, Secemsky EA, Kereiakes DJ, et al. Development and validation of a prediction rule for benefit and harm of dual antiplatelet therapy beyond 1 year after percutaneous coronary intervention. JAMA. 2016;315:1735–1749.

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