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EDITOR'S PAGE

So We Have Bioresorbable Scaffolds

Now What?

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The American College of Cardiology's annual Scientific Session was memorable for several things, notable among them the results of the percutaneous aortic valve studies on lower risk patients, which were very encouraging. The conversations outside the presentations, however, often focused on developments that occurred a week or 2 earlier and involved the U.S. Food and Drug Administration (FDA). Most of us were excited and very pleased that Rob Califf was finally confirmed as the FDA commissioner. Good thing that he was not nominated for the Supreme Court! How important is that nomination? Well, a magazine with his picture on the cover just crossed my desk, and when I opened it, I saw that he was listed as the most influential physician leader in America. He outranked the head of the National Institutes of Health, the Centers for Disease Control and Prevention, all the health care financing systems, and all of the health care provider systems. The FDA is a big deal! Well, the action at the FDA that was long anticipated was the other big topic of discussion. The FDA device panel, considering the Bioresorbable Vascular Scaffold (BVS), gave a unanimous recommendation for approval. This "stent," of course, has been used extensively outside the United States, and now that pivotal trials, including those in the United States, have been completed, it appears it will be available for us.

Now that we will have it, what do we do with it? The promise of a device that can function as a stent but then go away when no longer needed is a very old dream. The idea of a temporary metal stent that would hold the artery open for hours and then be collapsed and removed to prevent acute closure is an idea from the 1980s. Bioresorbable technology, first suggested to me in 1986 by Jack Whitehead, the benefactor of the Whitehead Institute at Massachusetts Institute of Technology, first introduced me to Bob Langer, the polymer chemist whose research has been central to much of the development of the use of polymers in medicine. We entered into a fledgling effort with Joachim Kohn of Rutgers, another prominent polymer chemist, but those efforts are just a memory. Others have now made it work. The problem of polymer degradation and toxic byproducts seems to have been largely resolved. The design features to obtain adequate radial strength to provide acute scaffolding have been accomplished.

Randomized trials have shown essentially comparable low intermediate-term complication rates compared with our best-in-class drug-eluting stents (DES). The aspiration for vanishing stents is to eliminate anything left behind. It seems almost ecologically responsible, like outdoor camping (leave nothing behind save memories), or like composting to reduce the impact on landfills. The emotional appeal of an artery that returns to near normal is compelling, although true normal is not a claim that has been made. Nonetheless, absence of a permanent metal stent is appealing.

Why not use them in everybody? The FDA panel review of the evidence did reveal some reasons not to. For one thing, the current metal DES have advanced so far that adverse outcomes are now unusual, so the comparator group for BVS presented a very high bar. Of greatest interest, although rare, stent thrombosis in all the studies was more likely with BVS than with the comparator DES. Subset analyses seem to suggest that most of the stent thrombosis difference was in vessels smaller than 2.5 mm. This may lead to a warning to use the stent only in vessels larger than this. Such a suggestion came from the sponsor.

So what will interventional cardiologists do when the scaffold shows up on the shelf in the cath lab?

JACC: CARDIOVASCULAR INTERVENTIONS VOL. 9, NO. 10, 2016
MAY 23, 2016:1087–8

I predict there will be 2 extremes. There will be early adopters. Those who are very enthusiastic to implant the device and perhaps gain some market differentiation from competitors. On the other end of the spectrum, there will be the operators who feel they are getting great results with what they are doing now and will hold back waiting for more observations of this new technology before trying it themselves. There will be a middle group of cardiologists struggling along with their patients about when to use BVS and when to use DES. I doubt the conversations will move to denigrate the current practice as it did with balloon angioplasty (plain old balloon angioplasty) or bare-metal stents, which are about to lose their last rationale for use (patients unable to take dual antiplatelet therapy long term). Like stents, any price differential may be a tie-breaker when equipoise for device selection exists. The other experience that may influence acceptance is the ease of implantation. Because of the stent thrombosis issue, guidelines for deployment technique including lesion preparation (high pressure noncompliant balloon pre-dilation or, in some cases, rotary ablation, orbital atherectomy, or cutting or scoring balloons) are advocated. The technology of ensuring full, noncompliant balloon inflation before making the final decision to place the scaffold, selection of the scaffold to match the balloon size, and post-dilation with a noncompliant balloon <0.5 mm larger than the deployed scaffold have been recommended. Intravascular ultrasonography or optical coherence tomography guidance are also suggested by some.

There is no doubt that new operators should at least be aware of these recommendations, and maybe some of them will become unnecessary over time. Observation of outcomes by the FDA (post-market surveillance) will also go a long way to assure all of us that general use of the scaffold does not give up any ground gained in the era of DES evolution. The great hope for BVS will only be revealed over time. Will the absence of anything left behind, partially restored vasomotion, and positive remodeling translate into very long-term benefits? A lot remains to be learned. If the promise is achieved and bioresorbable scaffolds evolve, as did DES, we may someday have to refer to them as "plain old drug-eluting stents," or PODES. But for now, PODES are pretty good.

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