

# Steven R. Bailey, MD

SCAI Executive Committee member and coronary expert discusses nanotechnology, fellowship training, and concerns about technology development.

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**Please tell us about the invasive cardiology lab at the University of Texas Health Science Center.** Our invasive facility is a multicentric endeavor. We have a laboratory at the university hospital and a second lab at the Veterans Affairs hospital. This conjoined program between the two facilities allows us to have a very broad spectrum of care. We have had the opportunity to partner with our vascular surgeons, who we have incorporated into our lab, for endovascular and peripheral vascular procedures.

Our full-service lab is available for coronary applications, and we are very proud of our door-to-balloon times, with an early and rapid alert system, including patients in the Veterans Affairs. Even in the Veterans Affairs situation, we have been very successful in meeting the current door-to-balloon times.

Our door-to-balloon program developed from a pioneering grant from the Robert Wood Johnson Foundation called Urgent Matters. As part of that grant, 10 hospitals throughout the US evaluated impediments to door-to-balloon times through the emergency room. That initial grant was supplemented by a second Robert Wood Johnson Foundation grant called Expecting Success, one component of which was to continue investigating the problems associated with rapid door-to-balloon times.

In addition to aggressive and extensive coronary interventions, we have a long history of treating structural heart disease. Our program integrates our pediatric and adult cardiologists to provide a high level of interventional care that covers atrial septal defects, ventricular septal defects, patent ductus arteriosus, branch pulmonary stenosis, and coarctations.

**What role does/will nanotechnology play in interventional cardiology?** Over the last 30 years, we

have seen an explosion of technology and technical options for treating patients. We have adopted devices and materials that were never intended to be used inside the human body; the stent is being a prime example. Stents were adapted from metals to be flexible and of greater strength, but the result has been a new disease (ie, neointimal hyperplasia).

Unfortunately, we have taken existing technology and existing processes and modified them to medical applications. Nanotechnology, because it is so new and because it involves converging specialties, is the first technology to allow us to think first about what it is that we want to build, and then build it. Certainly, in interventional cardiology, the opportunity presents itself to change materials. Instead of having a stent that we polish down to its lowest thickness, nanotechnology allows

us to build up that stent, which allows us to radically change the materials used and the properties they possess. In fact, on the nano scale, most of the properties are quite different.

Currently, to be able to place material on a stent, we first have to place a polymer or plastic and then place the intended material. Nanotechnology allows us to actually define what to place on a stent and to attach it directly using physical properties. Instead of requiring a polymer, you can place a protein, another metal, or some type of sensor. Using heart valves as an example, we are liberated to pursue a valve leaflet that is only a few microns thick, allowing the body to help heal it by growing tissue on it. The leaflet is still very thin and flexible, thereby allowing it to be as small as possible. Or, you could change the radial force on a stent, not just by changing the stent's thickness but also by changing the materials that the stent is composed of and how they respond to the environment. Nanotechnology allows us to tailor devices and materials to very specific physiologic

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responses, which will result in more effective healing.

**What is the current focus of your research energy?** We believe that the opportunity for engineering changes holds great promise. One of the components of these engineering changes is nanotechnology and using the integration of chemistry, physics, optics, and electronics in combination to develop completely new processes.

We are actively involved through grants in developing sensors and sensor technology that is integrated into implantable devices. We are looking at sensors that respond not to pressure but to direct increases in biomarkers (eg, brain natriuretic peptide). Would such a sensor allow us to identify patients earlier? Could we treat patients earlier? Could we tailor our treatment of patients by having this information available more readily?

**What do you think will be the next big development in interventional cardiology in the next 5 years? 10 years?** In the 1980s and 1990s, we recognized a pattern of rapid technological growth and then plateau. I think we are again coming up on a period of plateau. The immediate future will involve a retrenchment and evaluation of investment dollars, especially after the recent development of drug-eluting stents. I think there will be a lot of focus on areas that we have not been able to treat, such as strokes and intracerebral vascular events.

**What areas of cardiology need the most attention from physicians and industry in the next several years?** We have a lot of opportunity and a lot of needs. Some are larger than others. There is a dichotomy between business forces and clinical needs. By nature, businesses are judged by how well they do financially. When faced with the question of doing the most good for the dollars invested, a limited number of patients with great needs will not be addressed as effectively as a larger group of patients that has possible less dramatic outcomes. It is understandable why industry makes the choices they make; they are following their mandate.

However, from a physician and patient standpoint, industry is not prepared financially or emotionally to address the needs of the smaller sub-

sets of patients. Why don't we have treatments that have been optimized for intracerebral aneurysms? Or even coronary aneurysms? The reason is that these are areas with fewer patients, less need, and less reimbursement.

The other side of this question has to do with regulatory oversight. In fact, our current regulatory process mandates that we have a slow and deliberate evaluation, which probably interferes with our ability to be facile. New changes in smaller groups of patients cannot be evaluated; you cannot achieve statistical significance in small numbers of patients. Some of this innovation is occurring outside of the US because of the different regulatory climate, but in the US, we are left making difficult decisions for individual patients about how to care for them and how to adopt current technology in the absence of any evolution of the technology.

Within the coronary arena, we are now seeing stent fractures emerge as an issue, which illustrates limitations of technology. Also, we still have a large group of patients who need more attention paid to below-the-knee revascularization.

**What is the current state of interventional fellow training in cardiology?** Our current training programs are in a major transition phase. They started out recognizing our historic roots of coronary intervention. However, during the past 10 years, there has been a major shift in terms of the educational focus, as well as the practice patterns in many of the programs. We are faced with a program with content designed to, in a year, do a great job of teaching the interventional fellow how to perform coronary intervention; it still does that.

The problem has become that practice patterns in many communities have grown to include peripheral interventions. It has become necessary to recognize that there is a different set of cognitive skills and data required for peripheral interventions and certainly a different set of equipment, which in turn requires a different set of tactile skills. In many programs, we are seeing the emergence of a 2-year fellowship to allow for this dual training.

Also, we now have a new structural arena coming into prominence, in particular with percutaneous valves on the horizon. There is a lot of enthusiasm, but there is currently a limited ability to translate this into clinical training. However, there has been discussion about when such training should occur.

**How effective is simulation training in interventional cardiology?** Technology and industry have finally

grown to the point where simulation has application. We have gone through that initial enthusiastic phase where we recognized the analogy to complex skills and failure modes, but we did not really have any types of technology that were adapted to our specialty. We now have many different versions and approaches at our disposal; some are more cognitive, some are more tactile. I think it is important to recognize that simulation should test both. We are seeing validation of this approach, especially in the carotid arena. There now are objective performance criteria that can be used to identify the beginner from the expert. More importantly, simulation allows a broad range of skill sets (surgeons, radiologists, cardiologists) to be evaluated for their limitations and then focused instruction to improve skill sets.

We are also beginning to see the results of simulation training manifest as improvements in the clinical environment. These data are just starting to emerge, but we are seeing them presented at meetings more often. This is a critically important step forward as we move to very difficult procedures—not just carotid procedures but also stroke. I think acute stroke care is a horizon that will demand interventional cardiology support. I say this because it builds upon our experience with myocardial infarction door-to-balloon time. If you are going to treat stroke, you must have a team and a process in place for getting patients identified and into the lab. Interventional neuroradiologists are very important in this, but there aren't that many of them. If you want active stroke programs, not only in major centers but also in the smaller ones, you must train enough people. It will be necessary to involve simulation in moving us through the initial phase of implementation.

**What can you tell us about the SCAI and its current role?** The Society of Cardiac Angiography and Intervention is doing a wonderful job of addressing and promoting the concerns and needs of interventional cardiologists. It serves as the entity that bridges interventional fellow training and promotes all of the educational topics that we have discussed. It has recently assumed the mantle as the organization that will be providing grants to fund fellows in training. The SCAI has also undertaken a leadership role in dealing directly with industry. The SCAI has emerged as the voice and heart of interventional cardiology. ■

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