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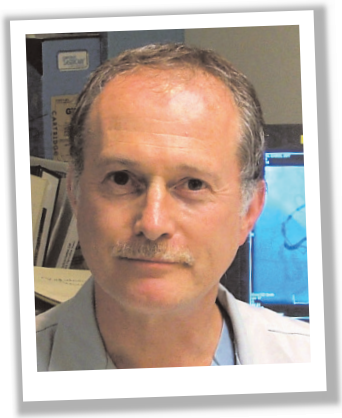
A leader in structural heart repair discusses cardiologists' increased role in the periphery, his multidisciplinary practice, and the EVEREST trial.



Much of your major research and clinical experience involves structural heart repair, but you have also done extensive work away from the heart. Have you observed a similar movement by other cardiologists? In the last decade, as cardiologists have become more involved in interventions in multiple vascular beds, we have learned that a cross-pollination of approaches is invaluable. The ability to recognize and manage both pathology and complications systemically is an important part of being a better physician. Everyone involved—physicians from multiple specialties and patients—has benefited as we extended our reach beyond the heart.

Can you explain why cardiologists began doing peripheral or noncardiac/coronary procedures? Most of the impetus and development of extracardiac intervention in cardiology, radiology, and vascular surgery has been fueled by improved technology. Many cardiologists did not recognize pathology outside the heart. The concept of passing the wire from a femoral access point to the coronaries, without considering everything in between, had become a paradigm for cardiology practice. Fortunately, I think we have recognized that we cannot ignore the rest of the vasculature. In the early 1990s, we acquired tools that made it possible to access and treat virtually every vascular bed in the body with very reasonable results. Patients with coronary disease have a high incidence of peripheral-vascular, renovascular, and cerebrovascular disease. The development of peripheral intervention was more an effort to correct a deficiency in our approach than anything else.

What is unique about the structure of your practice at Evanston Northwestern? How do the multiple specialties contribute to patient care? My own practice evolved over the years into one that is largely valvular and structural. Right now, less than one-third of the procedures I perform are coronary, and the remainder are closure device procedures, patent foramen ovale closure, and some odd procedures, such as shunt and fistula closures, paravalvular leak closures, aortic and mitral valvuloplasty, and procedures such as alcohol septal ablation for hypertrophic cardiomyopathy. There is a rapidly growing armamentarium of valvular interventions, such as mitral repair, and we are on the verge of starting up percutaneous aortic valve replacement.

The multidisciplinary involvement in these procedures varies significantly, but the best example is aortic valve replacement. This involves large-sheath access for femoral sheath placement and the evaluation of the patient before the procedure by a radiologist who performs and interprets a CT angiogram, a vascular surgeon who is involved in either sheath placement or removal, and a cardiac surgeon who is there for the patients who require apical rather than femoral access. We have a regular multidisciplinary vascular conference attended by people in different specialties, during which we review and share our experiences on everything from the mundane to the challenging cases. Most of us continue to perform the day-to-day procedures independently, but there are more situations where at least our shared experience—if not our shared effort—is required to approach the patients. These efforts have been wonderful in creating an atmosphere of group endeavor and collegiality.

What value do simulators lend to training programs? The advantages for practitioners are clear. The chance to practice a procedure, to understand device mechanics, and to solve problems are straightforward benefits that simulation provides an interventionist. Simulation companies featured their devices at many large meetings over the last few years to acquaint people with the technology. There are more and more training situations taking place on simulators. Anyone who has used one can appreciate its value, such as the substantial benefit to doing a procedure the first several times without worrying about the consequences of a mistake.

Coronary intervention has become so good that many fellows can undergo a 1-year interventional experience and see few or no major complications. There are simulator programs that give interventionists a sample of these complications and the opportunity to practice managing them. The management error of selecting the wrong drug or waiting too long to intervene on a complication are things we can endure a couple of times on a simulator. It is a phenomenal application in the training setting.

We are also seeing wonderful applications in the clinical

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research setting that enable people to receive training for new device procedures. An example is the Atritech (Atritech, Inc., Plymouth, MN) atrial occlusion procedure in which, before entering the trial, operators do a straightforward case with a novel device, then one of medium difficulty, and finally one complicated case, allowing them to approach their first patient with a real experience base. Edwards Lifesciences (Irvine, CA) has developed a similar program for percutaneous aortic valve replacement. When you consider that we still typically do two roll-in procedures in a new device trial, this practice doubles interventionists' experience levels as they start a new device trial.

The carotid procedure has benefited from some of the best simulator work for training and, also, now stratifying the competency level of carotid operators. With that tool, it is possible for interventionists to measure their abilities, practice on a simulator, and then come back and evaluate whether they have improved in their competence level.

I had a wonderful experience with simulators while teaching Chinese physicians to perform infarct angioplasty. The algorithm for some of the cases was set up so that the simulated patient would develop refractory ventricular fibrillation if the time from femoral access to balloon placement in the coronary artery took more than 10 minutes. The participants realized this quickly and were pouring sweat while working on the simulator, showing how remarkably real the case felt to them; it was clear that they were completely engaged.

There are relatively few simulators permanently installed in training programs around the country; most simulation is available through industry efforts. We think of simulators as being very high-tech; in reality, there are some very simple versions. One of the most familiar is the glass model of the aortic root with which a fellow can see how a right Judkins catheter torques in the root. We have an atrial septal defect closure model that is a plastic, two-dimensional model of the heart with an inferior vena cava and holes drilled in the atrial and ventricular septum. On the benchtop, you can practice passing a wire through these "defects" and practice deploying septal occluder devices. This form of simulation is useful yet simple.

What approach is at the forefront of the spectrum of modalities being developed to repair mitral regurgitation, and why? Leaflet repair with the MitraClip (Evalve, Inc., Menlo Park, CA) is furthest ahead in terms of trial enrollment. We have enrolled more than 200 patients in 36 centers in the EVEREST trial. We are far from answering the question of which of these modalities will provide the widest application or the greatest efficacy, because the other mitral repair modalities have experience with fewer than 100 patients using any one technology. Most of the devices are still in various early stages of development, with a wave of technology that is just approaching first-in-man experience.

Unsolved problems remain for the surgical community. The various approaches to percutaneous therapy for mitral repair, including coronary sinus annuloplasty, direct annuloplasty, leaflet repair, and chamber modeling approaches, are at the beginning of a very long development, a fact that becomes clear after reviewing the history of surgical valve intervention. Surgical efforts began in the 1930s and 1940s with mitral commissurotomy and some of the leaflet repair approaches, which began in the late 1950s. Today, surgical leaflet repair has been successful for relatively specific cases, such as posterior leaflet mitral prolapse, whereas the anterior and bileaflet prolapse cases and some of the more complex Barlow valves remain a challenge. Surgical repair is the gold standard, but even after decades of development, we still do not have the best results from surgery for MR of every etiology, including functional MR from ischemia and heart failure. We are still very much at the beginning for percutaneous therapies; the first patient treated with percutaneous mitral valve intervention was only in 2003.

What can you tell us about the EVEREST II trial? We have completed a phase 1 registry and have reported results on more than 100 nonrandomized patients. The randomized trial is still in the ramp-up stage. We have not yet opened all 38 sites. Most of those sites have finished their roll-in cases, most are randomizing at this point, and today we have randomized more than one-third of the total population needed to complete the trial. We are moving through the trial now, and its length depends on how enrollment develops. Screening of the target patient population is improving . Although the trial is well underway, I wish I could say when we will enroll our last randomized patient.

What advancements are on the horizon regarding percutaneous therapy? Each one of these various percutaneous valve therapies is marching ahead in a positive stepwise fashion. We have seen proof of concept for a variety of novel devices. Aortic valve replacement is already a real procedure. Technical advances have started to reduce the device profiles. We will see important changes in the next generation of aortic valves, such as repositionable and removable devices. We can look back at the evolution of balloon angioplasty and stenting in the coronaries throughout several decades, and we can reasonably expect that this spectrum of valve intervention will develop steadily. ■