

Steven L. Goldberg, MD

Dr. Goldberg shares his perspective on the wealth of information coming out of the interventional cardiology field today, as well as his philosophy on patient education.



Tell us about your role as Chief Clinical Officer at Cardiac Dimensions, Inc. and how this partnership came about.

Cardiac Dimensions, Inc. (Kirkland, WA) began from an incubator company that defined a clinical need for a

percutaneous therapy to treat functional mitral regurgitation. One of the first employees was the Chief Medical Officer, Dr. David Reuter, who is also an engineer. The Carillon Mitral Contour System was developed to take advantage of the close relationship between the coronary sinus and the posterior annulus of the mitral valve. The device consists of two self-expanding anchors with a curvilinear connector and was designed to be placed in the coronary sinus and provide a force on the mitral valve to reduce the annular dimensions. Of course, the circumflex coronary artery is also present in the posterior atrioventricular groove.

When it came time to begin implanting Carillon devices in humans, there was a perceived need for regular input from an interventional cardiologist, over and above the input they were already receiving from the distinguished members of the scientific advisory board and investigators. They approached me, and I believed this was an area that coincided well with my interest in structural heart disease. I immediately perceived the clinical need for a percutaneous treatment for functional mitral regurgitation, in part because the University of Washington has a large heart failure/transplant program. I am also pleased to note that, so far, we have not seen a case of myocardial infarction caused by the Carillon device compressing a coronary artery.

Where does clinical study on functional mitral regurgitation treatment stand at this time?

Functional mitral regurgitation is an interesting condition, and one of the curious aspects is that it appears to be a rather silent epidemic, infrequently recognized despite being quite prevalent. In nearly 5,000 patients with congestive heart failure examined with echocar-

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diography in a variety of studies, functional mitral regurgitation was seen in nearly two-thirds, with 40% of heart failure patients having more than mild functional mitral regurgitation. This represents an astonishingly large population of patients who might benefit from an effective therapy, more than 10 times the number of patients in whom TAVR might provide a clinical value.

Incidentally, these numbers may even underestimate the number of patients with clinically important functional mitral regurgitation because those assessments are done in supine, resting patients. It is likely that exercise mitral regurgitation is even more relevant clinically, and some patients with mild mitral regurgitation at rest will have more significant degrees of mitral regurgitation with exercise, and these patients may well benefit from mechanical therapy to prevent this from occurring. If one assumes these prevalence studies are reasonably accurate, the question becomes, why don't we recognize this epidemic? I suspect it is because we don't pay any attention to things for which we don't have a specific treatment. Of course, when an acceptable treatment is found, suddenly the condition seems to be omnipresent. I doubt there were too many diagnoses of patent foramen ovale made 15 years ago, but now that closing them has become popular, it is quite a common diagnosis.

I also think that the MitraClip (Abbott Vascular, Santa Clara, CA) experience in Germany supports the contention that there is a lot more functional mitral regurgitation than has been recognized. Most of the MitraClip procedures being done in Europe are in patients with functional mitral regurgitation, and there has been an exponential rise in the uptake of this therapy, despite

(Continued on page 72)

(Continued from page 74)

the complexity and steep learning curve. Additionally, it seems that clinicians have been pleased with the patients' clinical response to this percutaneous option. The percutaneous Carillon Mitral Contour System has been designed specifically to treat patients with functional mitral regurgitation. We have seen that after implantation of the device, 80% of patients have improvement in their MR, with 1-year results even better than at the time of implantation. It is CE Mark approved, and the company has now been approved for reimbursement in Germany and is pursuing reimbursement strategies in other countries as well. In addition, we are preparing for a randomized pivotal trial in the United States. This is an exciting time in the field of functional mitral regurgitation.

Can you tell us about some of the clinical trials you are currently involved in?

The University of Washington in Seattle is a PARTNER site—the only one in the Northwest. We are one of the top enrolling sites in the RESPECT and PREMIUM trials evaluating Amplatzer PFO occluder devices (St. Jude Medical, Inc., St. Paul, MN) for the management of cryptogenic stroke and migraines, respectively. We plan to participate in the trial evaluating the Amplatzer Vascular Plug to close atrial appendages in patients with atrial fibrillation, to avoid the need for anticoagulation. As part of my work with Cardiac Dimensions, we are actively doing human studies with the Carillon Mitral Contour System in Europe and South America.

What is your opinion of the ongoing PARTNER trial and the recent FDA approval of the Edwards Sapien device (Edwards Lifesciences, Irvine, CA)?

The PARTNER trial is landmark on so many levels. It is causing the interventional cardiology and cardiac surgery communities to change practice patterns and allows us to be effectively treating patients who otherwise are undertreated. It has altered the relationships between interventional cardiologists and cardiac surgeons in truly “partnering” with each other to select the optimal treatment for patients, and there have been ramifications of that beyond treating aortic stenosis. The landscape will be rapidly changing, with future miniaturization, improvements in architecture and delivery, not only with the Edwards valve, but also others. The economic impact of treating such an elderly population, as has been studied in PARTNER, is going to represent a benchmark for other therapies and is likely to spawn a whole area of research in cost-effectiveness and medical ethics.

For which procedures do you use IVUS imaging? What do you think this technology might be capable of in the future?

My experience with IVUS dates back to the early work that I participated on with Drs. Antonio Colombo and Jon Tobis on optimizing stent implantation. It was very exciting to be a part of something that helped to usher in the period of “stent mania” and then to see that phase become mainstream. I have always appreciated the information that IVUS provides for us, and I continue to have a low threshold for using it for lesion assessment, to guide placement of stents in terms of location and sizes, and to assess optimal stent expansion. I also find it important in the evaluation of a restenotic lesion, as well as a useful tool for certain chronic total occlusions. There might be a role for IVUS in helping to accurately size the coronary sinus to assist in deciding which size Carillon device to implant, but that will represent a “fine-tune” adjustment to the current procedure.

I am excited by the potential for forward-looking IVUS, which may open up a whole range of new possibilities. This technology may help simplify the access of the coronary sinus and great cardiac vein, which is usually straightforward, but occasionally challenging. I also am quite interested in the use of intracardiac echo and have explored this technology in a variety of less common conditions. For example, I will sometimes place the intracardiac echo probe in the ascending aorta to help guide a percutaneous closure of an aortic pseudoaneurysm. I use intracardiac echo to help guide percutaneous biopsies of intracardiac masses, and it has been very helpful in ensuring that sufficient tissue is safely obtained.

What do you believe is the motivation of the anti-technology, anti-interventional cardiology movement that seems to be surfacing?

There seems to be a cadre of individuals who build their academic careers tearing others down. It is understandable that there are going to be critics of expensive technologies; however, there are those who are furthering their careers and notoriety simply by criticizing. It is interesting that they are accruing secondary gain from this behavior, yet fail to acknowledge the secondary gain—even when cash is received from antitechnology organizations. Even though such individuals may not be paid by traditional pharmaceutical or device industry, there may be payments and tangible benefits, such as academic advancement that should be disclosed but is not.

Criticism requires some degree of constructionism to be meaningful, otherwise there is little value. Because so many patients are treated by cardiologists, and the

resources are high in interventional cardiology, we are targeted for criticism; especially, it seems, by those who further their own careers primarily by criticizing others. What is so strange is that by and large our patients are very happy with us because we make so many of them feel better, but it seems that is not enough: if we aren't saving lives with our therapies, we are criticized.

How did you develop a medical philosophy based on individualized care and patient knowledge/empowerment? Why is this important to your practice?

What an interesting and philosophical question. It strikes me also as quite personal because each of us has to come to terms with how to care for patients given the imperfect knowledge base we have to work with. But the question does reflect my preferred approach, which is to involve the patient in the decision-making process as much as possible. In order to do this, I spend much of my time educating patients and their families so that they can have as much information as I do, and then I encourage them to decide for themselves how they wish to proceed. This means that sometimes patients do not choose the course that I would personally choose for them, or for myself if I were in a similar situation. But if that approach is not unreasonable or dangerous, I will put their educated wishes over my biases.

We all struggle with this at times, but, as the question poses, my philosophy is to educate patients and allow them to choose their treatment whenever possible. I think that this philosophical approach arose not only from the current ethical climate, but perhaps was explored by my exposure to working in fertile cutting-edge environments, wherein there are limited data from which to make decisions. When there is a solid set of data, it is natural to lead the patient a certain direction. For a patient presenting with a STEMI, like most cardiologists, I strongly recommend an invasive approach with stenting. But for a patient with a PFO and a cryptogenic stroke, I want the patient's philosophical approach to life be an important component to the decision process, which is less straightforward than deciding what to do with a STEMI. ■

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