

AN INTERVIEW WITH...

Saibal Kar, MD

Dr. Kar shares his insights on current left atrial appendage closure data, as well as his thoughts on transcatheter mitral and tricuspid repair.



What is the current focus of your clinical research, and what areas of focus do you want to move on to next?

In broad terms, my current focus of research is interventions for structural heart disease. I've been involved in

the ongoing trials of the MitraClip device (Abbott Vascular); I'm trying to complete enrollment in the COAPT study, and we have the highest enrollment in the country. The second study I'm involved with in the mitral arena, is early feasibility trials of transcatheter mitral valve replacement.

In addition, I am very interested in the tricuspid valve. I'm working on the Trialalign device (MitrAlign, Inc.), as well as using the MitraClip for tricuspid repair (which is a new study that I'm going to start).

A third focus has been on transcatheter occlusion of the left atrial appendage. We are now enrolling patients in the study that is comparing the Amulet device (Abbott Vascular) to the Watchman device (Boston Scientific Corporation). I'm also doing a study on contraindicated patients (eg, those patients who cannot take any anticoagulation) that will evaluate the use of the Watchman device in patients in that category.

I am also working on the future development and testing of the new Watchman Flex device (Boston Scientific Corporation). Hopefully, once the design is set, I'll be one of the initial investigators of the Watchman Flex study in the United States.

Which patients should be considered for left atrial appendage closure?

The ideal patient has paroxysmal or chronic atrial fibrillation and is at risk of stroke. There are certain scoring systems, such as the CHADS score and CHADS₂VASC score that determine the risk of stroke, and those patients who are at risk of stroke should be considered. But, I would say the three categories of patients are those who cannot, those who will not, and those who should not be taking long-term anticoagulation.

Please provide some insights on the postapproval WATCHMAN results you recently published. What do you think these data tell us about the therapy in a real-world setting?

The initial paper that was published was just a glimpse of the initial key safety results of this procedure in the commercial setting. It must be remembered that this was the first commercial phase of this device in the United States, and the majority of the implanters in this study were actually new investigators. However, the difference was that they were properly trained because now there is a very good training protocol developed by the manufacturer. The study showed that the success rate has remained very high (> 96%) and the overall acute complication rate has remained very low, even though 70% of the operators were new to the procedure and they performed 50% of the procedures in the study.

These data tell us that in the real-world setting, the procedure has become mature and now we can train new physicians because we've come up with a standard approach of how we should do the procedure.

The FDA has mandated that there has to be a clear-cut training protocol. Boston Scientific has come up with proper guidelines, as well as a system for training new physicians that has been effective.

Every new physician must complete an online course. They then take part in a 1- or 2-day training course where each physician goes through the literature, as well as reviews and learns the imaging, the actual procedure details, and the device and the complications. Some training sites, including Cedars-Sinai, allow attendees to observe live cases as well.

What advice would you give to someone who is new to Watchman implantation? What role do coordinators play in structural heart and left atrial appendage closure programs?

First, I would say that the field of left atrial appendage occlusion is a very large field. In the United States alone, there are 6 million patients with atrial fibril-

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lation, and at least 1 million of these patients are at risk of stroke and are not on any blood thinners. So, there's a very large population of patients who remain unprotected.

The field of left atrial appendage occlusion is gradually going to expand as we gain experience and more physicians who are interested in structural interventions become very efficient in the procedure, as well as in the workup of these patients. It will be essential to have a coordinator (ie, a research coordinator) who helps in the education of the patient as well as the workflow.

At Cedars-Sinai, we have an excellent physician assistant who is very well versed with the procedure, the complications, the therapeutic benefits, and the follow-up. When we see a new patient, this coordinator sees the patients first and describes the procedure, the literature, the benefits, and the follow-up. I then talk just about the procedure. In this way, we can include the workflow integration into seeing patients.

Also, the TVT registry requires that these patients be followed-up with for at least 2 years, and that is a lot of follow-ups. The coordinator helps to manage that follow-up.

What future interventional cardiology technologies are you looking forward to most?

I'm looking forward to the next generation of left atrial appendage occlusion devices. I think there should be some modifications to the current-generation device that should focus on furthering the safety of the procedure, as well as some changes in device design to reduce the rate of perforation and reduce the risk of embolization. Perhaps even a change in the material to reduce the risk of thrombus formation on the device.

Besides left atrial appendage occlusion, I'm excited about new forms of transcatheter mitral valve repair and transcatheter tricuspid valve repair.

Are there any remaining issues or concerns regarding reimbursement for Watchman?

Medicare has had national coverage determinations since February 2016. I think it's a very reasonable decision that Medicare came up with.

I think there may be a problem regarding physician fees. The relative value units assigned to the new CPT code for the Watchman procedure seem to be lower value than comparable procedures.

For example, patent foramen ovale closure is a much simpler procedure, but the relative value units associated with patent foramen ovale closure are higher than for left atrial appendage occlusion. That doesn't make any sense. I hope that the professional societies appeal this decision and make the appropriate recommendations.

What advice would you give to a fellow who was considering entering the structural heart arena?

We have a lot of fellows who apply to our program. The first thing we tell them is that they must have proper training in imaging. And, imaging means echocardiography, transthoracic and transesophageal echocardiography, and CT scan and MRI. Most of these procedures are image guided, so imaging is a very important part of the procedures. Once they can image these three-dimensional structures, then they will understand the procedure.

Second, I always tell them to properly understand and learn the physiology of valvular heart disease. You need to understand the physiology. You can't just put in a valve, you have to know when to put in a valve and who will benefit.

Third, they should learn the details of the procedural steps, focusing on the safety and efficacy of the procedure.

Structural heart disease intervention is a new expanding field of interventional cardiology. The scope and the practice of structural heart disease interventions is going to continue to increase, and this is going to be to the great advantage of patients because now patients and providers will have safe and less invasive approaches for the treatment of their disease. ■

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