

# Susheel Kodali, MD

An expert in the field discusses the current status of TAVR research and looks ahead to the challenges of mitral valve replacement.



**One-third of patients who have aortic stenosis fail to receive proper treatment. Do you attribute this to a lack of patient awareness or an inability to treat them due to comorbid conditions? How can the interventional cardiology community reach out to these patients and make them aware of the latest technological advances in treatment?**

The reality is that patients have certain biases about going through treatment, and as they get older, they are more reluctant to undergo large-scale surgical procedures. Therefore, they minimize their symptoms and often don't seek treatment. The same kind of bias exists among referring physicians to an extent, in terms of reluctance to send older patients in for aggressive intervention because there are more risks and comorbidities involved. The interventional community can help by making sure that the treatment options for these patients are well known and understood by internists, who may provide the first line of treatment. However, some of these patients are appropriately left untreated, because they are too sick to undergo such procedures.

**How will the next wave of transcatheter aortic valve replacement (TAVR) devices improve upon the features of structural integrity and durability? What other attributes are you looking for in these new or adjunct devices?**

I think there are a lot of ways in which these devices can make progress, especially with size. Commercially available devices in the US are first generation, and to be honest, we're the only country still using them. Second-generation devices have a smaller profile; the third generation will surely continue this trend, which will increase the number of patients who can receive the devices through a transfemoral approach. If you can perform the procedure with minimal anesthesia or sedation, you can improve the patients' recovery time. The thoracotomy incision needed with transapical or transaortic approaches hinders the road to recovery, so I prefer to avoid those options.

Another issue has been paravalvular leak, so we are looking at next-generation valves, as well as adjunctive devices, that aim to reduce the amount of leakage by improving the seal at the aortic annulus with either different anchoring

mechanisms or a skirt to seal the paravalvular leak. Better sizing of the annulus will also reduce this complication.

**What issues are most imperative to address in the next round of TAVR trials? What has not yet been answered to your satisfaction in the PARTNER trial?**

We need data about longer-term durability, but this will take time. In order to obtain these data, we need to complete long-term follow-up; however, the early trials may not provide this information because the patient population in these studies was elderly with significant comorbidities that would limit their long-term survival independent of their aortic stenosis. PARTNER 2 and SURTAVI are enrolling lower-risk patients with less comorbidities, so that we may be able to get some of the answers we need from those patients. We also need to assess the stroke risk and paravalvular leak more closely as we go forward.

**Do you refer to the VARC guidelines to assess patients for suitability for TAVR and to measure success postprocedurally?**

I think VARC is a good standardized document for research purposes, because we need to gather data on real-world experience. In terms of preoperative assessment, we still mostly rely on our experience in the PARTNER trial and the large number of procedures we performed therein. So, we don't use the VARC guidelines strictly before a procedure, but I believe that they are a good way to standardize decision making in terms of which patients are appropriate to undergo treatment.

As a measure of postprocedural success, we use these guidelines to accurately assess and record complications and results that occur in the real world. I think this is an important part of how we should be using the VARC guidelines.

**What pre-, peri-, and postprocedural efforts do you make to reduce paravalvular leak after TAVR?**

Before the procedure, we perform cardiac CTs or transesophageal echocardiography with three-dimensional (3D) reconstructions to more accurately size the annulus. It is not a circular structure—there is an ellipticity to it. We take 3D measurements and calculate the mean annular diameter to better size the prosthetic valve. We also look at patterns of calcification with gated cardiac CT or 3D transesophageal

*(Continued on page 75)*

(Continued from page 74)

echocardiography to assess the annulus before we move forward with treatment.

Intraprocedurally, we continue to look closely at the valve. After deployment, if we see paravalvular leak, we consider postdilatation to achieve better valve expansion, which will potentially reduce leakage. Sometimes, you simply cannot get perfect apposition of the valve to the annulus due to bulky classification. I've seen a few patients in whom these gaps existed, and we used vascular plugs to seal them. We are fairly aggressive in treating patients who are symptomatic and in whom the paravalvular leak is significant.

### What concerns do you have about the expanding treatment of lower-risk patients with TAVR?

The procedural complications are still significant, and we need to understand that a patient who has a surgical risk of 1% or 2% may not be an appropriate candidate for TAVR therapy either. One of the major complications with TAVR is stroke. We know, based on the randomized PARTNER trial, that neurologic events are more frequent in TAVR versus surgery. As we move to lower-risk populations who have atherosclerosis, we may find this risk to be even greater. We want to understand whether adjunctive devices, such as filters or deflectors that are being used in human trials outside the US, will reduce the stroke risk. If so, before we begin treating a lower-risk population, we need to have these devices available. Durability is another issue. A patient who is 70 years old will need more than 5 to 10 years of durability, so we need to understand more about the long-term durability of these devices.

### What are the latest developments in mitral valve repair regarding devices and treatment options?

There are a lot of options on the horizon right now. The etiology of mitral regurgitation (MR) is not uniform (redundant tissue prolapse, dilated cardiomyopathy, functional MR resulting from annular stretch, or ischemic MR resulting from prior infarcts, leading to tethering of the leaflets). Because the etiologies are variable, the treatment options are variable. The device with the most experience in human patients is the MitraClip (Abbott Vascular, Santa Clara, CA).

Right now, we're enrolling patients in the COAPT trial, which is comparing the use of the MitraClip to best medical therapy in patients who have functional or ischemic MR and are not surgical candidates. I think this is representative of the population undergoing the MitraClip procedure worldwide. In clinical settings, many patients with functional or ischemic MR are not good surgical candidates. For patients who cannot undergo surgery, I think the MitraClip is a good option. There are already encouraging data from high-risk patient registries that this device might provide significant

benefit, especially in terms of symptoms and left ventricular remodeling.

Other devices are out there, but so far, they have only gotten as far as first-in-man studies. These involve direct annuloplasty methods that are performed in a retrograde manner through the aortic valve via an arterial approach. In this procedure, anchors are placed, and the annulus is plicated, similar to a surgical approach, but in a somewhat more limited way. Down the road, I think mitral valve replacement will be possible through a transcatheter approach. However, there are challenges we need to overcome because the mitral valve annulus is more asymmetric. It's larger than the aortic valve, so the catheter is going to be larger. Hopefully, it will be deliverable through a transvenous or transapical approach. However, I do foresee paravalvular leak as a complication for mitral devices because the mitral valve is an asymmetric structure (more so than with the aortic valve), and because the gradient between the left ventricle and the left atrium is large, this may predispose toward potential serious complications such as hemolysis. Some of these devices are currently undergoing study, but we are a long way from seeing approval at this time.

### Can you tell us about the Fraternity of Advanced Cardiovascular Techniques and Solutions Foundation and how it is working to educate those in the worldwide interventional cardiology community?

Right now, this project is in the early stages. I am originally from India, and I still work with colleagues there. One of the challenges is disseminating educational content to them. There is a lot of interest, but their conferences are not as well-established as others around the world. Many of the operators work in low-volume hospitals and may only perform a dozen interventions per year. So, part of our goal with this program is to help promote cardiology education in India. We transmit live case feeds to India from large meetings around the world. We also run a course there every August, where several interventionists from the US perform live cases. However, we also gain from this relationship because we have the opportunity to view and perform procedures there that we don't get to do often in the US, such as balloon mitral valvuloplasty. Our goal is to facilitate education back and forth. ■

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