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TAVR Talks: The Latest Minimally Invasive Technologies

Announcer: Welcome to ReachMD. The following program, “TAVR Talks: The Latest Minimally Invasive Technologies” is provided in partnership with Boston Scientific.

Dr. Birnholz: Historical approaches to treating aortic valve diseases have typically involved invasive open-heart surgery, which can be physically and emotionally difficult for patients who tend to be very sick and delicate to treat.

But now, new minimally-invasive technologies to treat both common and complex structural diseases of the heart are offering unique solutions to patient care. We’ve seen a boom in transcatheter aortic valve replacement, or TAVR, system advancements – the LOTUS Edge device, which was recently approved by the FDA and is providing a new experience for implanters.

Today, we’ll explore this latest advancement, including how far minimally-invasive procedures have come, where they’re going, and how-to better support hospitals as they expand the breadth of care for patients with structural heart disease.

Coming to you from the American College of Cardiology’s 68th annual Scientific Session and Expo in New Orleans, this is ReachMD, and I’m Dr. Matt Birnholz. First, joining us from Boston Scientific, is Chief Medical Officer, Dr. Ian Meredith.

Dr. Meredith: So, at BSC, we are trying to advance cardiovascular medicine for today and tomorrow because that is one of the largest problems that we’ll face in the 21st century. In fact, actually, it is the principal cause of ill health and indeed, death of all the non-communicable diseases we’ll face between now and 2050.

So, our approach at Boston Scientific is to provide a holistic approach to transcatheter aortic valve replacement, providing optimized valve solutions.

Boston Scientific have adopted a two-valve strategy, a dual-valve strategy. A complementary strategy of a supra-annular valve, ACURATE, and an intra-annular valve LOTUS Edge. These two valves cover most of the clinical workhorse opportunities for patients with varying clinical needs.

We live in incredibly exciting times. With exponential growth in digital technology and at the same time, material sides mean that we’re developing even more sophisticated medical devices.

Dr. Matt: That was Dr. Ian Meredith on the latest commercial developments for TAVR technologies. Starting off our interviews at the ACC conference is Dr. Dean Kereiakes, from Christ Hospital Heart and Vascular Center in Cincinnati, Ohio. Dr. Kereiakes overviews the impact of aortic valve disease and the latest TAVR technologies designed to address it.

Dr. Birnholz: I’m interested in your impression of just walking our audience through what aortic valve disease is, how it impacts patients.

Dr. Kereiakes: Well, aortic valve disease typically is a disease of an aging population. With every decade there is an increase, and over the age of 80, there is probably 10% or more of people over the age of 80 have some degree of aortic valve stenosis—particularly male patients. That elderly population, like it or not, is the most rapidly growing segment of the American population today.

Dr. Birnholz: Right, and that naturally brings us to this evolution of TAVR technology.

And since you’re an investigator in the REPRISE III and IV trials for this TAVR device, can you just walk us through what the approval of LOTUS Edge will mean for patients and their providers?

Dr. Kereiakes: Yes. You know, each of these valves are very different, with the Edge, I tell you, you rarely see more than a 10 mm drop in systolic blood pressure.

You can literally completely retrieve the valve even after it's completely deployed. You recapture, reposition, redeploy. Can you imagine the safety of that relative to the other valves that are out there? It's pretty remarkable.

Dr. Birnholz: That is. And those do sound like some remarkable differentiators from other devices. Are there any other differentiators?

Dr. Kereiakes: Absolutely. The peri-valve seal is second to none, bar none. And we've used probably, I'm serious, 8 different TAVR valves. Nothing seals like the Edge.

And, this seals where you can actually have a result of zero peri-valve leak. I mean, where else do you get zero peri-valve leak.

So, when we go into a LOTUS case, we're not so worried that we are going to rupture the annulus—because I don't know that's ever happened with a LOTUS valve—we're not so worried that we're going to put it in the wrong place or have to put a second valve in, which has happened with every other valve we've used potentially, and so you have the comfort of knowing that you're going to get a predictable, reliable, good result that you're going to be happy with or you're not going to walk away. Think about that. That's a huge comfort for the physician and the patient.

Dr. Matt: That was Dr. Dean Kereiakes talking about the evolution of TAVR technologies. Moving on, we caught up with Dr. Hemal Gada from Pinnacle Health and Dr. Samir Kapadia from the Cleveland Clinic, who shared their insights on the importance of cerebral embolic protection in TAVR procedures. Here's what they had to say at the conference, starting with Dr. Gada.

Dr. Birnholz: So, just to get us started, can you help explain what cerebral embolic protection is, specifically, and why it's so important during a TAVR procedure, from the perspective of the patient and the hospital, actually?

Dr. Gada: So, transcatheter aortic valve replacement as you are aware, is the actual act of implanting a valve within a heavily calcified, stenotic aortic valve, and that's often done transfemorally, percutaneously, needle-based procedure, very minimally invasive; but one of the risks with transcatheter aortic valve replacement is embolism, and what that means is, basically, particles that would then go from their native place somewhere else.

So, all of that debris can then embolize up to the brain, God forbid, and cause a stroke. So, the field of cerebral embolic protection was kind of built on the idea that putting an accessory device, potentially via the radial artery, potentially deploying filter-based technologies into these arch vessels, would help protect the brain during a transcatheter aortic valve replacement.

If they're anatomically eligible for the Sentinel device, it's our practice to put it in every single patient that we're doing a transcatheter aortic valve replacement on just because we've made that decision and we believe in the portion of the data.

Also, with the burgeoning amount of observational registry data that's coming out of Holm, Germany; Cedars-Sinai; Cleveland Clinic; a bunch of other places—including our experience where we've amassed now probably over 200 cases using the Sentinel device—our stroke rates are completely minimal versus what they had been previously.

Dr. Birnholz: And, what makes the Sentinel device so different in this space today?

Dr. Kapadia: I think the most important part is the fact... First of all, it's the only available device that is available for cerebral protection currently in the United States, and the second important thing is that it is a device that is relatively easily placed through the radial artery.

So remember, last year we did 500 TAVRs, and so if you consider the stroke rate is 2.5%, which is what is reported currently in the TVT registry, that amounts to almost 15 patients or 12 patients with stroke, and we didn't have—we had only 1 patient with stroke in the entire population and the only one that we did not use... In a few of the patients we cannot use a Sentinel device. This was one of those patients that we did not use Sentinel device.

There were no safety concerns in the sense that when you put the device, there were no device-related complications by putting the device in.

I don't see a big change in our practice in the sense that if patients are low-risk we are still going to use the Sentinel device even though the risk of stroke is extremely low. It is low but not zero, and the expectation is zero, so this is the challenge that you are going to face. It's very, very hard not to use the device when it is safe.

Dr. Matt: Those were Drs. Hemal Gada and Samir Kapadia speaking to the value of cerebral embolic protection for TAVR procedures. Next, we joined Drs. Michael Reardon from Methodist DeBakey Heart and Vascular Center in Houston, TX and Vinod Thourani from MedStar Heart & Vascular Institute to take us through the latest insights from clinical trials for TAVR. Let's take you to that coverage now, starting with Dr. Reardon.

Dr. Birnholz: So why don't we start by getting an overview, for the sake of our audience, of the REPRISÉ III LOTUS Valve Clinical

Program. And maybe you could just give us an overview and tell us what that's about.

Dr. Reardon: Sure. Well, the LOTUS is a very unique valve. As you know, there's a balloon expandable valve, a self-expanding valve, but LOTUS is halfway in between. It's a mechanically expanded valve. It's the only valve we have that I can deploy to complete deployment, look at it, decide if I like it, and if I like it, I'll let it go, and I know what I'm getting. If I don't like it, I can take it out, move it, change it, do whatever I want. It's the safest valve out there.

And because it is fundamentally different than balloon-expandable or self-expanding, it provides a real good third valve to have on your shelf because it's fundamentally different.

So, some of the things that caused a death in TAVR, which are almost all procedural, can be eliminated.

As we move into lower risk and we have more patients, we need more choices as implanters as to what to use for each individual patient. Getting LOTUS out there is going to be great; getting ACURATE out there, better. And let's continue to develop things such as embolic protection and other ancillary devices that continue to make this procedure safer and safer and safer.

So, REPRIZE III came along when we could really no longer randomize against surgery.

So, we randomized 2:1—2 LOTUS to every 1 CoreValve, so we're randomizing against the commercially available valve, and we're looking at things such as survival; we're looking at things like stroke; we're also looking at PVL. And what we found is, for safety, we did really, really well. But most importantly we have essentially no PVL. That's the real strength of this valve and this skirt is no PVL.

Dr. Birnholz: So, why don't we dive right in and move right into REPRIZE IV. Why is the REPRIZE IV study such an important part of the LOTUS Edge clinical story?

Dr. Thourani: The REPRIZE III study really was of the LOTUS Valve, not the LOTUS Edge Valve, for all practical purposes, and so now bringing the LOTUS Edge Valve—which has a new variety of mechanical features that are going to be very powerful, we believe, in the field of TAVR—bringing that to not only intermediate-risk patients but bringing that valve out for us to be able to use, I think, is going to be very important. And so, I think that there's going to be a variety of things that the LOTUS Edge in the REPRIZE IV is going to be just a wonderful thing for us to look at. It will be, hopefully, the continuing of the low paravalvular leak rates that occur with the LOTUS Valve, but also hopefully decreasing the pacemaker rates which were a little bit high in REPRIZE III, and we want to get those down to show really what this valve has the capability of doing.

I think that having almost no paravalvular leak in a patient is very satisfying, and that's for me personally very nice, because as a surgeon, when I finish a surgical valve replacement, I have almost never any paravalvular leak, and so kind of putting a TAVR valve in the same light as a surgical valve personally makes an impact.

If you look at it in the United States, there are about 1,100 to 1,200 cardiac surgical programs and there are about 600 TAVR programs, and so I think we need to make sure that patients need to know that there are options, and the heart team together should make a decision on what TAVR or SAVR is the best modality for them.

And over a 10- to 12-year time period, we've completely revolutionized how we're going to manage aortic stenosis. I can't think of the last time we've really done that in medicine and in surgery, and I think that's what excites me, is we've now done that, but there's a lot more in the next decade. There's mitral, there's tricuspid, so we're really scratching the surface, and I think we've set the bar that randomized trials and a good clinical evaluation really makes guideline-changing practice.

Dr. Matt: Those were clinical trial updates from Drs. Michael Reardon and Vinod Thourani. Applying these clinical insights into real-world experience, our last interview focused on the impact of LOTUS Edge on patients and their caregivers. Let's take you to that conversation now.

Dr. Birnholz: Joining me today are Allen and Diane Brady. Mr. Allen Brady is a retired Navy Captain, Purple Heart recipient, avid golfer, and author of a newly published memoir. He recently received a LOTUS Edge device and is here to share his experience from a patient perspective. He's joined by his wife, Diane Brady, who, as a family member and caregiver, represents a critical support role that sometimes goes missing from treatment conversations for patients with cardiovascular disease.

So, Mr. Brady, I want to start with you and get an overall sense... It's a bit of the impossible question, but it's a question that I'm going to pose—

Mr. Brady: Sure.

Dr. Birnholz: And one that is simply, can you tell us a little bit about your journey, from being diagnosed with aortic valve disease, and the impact that this had on your life? Can you tell us a little bit about that journey?

Mr. Brady: Well, the journey... I have a cardiologist in Pensacola, and I see him every year, and I've always had a heart murmur—I had it for years—and he told me about a year or so ago that he thought that I may end up needing a valve change, and I said... You know I'm thinking rip open the chest and grab it out of there. But he didn't say anything about it, and I said, "No, I don't want to do that," so we moved on. So, the next year, which is this last year he said, "You're going to have to have this done. You may not have much time left. You might only have a year or a year and a half or something." And then he told me about TAVR, and it just stunned me that there was such a procedure, and so I said, "Absolutely."

Mrs. Brady: And so, between what they told us that day and then what I know as a caregiver, I was very comfortable going into this procedure. I was almost... If you can be excited about a surgery, I was because I had seen where he was headed with his breathing and exertion with exercise and not finishing his 18 holes. I knew when he couldn't finish a round of golf, we were in trouble.

Mr. Brady: We have a 2-story house, and it was getting to when I had to go up to the second floor, start to huff and puff a little bit, and now I can run up the stairs, play golf. They told me, "You're completely unrestricted. Do what you want." And everybody says I look better. I don't agree with that but...

When I was a POW, it went on and on and on for 3, 4, 5 and 6 years, 6 years and 2 months before I got out of there, and we used to say, "You know, I just had 6 years ripped out of my life." And I'm not bitter. And then when this heart thing came along... I was 88 years old when I started writing the book—while I was writing the book. Then I had finished it by the time the TAVR came along, and I feel like I got those 6 years back with this, and maybe more. I'll be 90 next August, and it absolutely makes me feel that way, that I got a payback for it. I thank the doctors and the scientists and the people that are constantly trying to improve things and so forth.

Mrs. Brady: You know, of course you want your spouse to have a good quality of life, and as a wife and a caregiver, professional caregiver, what TAVR has done for him is given him the time for another mission in his life whatever that might be. He wouldn't have that chance if it weren't for this heart valve and every day I wake up and I thank God otherwise, we could be counting the days right now. I'll never get over... I'll never forget it, that TAVR gave him another mission, and that's to spread the word to other people that there is hope out there for aortic stenosis.

Dr. Birnholz: Well with that, I'd very much want to thank all of my guests for joining me today at the American College of Cardiology to talk about the latest advancements in minimally-invasive structural heart technologies. For ReachMD, I'm Dr. Matt Birnholz. Thanks for joining me.

Announcer: The preceding program was provided in partnership with Boston Scientific. This is ReachMD. Be part of the knowledge.