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Experts Discuss Longevity and Durability with TAVR

Announcer:
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Dr. Baron:
What are the advantages of using transcatheter aortic valve replacement, or TAVR, in different patient populations with aortic stenosis? And how do we translate the recent findings from the CoreValve US Pivotal and SURTAVI trials into long-term clinical benefit for these patients?

This is CME on ReachMD, and I'm Dr. Suzanne Baron. Joining me today in the studio is Dr. Kendra Grubb, and from Montefiore Medical Center in the Bronx, New York, is Dr. Jonathan Bradlow.

Dr. Grubb:
Thank you for having me. Good morning.

Dr. Bradlow:
Nice to be here.

Dr. Baron:
Well, it's great to have you both here today. We've got a lot to discuss, so let's get started!

To start our conversation, Kendra, as a cardiac surgeon and one of the preeminent physicians in the structural heart valve disease space, can you talk to me a little bit about what the differences are in the approaches to aortic valve replacement and how you're using the recent findings from this 5-year analysis to impact your decision-making for TAVR versus SAVR [surgical aortic valve replacement] in certain populations?

Dr. Grubb:
Well, thank you for that. You know, aortic stenosis was traditionally a surgical disease. Calcification or hardening of the valve, resulting in heart failure for the patient, we would take the patient to the operating room and through a median sternotomy actually cut out the valve and sew a new valve in. And that's still the way that we offer patients surgery, even though there are some minimally invasive approaches. And the track record is actually very good.

But there was a large patient population who we weren't treating. So many octogenarians or patients with multiple comorbidities, they were never even being sent for consideration. And so the transcatheter aortic valve replacement, or TAVR, became an option for these patients, where a puncture in the groin and placing a wire into the heart and then a catheter inside of their diseased valve, pushing that valve out of the way, and the new valve kind of holding on by radial force and friction became very mainstream for this older, sicker patient population. Then we studied it in intermediate-risk patients and then low-risk patients. But still, even the low-risk patients are

patients in their 70s. And so we don't quite know if those patients that are younger are really appropriate for TAVR yet.

And so that leads me to this 5-year data that you mentioned. And so this was an analysis of SURTAVI, which was that intermediate-risk group, still 80-year-olds but intermediate risk, comparing surgery versus transcatheter aortic valve replacement with a self-expanding supra-annular either CoreValve or Evolut. And they followed these patients out at 5 years. And based on VARC-3 definitions of structural valve deterioration, they found that there was less structural valve deterioration at 5 years in the TAVR group. And so these patients were doing better with TAVR than with surgical aortic valve replacement; fewer valves failed. In fact, about half as many valves had failed.

And so, you know, who really benefited? Well, I can tell you who didn't: the patients with a small annulus, women, anybody with a small annulus. The valve, from a surgical standpoint, the inner diameter is smaller, and so those patients had even more accelerated structural valve deterioration.

What do we know long term? Well, we don't know a lot. But as we follow these patients out to 10 years, we're going to learn a lot more about what is the right valve for these patients.

But one of the other things that the trial showed was that there was a price to be paid for this early structural valve deterioration. And there was higher mortality in those patients who had early structural valve deterioration than those patients who did not. And that favored TAVR again.

So this is really, really important in our heart team decisions. This is important in individualized care and certainly important when we talk about the lifetime management of the patients that are being sent to us. We have to really think about what this data means for them and their lifetime as we care for them.

Dr. Baron:
I think that's a really important point.

You know, Jonathan, as one of the referring cardiologists to the heart team, you know, how do you monitor your patients who have either received TAVR or SAVR for structural valve deterioration? What are the criteria that you're looking at? How do you monitor, and when do you decide when to send patients back?

Dr. Bradlow:
Well, the first thing is, obviously, an early baseline echo post implant, usually within 30 days. After that, maybe at 3 months, then at 6 months, then annually thereafter, provided nothing has clinically changed with the patient. And we are essentially following VARC-3 in terms of looking for increasing in gradient or issues with prosthetic valve dysfunction in terms of paravalvular leaks, regurgitation, and worsening stenosis.

In addition, in terms of sending the patient back, really, as soon as we start to think that there's a problem, we like to get the heart team back involved. Because, again, early intervention is probably better than waiting to the point where, again, the patient is so highly symptomatic. We believe that the heart team should be involved earlier, always.

Dr. Baron:
Well, let's continue on to our next topic. The recent analysis of the CoreValve US Pivotal and SURTAVI trials showed that the rate of structural valve deterioration was lower with TAVR than with SAVR. Now taking those results, as well as the guidelines into consideration, Jonathan – I'm going pick on you this time – what do we need to focus on when discussing treatment options with a patient with severe aortic stenosis?

Dr. Bradlow:
I think that this is where shared decision-making really comes into play. You need to have an extensive discussion with the patient and often their family with what do you expect as an appropriate outcome, given both the age and frailty and risk of surgery, as well as the risk of TAVR and the durability of the valve and, frankly, the durability of the patient. This is an important thing to understand, that obviously, we started out with the highest risk and then we've moved into intermediate risk. And I think that both of those populations do very well with TAVR versus SAVR, unless there's a reason not to operate, such as aortopathy or severe critical coronary artery disease, in which case, SAVR is still probably the best option. Again, your first valve really needs to be your best valve.

In addition, you need to refer these patients early. You can't wait until somebody is really in extremis to start asking somebody to go off and do a TAVR to them. So patients need to understand when they're even mild to moderate that you're following this and that this is the kind of thing that's potentially in your future. You need to have these discussions with the patients long before they get critical.

Dr. Baron:

I absolutely agree.

Kendra, your thoughts?

Dr. Grubb:
Well, I think that he hit on a lot of it. One of the things that is really important is that we're making sure that we understand the data available to us. I mean, we talked about this difference in TAVR versus SAVR, but that's at 5 years. And so for our high-risk patients, and really what we're saying is older patients, those patients' 5-year data is sufficient. But when we talk about the lifetime management of younger patients, patients who are in their 50s or 60s, and they're coming to us saying, "I want the least invasive approach," we have to also educate them that we've never studied the valves in their patient population. We don't know how long these valves last.

Also, as Jonathan alluded to, there were patients that weren't necessarily studied. Now he mentioned the aortopathies. So not only the aortopathy, so aortic aneurysms, but also heavily calcified valves or bicuspids. These patients were not followed and studied in a randomized controlled trial in the United States. And so do they really fall into the same category? We're finding that with newer-generation devices, TAVR is appropriate with slightly higher complications. But as we get into our younger patients, is this really the right platform to start with? And so I think that this conversation with the patients has to be around, you know, what's the best thing for this individual patient, not necessarily population medicine of what did the trials show.

Dr. Baron:
I think that's a really important point, because we really do want to treat that individual patient. And different patients have different preferences and different values. You really want to take the time to try to understand where is that patient coming from? And that really is where the shared decision-making and spending the time with the patient and their family and really getting to understand things comes into play.

For those of you just tuning in, you're listening to CME on Reach MD. I'm Dr. Suzanne Baron, and here with me today are doctors Kendra Grubb and Jonathan Bradlow. We're evaluating the use of TAVR and SAVR in different patient types, and also the value of collaboration with the heart team.

So let's turn our attention now to our final topic. Kendra, you know, as a surgeon, I'd love to know your thoughts on the heart team approach and how after 20 years it still remains a vital part of improving care for patients.

Dr. Grubb:
Well, this is a really important time for the heart team, actually. It's probably even more important than when we were in the high-risk and intermediate-risk trials. Because frankly, those patients, they should have TAVR: the older patients, the sicker patients. It's a great platform for 70- and 80-year-olds or those with multiple comorbidities. But now the heart team is being sent patients who are young and, as I just mentioned, weren't necessarily represented in the trial.

And so now that collaborative team approach between the cardiologists, the referring cardiologist, the interventional cardiologist, the cardiac surgeon, the imager, who's now becoming even more important, to help us truly understand the right first valve for that patient. You know, in surgery, we often say that the tissue valves will last 10 to 15 years. Well, none of the TAVR data is out far enough for us to be able to say how long the valve is going to last. And so that very first platform is what we have to build on. And for some patients, a TAVR first will make sense. You put a TAVR in a 70-year-old – I'm going to extrapolate – let's say it gets them 10 years; I put a second valve inside. And that's a fine strategy.

But for a 50-year-old, you would run out of how many valves you can fit inside. And so at some point in their trajectory, you have to assume that they're going to need a sternotomy and a traditional surgical aortic valve replacement, removing all of the valves and starting from scratch. Now is that more challenging with 2 TAVRs and the native valve? Nobody really knows. We haven't gotten that far with the devices to know because our early trials were on older, sicker patients where the valve outlived them.

Dr. Baron:
You know, I think that that's a really important point. Particularly, you know, from a heart team approach, I think when we think about this, you know, I certainly know as an interventionalist, what are the things that I'm thinking of down the road? So if I'm thinking about placing a TAVR, I'm thinking about coronary access down the road. What if this patient needs a coronary stent down the road? And that's the way that I'm coming at it.

You know, it's wonderful to be able to have a surgeon as part of a heart team that is collaborative, because they're thinking about those things that you just said, Kendra: How do we do a sternotomy on an older patient? What am I thinking about in removing 1 or 2 TAVR valves? What does that do to the operation? And frankly, you know, that's not something that I'm as familiar with.

Jonathan, what's your approach to communicating with other members of the heart team?

Dr. Bradlow:
Well, we are in constant contact once I refer the patient. And our heart team, again, is comprised, like most, of surgeons and interventionalists. And my approach is to – I like to speak with them before the patient even sees them to give them my own general thoughts, because I've often known the patient for a long time. And, you know, I agree that the high risk and the intermediate risk, those are relatively settled questions at this point. But some of the intermediate-risk patients still may qualify more for surgery than TAVR. But I like to let the heart team, especially after the imaging, come back to me and the patient, and then we all sort of talk about it. Because my concern is that as we get these results, such as our recent SURTAVI, that things are going to start diffusing out to patients that were never included in these trials. And then we're going to start to see it fail.

Dr. Baron:
So, this has definitely been a fascinating conversation. But before we wrap up, Kendra, Jonathan, any take-home messages that you'd like to share with our audience?

Dr. Grubb:
Well, thank you. I think that one of the things that is really important that's been highlighted is this lifetime management of these patients. But even within that discussion, it goes beyond just TAVR versus SAVR because these are not class effects. Surgeons know that every tissue valve has its own longevity, and TAVR valves I don't think are going to be any different.

So we say TAVR, as if all TAVR valves are going to last the same amount of time. The trial that we've been mentioning, that 5-year SURTAVI data was really about the self-expanding supra-annular CoreValve and Evolut. It may not apply to intra-annular valves, balloon expandable valves, or even other self-expanding platforms. So we have to be very careful.

You mentioned coronary access. Certainly a bigger concern with a supra-annular valve than an intra-annular valve. So it's not a class effect. And you know, TAVR is now 20 years in since the original TAVR. And I have more questions than I think I have answers today. We still have so much to learn about these valves, and more importantly, about which valve is right for which patient.

Dr. Baron:
Jonathan?

Dr. Bradlow:
I fully agree. And, you know, there are so many questions still to be answered. And my own bias is obviously towards the heart team approach. And also early referral. My feeling is, I tend to refer when people are at moderate, not even necessarily severe, but they've been progressing. Because the other thing that we know is that progression isn't always linear and that people can go from mild to moderate over long periods of time and then moderate to severe very quickly, because it's not a fully symmetrical circumferential narrowing that happens to the leaflets; it's often very eccentric.

In addition, patients need to come to grips with what is their therapy going to be when it comes time to do it? There's obviously a lot of data we still need for many of these patients. And I agree that the generalizability of one trial to the other is impossible at this point and probably academically unreasonable.

Dr. Baron:
So unfortunately, that's all the time we have today. But I really want to thank our audience for listening in, and I want to thank Dr. Kendra Grubb and Dr. Jonathan Bradlow, for joining me and for sharing all of their valuable insights and expertise. It was great speaking with you today.

Dr. Grubb:
Thank you, and goodbye.

Dr. Bradlow:
Thank you, and goodbye.

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