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Beyond Longevity: Discussing TAVR Durability for Women & Patients With Small Annuli

Announcer:
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Dr. Koss:
This is a CME activity on ReachMD. I'm Dr. Elana Koss and here with me is Dr. Hemal Gada.

Hemal, can you give us an overview of the importance of valve performance and durability in transcatheter aortic valve replacement, and address specific patient populations?

Dr. Gada:
Thanks a lot, Elana. It's a pleasure to be here. I think that we've gotten really great durability data over the past year, starting with the Evolut low risk trial. With regards to transcatheter aortic valve replacement, we have 4-year data now and PARTNER 3 of 5-year data, and then we have some really exciting data that just came out within the past few months. The SMART trial, which was a randomization in smaller annuli patients, between two transcatheter aortic valve replacement platforms that we'll go over. And then finally, we had a really exciting, pooled analysis that was just presented at New York Valves. And so, I guess we'll walk through all of those things. But I think that we have a lot of data to talk through.

Dr. Koss:
Yeah, very exciting.

Dr. Gada:
So, I'll start a little bit about, you know, kind of, what got us here. And of course, we've got low-risk patients that need durable transcatheter heart valve outcomes. In the 4-year data from the Evolut low-risk trial, we saw continued divergence between surgical aortic valve replacement and transcatheter aortic valve replacement with regards to very important clinical outcomes, including all-cause mortality and disabling stroke.

In the SMART trial, we saw a very large, randomized control trial, over 700 participants, 83 countries randomized between the Edwards Sapien 3 platform and the Evolut transcatheter heart valve platform. What we saw there is a significant difference in favor of the self-expanding supra-annular Evolut valve, as it would relate to bioprosthetic valve dysfunction outcomes. Over a fourfold difference between those two platforms. And then finally, the pooled analysis that was done in New York Valves just recently was over 5,000 patients, and we're talking about SURTAVI all the way back to US Pivotal in the high-risk CoreValve trials looking at the randomized control trial cohorts therein. But then also looking at the continued access studies and getting a real pulse what BVD outcomes are with regards to CoreValve Evolut versus surgical AVR. And obviously, significantly different in favor of the Evolut platform. That also translated the clinical outcomes out to 5 years.

But I think a lot of what we should be talking about is the SMART trial, smaller annuli, and how that may relate to females.

Dr. Koss:
I think what's really interesting was, this trial that was just supposed to be a small annuli trial essentially became a trial about females. And this was the largest female representation we've had in any structural heart trial, I believe, to date. And this is really an opportunity to study women and understand women and understand the disease process in women.

Dr. Gada:
So, as far as how women present with regard to severe aortic stenosis, do you think they present differently than men?

Dr. Koss:
So, women are presenting very often with this low-flow, low-gradient, severe aortic stenosis with preserved ejection fraction. And I think that those patients are often misidentified.

And the other piece with women is that the amount of time from identification to treatment is longer in women than in men. And we see mortality differences in that. So, women are not the same as men, they're presenting differently. They have small annuli. They're hemodynamics are different. And we really need to be very thoughtful in our valve selections for these patients.

So Hemal, which patients do you think should be referred?

Dr. Gada:
You know, I think any patient that presents with severe symptomatic aortic stenosis, but as you mentioned, it's such a complex diagnosis to ascertain, and we have to really be aware of sex-specific differences. And as you pointed out, the rates of paradoxical low-flow, low-gradient aortic stenosis are significantly higher in females.

Dr. Koss:
I think this is just to remember to refer your patients with aortic stenosis with valve areas less 1 cm2. We need to really pay attention to women with aortic stenosis. Understand that they present differently phenotypically and get these patients earlier to treatment.

Dr. Gada:
Yeah. And I know we're running out of time, but I just want to mention how critically important annual follow up of all of these trials are, and for us to have kind of public disclosure of that annual follow-up data, I think is so critically important.

Dr. Koss:
Yeah. And that's what the next 10 years are really going to be, really understanding valve-in-valve performance in these patients.

OK, well, this has been a great bite-size discussion, and our time is up. Thank you so much for listening.

Announcer:
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