Title: ACC.24: Self-Expanding vs Balloon Expandable TAVR: The SMART Trial
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"Hi. I'm Howard Hermann from the University of Pennsylvania in Philadelphia. I'm an interventional cardiologist there.

Study Rationale and Design

Well, we did this study because it's been recognized for a long time that the Evolute self-expanding suprannular valve has better hemodynamics than intraannular balloon-expandable valves. But the importance of that and the exact number and differences has not been known because there have been almost no randomized trials comparing TAVR devices. We have lots of trials that have compared TAVR to surgery, but we can't compare those trials to each other. And so this is a randomized trial comparing the two most widely used TAVR devices. And we did it in patients with a small aortic annulus, because that's where the hemodynamics matter the most. So we randomized patients between the Medtronic Evolute, Evolut Pro Plus and FX devices and the Sapien 3, Sapien 3 Ultra devices. The Evolute device is a supraannular self-expanding valve. So the actual leaflets are above the annulus, and that means we can get a larger orifice area for the same annulus. In addition, there are differences in the two valves in terms of where their struts are and how much tissue is within the metal frame of the two valves. But the hemodynamics do seem, and have been shown to be better for the self-expanding supraannular valve. This was an all-comers trial. We enrolled patients of all surgical risk, including bicuspid valves, and we performed it globally at 83 sites in 13 countries in North America, Europe, and the Middle East. We randomized 716 patients, one-to-one, and then we had two co-primary endpoints at one year, and we're planning to follow up the patients for five years.

Key Findings

So the key findings for the two co-primary endpoints, which were both met, were that the first co-primary endpoint was clinical outcomes, one based on mortality, disabling stroke, and heart failure rehospitalization. And there was a difference of about 1.2% favoring the self-expanding valve, but that was within the margin for non-inferiority, and that was the planned endpoint. So we met that endpoint with a significant p-value of less than 0.001 for non-inferiority. The second endpoint looked at bioprosthetic valve dysfunction, and that was a composite of hemodynamic structural valve dysfunction, non-hemodynamic structural valve dysfunction, which includes prosthesis-patient mismatch and aortic insufficiency thrombosis, endocarditis, and aortic valve re-intervention. That endpoint was powered for superiority and there was a more than 30% difference favoring the self-expanding valve meeting the endpoint of superiority at a p-value of less than 0.001. Because we met both primary endpoints, we were then able to look in a hierarchical fashion at a number of key secondary endpoints, things like the mean gradient, which was eight millimeters of mercury less for the self-expanding valve, effective orifice area, which was 0.5 centimeters squared larger for the self-expanding valve, 2.0 versus 1.5 centimeters squared, and then some other endpoints, such as DVI, which was 0.19 higher. Severe prosthesis-patient mismatch at one year, which was 7% lower for the self-expanding valve and aortic insufficiency. We found that for patients who got the self-expanding valve, they had significantly less mild or more aortic insufficiency at one year, 7% versus 20%.

Importance of Findings

So one of the most important findings of the study is that patients with a small annulus are mostly women. 90%, 87% in this trial, 90% in other trials of small aortic annulus are women. So this is really the first randomized trial not only looking at the two valves, not only looking at small aortic annulus, but the only one to enroll predominantly women. So for these patients, women with a small aortic annulus, what we found was that the self-expanding valve offers markedly better valve performance without any sacrifice of the clinical outcomes at one year. And so for those patients, I think this should be a major consideration, to use this valve, the self-expanding suprannular valve, as an ideal choice for them, maybe even the preferred choice for them. And we'll see over the next five years whether this difference in hemodynamics also affects clinical outcomes. I

suspect it will, that if you're not using the self-expanding suprannular valve, you should be at least considering it. It should be part of your heart team. Discussion there are many factors that go into the choice of a valve in an individual patient. This is now an important data point. That should be one of the things that you consider when choosing a valve and given a choice. If all things are equal and you have a choice between the two valves, and they both look like they could be safely implanted in a patient, I would rather have a larger valve with no detrimental clinical outcomes than a smaller valve, banking on the fact that that will eventually turn into improved durability and clinical outcomes in the long term.

Future Directions

So we're going to do a number of substudies from this trial. We're going to look at women alone. This is only made up 87% of the patients. We want to look at that group completely separately. We're going to look at different annular sizes. We're going to look at the predictors of bioprosthetic valve dysfunction, so we can understand that a little bit better. And of course, the most important thing is to follow these patients for five years and continue to understand the importance of those hemodynamics on clinical outcomes.