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New TAVR Data – New TAVR Talk Track

Announcer:

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Dr. Gada:

Welcome to Episode 3 on new TAVR data. This is CME on ReachMD and I'm Dr. Hemal Gada. I'm going to review the latest data on the use of transcatheter aortic valve replacement, or TAVR, in low-risk patients. Let's dive right in, there's a lot to go over.

So, we had two very exciting analyses that were presented at the recent TCT. The first one I'll present is the Evolut Low Risk 4-year data. So, the Evolut Low Risk trial was a trial that was presented at ACC in 2019. And this was a randomized controlled trial that randomized to transcatheter aortic valve replacement with the Evolut supra-annular transcatheter heart valve versus surgical aortic valve replacement. This was in a low-risk population. These results have now been followed out to 4 years.

So, when we look at the composite primary endpoint of all-cause mortality or disabling stroke, we see a widening of the delta in favor of transcatheter aortic valve replacement out to 4 years, with 10.7% of the clinical trial population having that all-cause mortality or disabling stroke in the TAVR arm, and 14.1% in the surgical aortic valve replacement arm. This was a 26% relative reduction in hazard for death or disabling stroke which was significant with Evolut TAVR versus surgical aortic valve replacement. And again, the curves appear to separate over time.

When we look at what drives this difference, it's a difference in all-cause mortality in favor of transcatheter aortic valve replacement. Out to 4 years, 9% of the patients in this study who received transcatheter aortic valve replacement, achieved the endpoint or had the endpoint of all-cause mortality, versus 12.1% of the surgical aortic valve replacement patients. And again, this delta appears to be widening as the years move on.

When we look at disabling stroke or the composite endpoint of all-cause mortality, disabling stroke, or aortic valve rehospitalization, it seems there's a plateau of the effect, the widening delta appears most palpable in all-cause mortality.

Comparative hemodynamics, Evolut transcatheter aortic valve replacement achieved superior hemodynamics versus surgery. That is seen out to 4 years now in this study, with the mean gradient across surgical valve being on average 2.3 mmHg higher than that of a transcatheter aortic valve replacement with the Evolut transcatheter heart valve.

When we look at key secondary endpoints, again, the rate of permanent pacemaker implantation, higher with transcatheter aortic valve replacement. But in contemporary analyses, this seems to have been mitigated with the use of the cusp-overlap technique in reducing pacemaker implantations with the Evolut transcatheter heart valve.

Another very, very important study that was presented at TCT was the PARTNER 3 5-year data. This was a 5-year analysis off of the work that had been done and presented at the very same ACC Congress in 2019. What we see here is a converging of the curves. Again, this was a randomized controlled trial in low-risk patients. Again, randomizing between the SAPIEN 3 transcatheter heart valve

and surgical aortic valve replacement. Again, this narrowing of the delta was still showing favorable outcomes with transcatheter aortic valve replacement, but no longer was TAVR superior to SAVR in this study out to 5 years.

We see that this outcome was also driven by mortality differences, now in favor of surgical aortic valve replacement. And in fact, when we look at death from any cause, those curves crossed in favor of surgery. When we look at a landmark analysis of death or disabling stroke, when we go from 1 year out to 5 years, there's a widening of the delta in favor of surgical aortic valve replacement.

Another important study that was recently published was the 10-year NOTION data. This gives us more of a longitudinal purview with some of these low-risk patients. This was an all-comers low-risk study done on a small number of patients with original generation devices that were placed in years ago. Going out to 10 years, obviously, the attrition rate in this trial has been significant, with about a 63% mortality in both surgery and transcatheter aortic valve replacement out to 10 years. However, the most meaningful thing to glean from this study were less rates of structural valve deterioration, in severe forms less than a third with transcatheter aortic valve implantation versus surgical aortic valve replacement.

So, could this be a sign of why Evolut appears to have better, longer-term outcomes than surgery? Only time will tell. But one thing is for sure, we need more frequent and longer-term data from these studies, from these important low-risk studies.

Thanks so much for your time. I hope this was edifying. And I'm looking forward to the next segment.

Announcer:

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