Title: TCT 23: 5 Trials That Will Change My Practice
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Dr Kendra Grubb

"My name is Kendra Grubb. I am the surgical director of the Structural Heart and Valve Centre at Emory University in Atlanta, Georgia. So, this TCT was particularly interesting because we had kind of the ends of the spectrum, some new technology highlights, as well as the continuation of some of the large trials.

So, I'm going to talk about some of the large trials first. One of the biggest things coming out of TCT, especially in the late-breakers, was the TAVR trials for severe aortic stenosis in low-risk patients. So, both the partner three five-year data and the EVOLUT low-risk four-year data were presented back-to-back. And the takeaway really is, at this stage, there is no statistical difference between the TAVR arms and the surgical arms of the individual trials.

We must be careful that we can't really compare trials head-to-head. That's not the way trial design works. But each individual study basically showed that for patients in their 70s, because on average, that was the age of the patients, that choosing either TAVR or SAVR is going to be a good option out to five years. There were some subtle differences and some things that I think we need to be keeping our eye on as we go forward.

The PARTNER 3 study, the primary endpoint is death, stroke or rehospitalization. And for that composite endpoint, we must remember that most of the difference is driven by rehospitalizations that happened after the initial surgery. So that same group of rehospitalizations keeps being perpetuated because any of those three things could trigger that endpoint.

No statistical difference and the mean gradient and the EOAS of the valves pretty much the same. So, so far, we're not seeing any signals for early structural valve deterioration. And for the primary endpoint, from the PARTNER 3 study of the Sapien valve, things

look pretty good. I will say. One of my personal concerns is that if you do a little deeper dive, you do notice that the curves for just one endpoint, and that being death, those curves cross between two and three years, doesn't meet statistical significance.

Could they recross? Could they stay exactly where they are for the remainder of the five years of follow up getting to the ten years? They could. But it's something that I want to keep an eye on and it's different than the EVOLUT low-risk trial.

So, for the EVOLUT low-risk trial, the separation of the curves that you saw early into the second and third year, at the fourth year, those curves continued to separate. Now, their primary endpoint was different. It did not have hospital excuse me, rehospitalization in it. It's just death and stroke. But again, statistics are statistics. Both valves in their respective trials, Sapien or EVOLUT, no difference in surgery.

So, I think that this is affirming for those of us who are implanting TAVRs or offering SAVR to our patients in this low risk but older patient population changing gears to some of the newer data.

One of the other exciting things coming out of TCT 2023 was the Jenavalve study, and this was a designated valve just for aortic regurgitation. It is a single arm study but showed excellent results. Little concerning about the pacemaker rate in the 20s, but they changed their technique and sizing, and the pacemaker rate is about 14%. So, I think that what they've shown is they have a safe device.

And so, for patients who are high risk for surgery who have severe aortic regurgitation, my hope is that soon we will have a designated device on the shelf that's approved for these patients because, as you know, currently we're using off-label devices that aren't really made for that pathology. And so having designated devices, I think will be important as we move forward in this space.

Changing gears to the mitral space mitral trials, we're starting to get some data. The Tendyne data looks reasonably good for their MAC arm and their roll-ins. Do I think that a transapical surgical incision is going to be the way that this field goes? Maybe not, but

they have it available in Europe, and so it may be what we must start with before we can find other devices.

The data from Medtronic on the early Apollo study looks quite good, and they're going through some re-engineering and redesign that may make that valve even better with larger sizes, smaller delivery systems, all the things that we as operators have been asking for, and more importantly, a transseptal delivery system.

A lot of the new up-and-coming devices that were presented in small numbers of patients, early feasibility studies in the mitral space, we're getting better, we're getting closer to having a solution, but still, we seem to be a long way away. In the tricuspid side, however, partially because the bar is much lower, there is not necessarily a surgical precedent for repair or replacement of tricuspid valves.

That space is a little wider open for any technology that proves to be safe, and that helps patients. And we may find that on the right side, that helping patients doesn't necessarily mean that we decrease mortality, but making patients feel better and reducing their tricuspid regurgitation may be enough to have these patients receive these treatments, have the FDA approve them.

So last year, the TRILUMINATE data with the TriClip was presented, and it showed you can make patients feel better at one year. This year they built on that message that not only is the tricuspid regurgitation sustained, but patients continue to feel better. With improvements in KCCQ, it remains to be seen whether this has a dramatic impact on mortality. But over time, we may find that that reduction in tr does translate to a mortality benefit.

Also encouraging some of the data coming out for the transcatheter tricuspid valve replacement devices. Still early experience, but very encouraging data that we are now able to help a patient population that we really haven't had very many options for.

So, what was my main takeaway from 2023 TCT? Well, that the mature technologies are continuing to get better. They are continuing to provide us newer devices that are

addressing the issues that we've seen in the past. Paravalvar leak, vascular access, pacemakers. All those things are being addressed, and now we're moving forward, and we'll be watching, as the extended data out to ten years tells us is there a difference between surgery or TAVR in low-risk patients. But we still have a lot of work to do. And the newer technologies in the mitral space and the tricuspid space, there are a lot of interesting devices that are trying to figure out ways to help people and bring us technology that's easy to use, that's safe, and hopefully not only makes patients feel better but also live longer."