**Title: TCT 22: The PARTNER 3 Trial: SAPIEN 3 Ultra THV For Failed Aortic Bioprosthetic Valves**

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**Dr Santiago Garcia**

" - My name is Santiago Garcia, I'm the director of the structural heart programme at The Christ Hospital in Cincinnati, Ohio, and the topic for discussion today is the safety and efficacy of valve-in-valve TAVR procedures with and without bioprosthetic valve fracture using the balloon-expandable SAPIEN 3 and ultra-platform.

Reasoning Behind the Study

Well, this procedure is, as you know, the use of bioprosthetic valve has increased, not only in the United States, but also around the world. And the rationale for that is that patients and doctors wanted to avoid, if possible, all the risk of long-term anticoagulation that is associated with the use of mechanical valves. However, the downside of bioprosthetic valves is that eventually all of them will degenerate and there will be a need for a second procedure. Valve-in-valve transcatheter aortic valve replacement has emerged as a very reasonable alternative to redo surgery. And it's increasingly used in the US to treat degenerative surgical valves. And one of the rationales for doing bioprosthetic valve fracture as an agent to these procedures is to try to mitigate the risk of patient-prosthetic mismatch with these procedures which is particularly important in patients who have small surgical prosthesis.

Rationale for Studying Sapien 3 in Pts with Failing Bioprosthetics

Well, it's one of the most commonly used transcatheter of our platforms, balloon-expandable valves in the United States. And the rationale is to avoid a redo surgery, a redo operation that is associated with significant risk. These patients who already have one operation to treat aortic valve pathology and now, you know, 5, 10, 15 years later, they need another intervention because the surgical valve is failing. So it makes sense to try to deliver the second valve from the groin to avoid a second scenario.

Study Design

Well, so this is an observational study using data from the TVT Registry which has been capturing data on the use of bioprosthetic valve fracture now for a couple of years. So this is the largest study today. Looking at the outcomes of patients with bioprosthetic valve fracture versus those patients who had valve-in-valve TAVR procedures without fracture. And the rationale was that we wanted to really assess the safety of this procedure and also the efficacy in terms of gradings reduction and so forth.

Main Outcomes

Well, the main outcomes are that, in relationship to patients who have valve-in-valve TAVR procedures without fracture, those patients who had a valve-in-valve TAVR with fracture were an increased risk of in-hospital and 30-day mortality, the risk almost doubled. The possible mediators of this increased risk are number one, life-threatening bleeding which was significantly more commonly seen in the group of patients who had bioprosthetic valve fracture, and also major vascular complications were higher. So clearly a safety signal was seen in the study. With regards to the efficacy of the procedure, we saw a modest reduction in gradients of approximately four millimetres of mercury which is significantly less than what has been previously reported. And also a modest increase in the aortic valve area of approximately 0.2 centimetre squares, which is also significantly less than what has been previously reported.

Clinical Significance

Well, the clinical significance of these findings is that this procedure provides some benefits in terms of hemodynamics, is also associated with some risk. We did some additional analysis because the bioprosthetic valve fracture procedure can be performed either before the valve-in-valve TAVR or after valve-in-valve TAVR, and we noted a significant difference between the two in terms of both safety and efficacy. The performance of bioprosthetic valve fracture after valve-in-valve TAVR is safer and more effective, and therefore, one of the conclusions so far, is that the timing of bioprosthetic valve fracture is very important. And that's one of the messages that we want to send to the interventional cardiology community performing these procedures. In contrast, those patients who had bioprosthetic valve fracture performed prior to the valve-in-valve TAVR had significant higher risk of death and life-threatening bleeding, which we need to better understand. But there is a clear signal here for both better safety and efficacy when the BVF procedure is performed after the valve-in-valve TAVR.

Challenges of the Study and Further Research Needed

Well, some of the restrictions that we have in accessing the TVT Registry with regards to all the surgical valves, we had information on the true internal dimension of only the Edwards Lifescience's surgical valves which was approximately a third of the cohort. I think it will be nice to have that information for all surgical valves, so one can do more sophisticated analysis and the data could be more granular with regards to gradients and changes in aortic valve area. But that's one of the limitations of the registry. The second consideration is the adjudication of what a successful bioprosthetic valve fracture looks like was done by individual sites. There was no core lab in our analysis and this can be sometimes challenging because not all the valves have fluoroscopic markers, and not all the valves are created the same way. So that's one of the limitations, it was site adjudicated and not adjudicated by an independent core lab.”