**Title: TCT 22: The SCOPE I Study: 3-Year Outcomes Comparing ACURATE Neo to SAPIEN 3 in Patients With Severe Aortic Stenosis**

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"- So my name is Jonas Lanz. I'm working at the University Hospital in Bern, Switzerland as an interventional cardiologist. We're going to talk about the three-year results of the SCOPE I trial, a trial that compares ACURATE neo's self-expanding transcatheter aortic heart valve to the SAPIEN 3 balloon-expandable TAVR device.

**Importance of SCOPE I**

Well, seminal trials comparing transcatheter aortic valve implementation to surgical aortic valve replacement have established TAVI as a standard therapy for the treatment of severe aortic stenosis across the surgical risk spectrum. In these trials, in these landmark trials, different generations of two distinct TAVI platforms, the balloon-expandable SAPIEN and the self-expanding CoreValve from Evolut platforms have been used for TAVI. So additional devices later on with different properties have become available, but evidence from randomised trials to benchmark these newer platforms against the ones established in the landmark trials are scarce. And in order to address this gap in knowledge, we performed a SCOPE trial. We included 739 patients with severe symptomatic aortic stenosis, and randomly assigned them either to the ACURATE neo device or the SAPIEN 3 device. In the light of the very scarce data available, especially for the ACURATE neo to date, even from observational data with regard to its long term performance and durability and the fact that its successor device, the neo2 is currently being investigated in an IDE trial, the long term outcomes of the Scope I trial are of particular interest.

**Key Differences Between SCOPE I and SAPIEN 3**

Both of the two devices have a CE Mark and they are actually clinically used in Europe since 6 or 7 years and the comparative device, the SAPIEN 3 is a worldwide, widely-used transcatheter aortic heart valve whose performance has been very well established, and PARTNER II and 3 Registry, And also, of course, in the PARTNER 3 low risk trial. So even though it's implantation mode, and one of the SAPIEN 3, which is implanted by means of balloon expansion of the stent frame differs diametrically from the self-expanding top-down implantation mode of the ACURATE neo, the to two devices share some similar features, namely ease of coronary access and suitability for horizontally angulated, descending aortas. And hence the target population for the two devices have had some overlap.

**Key Results**

At 30 days target with neo failed to meet pre-specified criteria for a non-inferiority compared to the SAPIEN 3 device regarding a primary composite efficacy and safety endpoint. And that was due to higher rates of moderate paravalvular, paravalvular regurgitation of acute kidney injury. Considering that meta-analysis and also several subanalysis of randomised trials and registries have shown an increased risk of death and rehospitalization associated with the presence of moderate or severe PVR after TAVI. One could hypothesise that the shortcomings observed at 30 days, may translate into worse clinical long term outcomes in the long run. However, this was not the case as we observed in the three year analysis, at three years follow up, 24.3% of patients in the ACURATE neo, and 25% of patients in the SAPIEN 3 group had died and rates of all-cause death, stroke or heart failure, rehospitalization for the two groups were similar at three years. Likewise, there was no statistically significant differences in acquired bioprosthetic, valve dysfunction or valve failure, which were actually rare in both groups. There was a numerically higher number of valve thrombosis in the SAPIEN 3 groups, six versus one, but that was statistically not significant. The favourable hemodynamic profile of this suprannular ACURATE neo, period preserved through three year follow-up, with lower gradients and higher effective orifice areas.

**Clinical Impact**

Well, I think the fact that the SCOPE I trial and the SCOPE I trial, there was now no sign that the early differences in device performance actually translated into differences in durability or clinical outcomes at three years. This is very reassuring for patients who received the ACURATE neo valve. And also for the IDE trial country are enrolling patients to compare the successor device to neo2, to patients treated with other commercially available TAVI platforms in the US. But nevertheless, one should keep in mind some limitations. First, the study was performed or conducted in an elderly type population at intermediate surgical risk. So applicability of findings to lower risk patients with a longer life expectancy may be limited. And furthermore, it has to be considered that overall 11 ACURATE patients underwent multiple valve implantations at the time of the index procedure or underwent the reintervention in the course of follow-up, due to paravalvular regurgitation. So careful patient selection should continue and take into account adequate device oversizing. And also the degree in pattern of calcification of the landing cell.

**Next Steps**

The successor device as mentioned before, of the ACURATE neo is the neo2. It comprises a higher outer sealing skirt to reduce paravalvular regurgitation. So one of the shortcomings we saw in SCOPE as mentioned there is a large IDE trial running now that compares neo to neo2 to commercially available TAVI platforms in more than 1,600 patients. So a really big trial and this will certainly generate a large body of evidence on the comparative performance of the device. And those are the most suitable patient population. Regarding the SAPIEN platform by state is already available. But future research will certainly keep an eye on the long term impact of hemodynamic properties associated with its intrannular position particularly with respect to the risk of valve thrombosis and durability in low risk patients.