**Title: TCT 22: The CONFIDENCE Registry: 1-Year Outcomes of Portico™ Valve in Patients with Severe Aortic Stenosis**

**Participants: Dr Helge Mollmann**

**Date: 23rd September 2022**

**Dr Helge Mollmann**

"- Hello, my name is Helge Mollmann. I'm the Head of Cardiology at St. Johannes Hospital in Dortmund in Germany, and I am the principal investigator of the CONFIDENCE Trial.

What is the importance of this study?

The CONFIDENCE Trial is a very important trial reporting the daily clinical practice of the Portico implantation in patients with aortic stenosis. I am of opinion that a lot of randomised clinical trials add important knowledge to this field, however, since there are a lot of inclusion and exclusion criteria, they do not necessarily reflect the daily clinical practice, and this is where a registry like trial comes into place and CONFIDENCE nicely shows the performance of the Portico Valve in 1001 consecutive patients, without any inclusion and exclusion criteria. Therefore, this is what the valve is really doing in clinical practice.

Please describe the difference between the Portico and FlexNav Delivery systems.

It is very important to make the difference between the delivery catheters, which were used in the beginning of the Portico era, the first generation delivery catheter, and the FlexNav catheter, which is a new catheter, and we used the second, the FlexNav catheter in the second half of the CONFIDENCE registry. So 500 patients were treated with a first generation and 500 patients were treated with a second generation, with a FlexNav catheter. The main difference is that the original, the first generation delivery system, needed a sheath which was 18 French for the smaller valves, and 19 French for the larger valve sizes, and it had a flexible capsule, so it was already able to recapture the valve, if necessary, however, there was always a tendency during the implantation of the valve to dive into the ventricle, so we have to constantly reposition the valve during the delivery. This is completely different with a FlexNav.

What was the study design and main outcomes?

So this is a system with an integrated sheath which therefore is much smaller. It's only a 14 French sheath, integrated sheath, and more important, there is a stability layer, which makes the implantation much more reliable without the need for repositioning of the valve, and this is important, we all know this for this sort of valve, for these self expanding valves, because we would like to have a very high position of the valve, and this comes much more predictable with this stability layer with a FlexNav catheter. So the study design was a prospective multicenter, non-randomized real-world study. 1001 patients were enrolled first half with the first generation delivery catheter, second half with the FlexNav catheter, and all patients of course had a symptomatic severe aortic stenosis, typical risk profile a little bit higher risk, a little bit over 80 years, all the patients. The primary endpoint were the VARC-2 criteria at 30 days and more important purpose of the survival status after one year, and we had a close look on the echocardiography after discharge and 30 days, this was controlled by Core Lab.

How should these findings impact practice?

So the main results were a very favourable outcome, a low VARC-2 rate after 30 days. Very importantly, we yielded a low rate of paravalvular leak in all valve sizes used and a very favorable hemodynamic outcome. So the design of the valve is an intra-annular design, but nonetheless, the hemodynamic outcome was very good with an effective orifice area of 1.67 centimetre squared already for the smallest valve size, and up to two centimetre square for the large valve size. So very good hemodynamic at 30 days very VARC-2 rate and last but not least the cardiovascular mortality was very low at one year with only 7.3% in the second cohort, FlexNav cohort, and 9.4% in the first cohort with the first generation delivery catheter. These findings are important to give Portico a certain position in the overall market of transcatheter valves, and these findings nicely show that the results are at least comparable to the competitors. We have a very favourable low VARC-2 outcome. We have a very good survival at one year and therefore I think it's important to really show these real-world clinical data on the Portico device especially used with the second generation FlexNav catheter.

Where are the knowledge gaps, and how can these be overcome with further research

The CONFIDENCE Registry provides very important data on the clinical outcome, on the survival of patients being treated with the Portico device. I think in important knowledge gap is how the second generation valve, the Navitor will perform in a similar cohort. The second generation has an additional skirt to further reduce the PVL, and these are important questions which have to be addressed in further research.”