

Title: EuroPCR 24: TAVR Vs SAVR in Younger Low-Risk Patients with Severe Aortic Valve Stenosis: NOTION-2

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Dr Ole De Backer

"Yeah. I'm Ole De Backer. I'm a structural intervention cardiologist working in Rigshospitalet in Copenhagen, in Denmark. Yeah.

Background of the Study

So if we look to the background of this study. Well, I would say there are the current randomised control trials comparing TAVI with SAVR or surgery in low risk patients. They have mainly included older patients, more than 75 or at least 70 years, and they all excluded bicuspid aortic valve patients. So what we wanted to do in the NOTION-2 trial is study and compare TAVI versus surgery, and this in low surgical risk patients with severe symptomatic aortic valve stenosis, but with specifically a young age. So 75 years or younger. In reality, this meant this was a patient population with an age between 60 and 75 years of age and also allowing bicuspid aortic valve stenosis. Yeah.

Patient Population

So the patient population was 370 patients in total. One to one randomised, TAVI versus surgery. As said, younger patients, we aimed for the median and mean age of this whole population was 71 years of age. This was a truly, really low surgical risk population with an STS score of only 1.1%. And 26% of these patients had a bicuspid aortic valve stenosis. Yeah.

Primary Endpoint

So the primary endpoint was a composite endpoint of that stroke or rehospitalization with the rehospitalization related to the procedure valve or heart failure. So if we look at this primary endpoint, really, then we saw a one year incidence rate of 10% in the TAVI

arm versus 7% in the surgical arm. So an absolute risk difference of roughly 3%, which was below our pre-specified non inferiority margin of 5%. However, due to the relatively small sample size of these 370 patients, the upper limit of this 95% confidence interval surpassed this non inferiority margin. So we were kind of pure. We've statistically seen non-conclusive on the non inferiority study hypothesis. Yeah.

Bicuspid vs. Tricuspid Outcomes

So this was the primary endpoint in the whole cohort, but with what made this study very interesting, as I told you before, were the bicuspid patients included in it? And we saw very discrepant outcomes in the tricuspid versus the bicuspid patients. Tricuspid patients, 74% of our population group. We had kind of clinical equipoise for outcomes for TAVI. So I would say they're equally good, at least when we look at this one year outcome. When we look, on the other hand, in our bicuspid patients, what the take home message was there that we saw a little bit more clinical events in the TAVI arm as compared to the surgical arm. So, of course, I have to warn you that this was still a rather small population group of 100 bicuspid patients. But looking at our outcomes, I think the conclusion could be that maybe in these specifically very young, robust, low risk patients with a bicuspid aortic valve stenosis, the data showed that surgery was kind of more favourable than TAVI. There are quite a lot of knowledge gaps still here because this study overall was slightly underpowered.

Future Research Directions

So I think for sure for the tricuspid patients, I think it confirms, in line with the other low risk trials, that maybe it's time to indeed that we can move down with TAVI in these really truly younger patients. However, there's a lot of knowledge gaps in these bicuspid patients. So I think the time is there that we really have to conduct some comparative trials, TAVI versus surgery and maybe even different TAVI platforms as well. In these bicuspid patients, we have to get to know much better. We have a knowledge gap on which phenotype of aortic valve stenosis is eligible for TAVI, yes or no? Which ones give high risk for moderate or greater PVL, or maybe stroke, because that was another signal we saw there was slightly higher stroke, non disabling stroke in the TAVI arm. So

maybe there's some knowledge gaps there as well. What implant techniques, what valves, maybe use of cerebral embolic protection.”