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Rationale of the Study

As we all know, TAVR's become an established treatment of a, a severe aortic stenosis, and because of a family of randomised trials we've run, it's now been approved at all risk levels. In fact, risk is no longer part of our guidelines. Therefore we're seeing younger and healthier patients in our clinics being considered for TAVR. Therefore, it's very important for us in advising these patients, to know between TAVR and surgical valve, what's the rate of structural valve deterioration, and if you get structural valve deterioration, what are the clinical outcomes of that? This study answers those questions.

Study Design and Patient Cohort

The study design, is we took the CoreValve High-risk, and SURTAVI randomised cohorts, which is over 2000 patients. We used a randomised cohort to compare the difference in structural valve deterioration between surgical biologic valves, and TAVR using a CoreValve or an Evolut. We then added the non-randomized continued access arm to get to almost 5,000 patients, and use this larger number to look at the outcomes and the predictors of structural valve deterioration.

Key Findings

The most interesting findings, are that that surgery has more structural valve deterioration than TAVI. It's something that most of us would not have initially predicted, and that this is accentuated in people that have a small annulus, less than 23 millimetres by CT scan, such as women or smaller, smaller people. We also found that if you did develop structural valve deterioration, whether you've had a surgical valve or TAVR, it basically doubled your risk of death, and doubled your risk of hospitalisation. We also found that people that tended to get structural valve deterioration, with those with a larger body surface area, women, younger patients, and patients that are healthier.

Influence on Clinical Practice

These results will influence clinical practise in a number of ways. My patients come in everyday, that are often candidates for both surgery and for TAVI. And they want to know, basically what they should have. And one question is, is how likely is the value you put in me, to develop dysfunction at some point? And if it does develop dysfunction, how is this dysfunction going to affect my health and wellbeing? This study helps answer those questions, and helps us make good decisions for our patients when they come to see us.

Next Steps

Well, the next steps are that this is a five year study. The SURTAVI, the intermediate risk trial, and the Evolut low risk trial will both be followed over 10 years. And we'll gather this data at 10 years, and this longer term follow up will further inform the field, our patients and practitioners, how best to make these decisions.

Take-home Messages

The take home message is, if you have, if you're at a high or intermediate risk for surgical aortic valve replacement, and you get surgery or TAVI using a quarter of Evolut super annulus self expanding valve, your TAVI valve will have less structural valve deterioration than any of the surgical valves used in the trial. If you get structural valve deterioration, whether you have a TAVI or surgery, it doubles your risk of mortality, it doubles a risk of hospitalisation. We also see that is, this is accentuated in smaller annuluses. So people like women, do much better.