**Title:**

**Participants: Dr John Forrest**

**Date:**

**Dr John Forrest**

" - Sure, I'm John Forrest. I'm a physician in interventional cardiology at Yale University in Connecticut. The Evolut Low Risk Trial follows in a family of trials.

We started looking at patients who were high risk for surgery and randomising them to transcatheter aortic valve replacement or surgery, then intermediate and then most recently, low risk. And so it was a natural progression, TAVR started off as a therapy really for patients who weren't good surgical candidates. But we quickly realised that, you know what, maybe this is something that should be offered to more patients, and to even patients who are low risk for surgery. So that was really the driving force. And I think the other thing that drove it was patients, patients want a less invasive therapy where they they can recover more quickly, get back to living their lives.

So this patient population, they needed to have severe aortic stenosis and an indication to have an aortic valve replacement. They had to be low risk from a surgical standpoint. So low risk was determined by the heart team taking care of them, including the cardiothoracic surgeons and interventional cardiologists. And they had to have a predicted mortality of 3% or less 30 days after surgery. There's some other things within that, they had to have a tri-leaflet aortic valve, so patients with a bicuspid aortic valve were excluded. And they couldn't have had a recent stroke or heart attack. If that was the case, they had to wait a couple of months.

So we presented today the three year data. And this is important because these are lower risk patients and they're going to live longer. And so it's not just the immediate upfront benefit that they get with TAVR which we understand, but it's also how does this valve last over a longer period of time? And we've seen in some of the higher risk data, which was with earlier generation valves, that there seems to be a convergence of the curves in terms of how patients are doing, raising questions about, in low risk patients, we understand they do better earlier with TAVR, but what's going to happen over time? So we presented the three year data and actually what we saw is that that early convert, that early separation of the curves, that occurs right after the procedure is done and favours a TAVR was actually not only maintained out to three years, but if anything, was slightly widening over time, showing that at least out to three years patients who had a transcatheter aortic valve with an Evolut family of valves were doing exceptionally well as compared to those who had surgery.

So the AHA and the ACC guidelines recommend that for patients between the age of 65 and 80, physicians sit down with the patients, talk to them about the options to fix their aortic valve, and those options are usually either surgery or a transcatheter valve. And one of the questions in these young patients is, well, I'm low risk for either of them, what about longer term? And this starts to give us a glimpse into the longer term results from them. And also I think reaffirms that, you know what, TAVR should be offered to these patients if they have suitable anatomy for it, it makes sense as a therapy to be performed in these lower risk patients.

TAVR's now approved for all patients regardless of their surgical risk. But we need to understand there are subtle differences that we saw in this study. There are differences in hemodynamics across the valves, there are differences in the incidence of atrial fibrillation. There are differences in the incidence of pacemaker. So what will those impacts have over not just one, two, three years, but over five and over 10 years? So patients in this study will be followed for a total of 10 years.”