- Nicolas Van Mieghem From the Erasmus University Medical Centre in Rotterdam and I'm going to discuss the three year outcome data from the FORWARD PRO prospective study.

Background of This Study

The FORWARD PRO is a prospective multicenter study evaluating the Evolut Pro transcatheter supra-annular functioning self expanding heart valve. In patients with severe symptomatic aortic stenosis both native aortic stenosis and degenerated aortic bioprosthesis. It's a prospective study with Echo Core Lab analysis of the Echo data at pre-discharge 1 year and 3 years and also an independent clinical event adjudication.

Patient Cohort and Study Design

So, the study design was according to the standards of good clinical studies that we have these days. So an independent core lab was evaluating the Echo cardiograms at pre-discharge 30 days 1 year and 3 years. There was also independent clinical event adjudication the trial enrolled over 600 patients and the follow up was complete for 87% of the patients at 3 years, which is quite okay. At the mean age of the patients was above 80 years old. So, 81 years old. The SDS score was quite high 4.7 and the majority of the patients included were female, were women. And the trial specifically was aiming not for the low risk patients, but for patients at a higher operating risk.

Devices Studied

So, the FORWARD PRO was the was the main trial evaluating the supra-annular functioning Evolut Pro transcatheter heart valve. And the, the major innovation in that device iteration was the addition of a pericardial wrap to mitigate paravalve release. At the same time, the device is repositionable and retrievable.

Key Outcomes at Three Years

The key outcomes are mortality was 25% at the 3 years, and you could see an annual mortality risk of between 8% and 9%. Which is totally in line with the risk profile of these patients. Again, these were not low risk patients. These patients had a significant comorbidities and also a 3rd of the patients were considered to be frail. So expectedly, you would see some kind of mortality. At the same time, stroke rate was relatively low. The disabling stroke rate was 6% that 3 years which also is completely in line with our expectations in this patient population with an annual stroke rate after 1 year of 1%, as expected. Pacemaker rates were 22% And we have to bear in mind that patients were enrolled in this study in the years 2018 & 2019. So we were not applying these new implantation techniques to lower pacemaker rates.

Take-Home Messages

There are two important findings I think; first of all there are no durability issues at least out of 3 years. So the valve performance was excellent with superior hemodynamics that we know with an Evolut platform PVL was low. The majority of the patients had no or only a trace para-valval leak. And the interesting finding is that 189 patients had Echos at pre-discharge at 1 year and at 3 years. In those patients we could tell that the rate of more of mild or more PVL was going down over time. And that was quite of interest and it's for the first time that that has been demonstrated with a TAVI platform. And one of the hypotheses could be that the Nitinol which is the framework of the Evolut Pro, that that keeps on expanding and becomes more circular as time progresses. So that is quite interesting. And another important observation is that the risk or the rates of thrombosis, valve thrombosis, endocarditis and need for a reintervention were super low, less than 1%.

Next Steps

So the next steps are basically what the community is already doing. We're moving to lower risk patients patients that are younger, have lower life expectancy. So lifetime management becomes very important. Obviously, in those patients you want to have a very reliable technology at hand Technology that probably should be repositionable and retrievable in order to optimise your implant and also should include a sealing fabric to mitigate paravalvular leaks. Obviously there are, there's also the conduction issue, but with new implantation techniques, that is the Optimize Pro study that also was presented here at EuroPCR. We are able to reduce the need for pacemakers to single digit numbers.