- I'm Josep Rodes-Cabau, interventional cardiologist from the Quebec Heart and Lung Institute in Canada. And today I'm going to talk about the Lyten trial that was presented in a late-breaking trial session here at EuroPCR.

Study Rationale

Yes, in fact, the study focus on the patients with surgical failed bioprostheses in aortic position. And in this field, all the data that they have collected have been of retrospective nature. Among these data, there were data suggesting that some types of transcatheter valves like those with supra‐annular valve position and sometimes with larger valves were associated with better hemodynamic outcomes. There was no randomised trial in the field up to now.

Study Design and Patient Selection Criteria

The patients included in the trial were patients with small stent surgical valves that failed either because of a stenosis or regurgitation. Meaning that all surgical valves were less or equal than 23 millimetres. These were the patients that were selected for the trial and these patients were, before the TAVI procedure, were randomised to receive either a balloon expandable valve, SAPIEN3 or SAPIEN3 ULTRA, or a self expanding valve system, Evolut R, PRO, or PRO+. Well, I think it's already well known. The balloon expandable valve is a balloon expandable valve. Maybe the differences are, as I said too, first in general, when sizing these valve with respect to the surgical valve, in general, the Evolut system will recommend larger valves for a specific surgical valve size. The other important differential aspect is that the SAPIEN valve is a valve that is located at the annular level, whereas the Evolut valve, the valve leaflets are located supra-annular. These could potentially be associated with some advantages in terms valve hemodynamics.

Key Findings

Yes, the primary endpoint of the study was the echo findings and the valve hemodynamics as evaluated by echo at 30 days. And all these echo findings were evaluated and measured and they are in a central echocardiographic core lab at our institution. The main finding showed that the Evolut valves were associated with lower transvalvular gradients, maximal, mean. Lower percentage of patients ended with mean gradients above 20 millimetres of mercury. In terms of another co-primary endpoint, which was severe participation mismatch, there was a tendency towards the lower rate of severe PPM among Evolut patients compared to the SAPIEN counterparts. These are the primary endpoint findings. There were two important, also, secondary endpoints. Clinical data at 30 days, which were very good for the two valve types. No deaths, no strokes, no pacemaker. Zero. Some vascular complications, but really no major events leading to patients death. And also we performed a substudy, an invasive substudy, measuring valve hemodynamics invasively during the procedure, during the second period of the study. Including about half of the patients of the total number, which was 102. About half had this invasive study. And in the invasive study, we realised also that at least during the TAVI procedure the measurements you have in terms of valve hemodynamics, the mean gradient, for example, was much lower compared to echo. And this translated, this was true for the two valves, but maybe these differences were more important in the SAPIEN group. This translated into the lack of significant differences between groups when we evaluated valve hemodynamics invasively. Again, was on a smaller number of patients. It was a secondary endpoint. But I think that it was also an aspect that should be highlighted.

Take-Home Messages for Practice

I think that the first take-home message is that, as it was already suggested in retrospective studies, this randomised trial confirmed that the self-expanding Evolut platform provided improved valve hemodynamics as evaluated by echo, compared to the SAPIEN valve. I think that this was the primary endpoint and this is the first take-home message. The second message could be also that the results, at least at 30 days, were excellent for both valve types. And this is also important to highlight. Then the aspect of invasive hemodynamics versus echo that, I think, opens the door probably for future research in the field.

Next Steps

I think that the next steps could be mainly to follow these patients and to see what is the clinical follow up. What is the potential impact that these hemodynamic differences can have at mid to long-term follow up in terms of clinical events. And, probably thinking about, really to have a comparison powered for clinical events in this group of patients. I think that this is something that probably will be needed in the future. Not only for these two valve types but for other valve types that are in the market, to see what is the performance of each different valve in this group of patients that remain challenging, these patients with surgical valve failure, with the small surgical valves. And, also, the second thing also is probably to see really what does it mean? These differences between echo and invasive hemodynamics. Whether or not these translate into differences in clinical events based on one type of measurement versus the other. I think that nowadays, we really don't know.