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[MALE RESPONDENT]

[Other comments:]

Hello, my name is Lars Søndergaard. I am a professor in cardiology based in Copenhagen, Denmark.

Tell us more about the studied device and how it differs from the Portico TAVR?

The Portico NG study is evaluating the safety of the next-generation Portico valve, the Navitor valve, to evaluate the safety and the performance of this valve in patients with severe aortic stenosis and high surgical risk. The Portico valve is a self-expanding technology with intra-annular leaflet position. So the iteration from the Portico through the Navitor valve is: first of all, there is an outer active sealing cuff in order to mitigate the degree of paravalvular leak. Also the radial force has been optimised across all valve sizes. They currently come in 23, 25, 27 and 29 millimetres. There will also be a fifth valve; the Navitor Titan valve, which is going all the way up to a size of 30 millimetres. Finally there will be a more curved outflow portion of the stent frame.

What was the study design, endpoints, and patient population?

The Portico NG study included patients from Europe, Australia and the US, and is going to be used, so hopefully it will gain both FDA and CE mark approval. The patient who is going to be enrolled are: patients at high surgical risk with severe aortic stenosis. The results which were presented at EuroPCR 2021 were the first 120 patients enrolled. This was actually used to now gain CE mark approval. There will also be, as I said, more patients included from the US and hopefully soon the application for FDA approval will be sent.

What are the key findings to date?

So, for the first 120 patients, we know that these patients were at high surgical risk both based on age, STS score and frailty score and very important: the results show that this was a very effective treatment. The patients had a very low transvalvular gradient, one digit, and a very large opening area, 2.0 square centimetres. Very importantly, this outer active sealing cuff did really mitigate the degree of paravalvular leak. So, 80 per cent of the patients had none or only a trace of paravalvular leak and the remaining 20 per cent of the patients had only a mild paravalvular leak. So, none of the patients had moderate or severe paravalvular leak. Also importantly, it was a very safe valve to use so the primary endpoint was 30 days' mortality and this was 0 per cent.

What conclusions can be made?

I think what we can conclude for these first 100 patients enrolled in the Portico NG trial with the Navitor value, is that it is very safe. As I said, none of the patients died within 30 days. It was very efficient, both offering a very large opening area and a very low transvalvular mean gradient and very importantly, none of the patients had more than a mild paravalvular leak. I think this is a valve which is very suitable for moving forward with TAVI, both in the current patient cohort we're treating, but also potentially for the future expansion into patients at a lower surgical risk.

Could the outer cuff in the valves increase the pacemaker rate? How can this concern be addressed?

One of the potential concerns about adding an outer sealing cuff is that it is going to increase the rate of conduction abnormality. But we actually saw in this study that it was unchanged, maybe even less than it was with the Portico first-generation valve. So, for patients at risk, 15 per cent of the patients had a new permanent pacemaker and almost all of these patients had pre-existing conduction abnormality. I think we can conclude that adding an outer active sealing cuff did not increase the risk of new-onset conduction abnormality.

What are your take-home messages?

So, my take-home message from this study is that the Navitor valve is providing excellent haemodynamics with large opening area, low gradient and a very low rate of paravalvular leak, with 80 per cent of the patients having none or only a trace paravalvular leak, and the remaining 20 per cent of the patients only a mild paravalvular leak. Once again this is a valve which will certainly meet the expectations when TAVI is going to move forward to patients with longer life expectancy.

What are the next steps?

The Portico NG study enrolled patients at high surgical risk. We will now see that the [unclear speech 0:05:51.9] study is going to be launched enrolling patients at intermediate and low surgical risk, which is going to be very exciting.

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