radcliffe cardiology

Title: EuroPCR 24: 5-year Results of the SOLVE-TAVI trial
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Dr Hans-Josef Feistritzer

"My name is Hans Josef Feistritzer. I'm an interventional cardiologist from Heart Centre Leipzig, and it's a great pleasure for me to talk about the SOLVE-TAVR trial today.

Trial Overview

SOLVE-TAVR was an investigator-initiated randomised controlled trial conducted at seven sites in Germany. It used a two-by-two factorial design and was the first trial comparing the anaesthesia strategy for TAVI, named conscious sedation versus general anaesthesia. This is of great importance because SOLVE-TAVI was the first trial using a hard clinical endpoint for this anaesthesia comparison. It was a randomised multicenter trial using a two-by-two factorial design.

Study Design and Participants

More than 400 patients were randomised in the first arm to either the EVOLUT-R valve or the Sapien 3 valve, and in the second arm to local anaesthesia with conscious sedation on one side and general anaesthesia on the other side.

Primary Outcomes

The primary results, the primary outcomes at 30 days, have been published a few years ago. The primary endpoint in the valve comparison arm was a combination of all-cause mortality, stroke, moderate or severe prosthetic valve regurgitation, and permanent pacemaker implantation, and this endpoint was equivalent between both valve types.

In the other arm, we used a combined endpoint of mortality, stroke, myocardial infarction, infections, and acute kidney injury. This endpoint was also equivalent at 30 days between the conscious sedation group and the general anaesthesia group.

Five-Year Outcome Data

Today, we presented the five-year outcome data from the SOLVE-TAVI trial. The combined endpoint was similar between the EVOLUT R valve and the Sapien 3 valve, but very interestingly, the stroke rate was higher, significantly higher, in the Sapien 3 group compared to the EVOLUT R group.

Regarding the anaesthesia comparison, the combined endpoint I mentioned before was not statistically significantly different between both groups. However, all-cause mortality after five years was higher in the general anaesthesia group. These are the major results after five years.

Take Home Messages

The take-home messages are that the Sapien 3 valve and the EVOLUT R valve can be safely used in the majority of TAVI patients. Of course, there are specific situations where one valve might be in favour of the other valve, for example, very calcified anatomies, small annulae, and so on, but for the majority of patients, both valves can be safely used.

Regarding the anaesthesia strategy, the SOLVE-TAVI trial showed that conscious sedation is the right way we should go in the TAVI business, and that conscious sedation is similar also in the long-term follow-up compared to general anaesthesia. However, the higher all-cause mortality rate in the general anaesthesia group we detected after five years is a cautionary sign for general anaesthesia, which requires further investigation and further studies.

Next Steps

The next steps, in my opinion, are to make the TAVI procedure a transfemoral procedure, less invasive. By this way, we currently perform the so-called DOUBLE CHOICE trial in Germany. It's also a randomised multicenter trial using again a two-by-

two factorial design. On the one hand, we compare the Accurate neo2 valve against the Evolut Pro+ or FX valve, and in the second arm, we compare conscious sedation versus local anaesthesia only. We hope that we can finish patient recruitment this year so that primary 30-day results can be expected for next year. I think this is the next step regarding the treatment strategy or anaesthesia strategy for TRANSFORM-TAVI”