radcliffe cardiology

Title: ACC.24: TAVI Vs SAVR in Patients with Severe Aortic Valve Stenosis: DEDICATE-DZHK6
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Dr Moritz Seiffert

"My name is Moritz Seiffert. I'm an interventional cardiologist and a professor of cardiology at Ruhr University in Bochum, Germany.

Overview of the DEDICATE Trial

The DEDICATE trial is essentially an all-comers trial comparing SAVR (Surgical Aortic Valve Replacement) and TAVI (Transcatheter Aortic Valve Implantation) in a low to intermediate risk population. Over 1400 patients were randomized to either SAVR or TAVI. Patients had to be low to intermediate risk and at least 65 years old.

Trial Design and Follow-up

The heart team was central to this trial, making decisions on eligibility, choice of device, and pre-procedural care according to the assigned treatment options. Patients were followed up to one year. The co-primary safety endpoint was all-cause death or stroke at one year, which was the primary outcome of this analysis. Patients will continue to be followed for an additional five years for the primary efficacy outcome of death or stroke at five years. At that point, if applicable, both non-inferiority and, potentially, superiority will be tested for the primary outcome.

Results

TAVI was found to be non-inferior to SAVR regarding the primary endpoint of all-cause death or stroke, with a hazard ratio of 4.53. Furthermore, some secondary endpoints and components of the primary outcome showed that the event rate for all-cause deaths was significantly lower in the TAVI arm compared to SAVR.

Clinical Implications

The clinical implications of the DEDICATE trial are significant. In addition to the evidence we have from the one-year timeframe, the trial provides a strong argument in favor of catheter-based treatment for these younger, low-risk patients, as opposed to previous trials. The DEDICATE trial is unique in that it is not sponsored by any specific device manufacturer but is funded by academic research institutions, allowing all devices to be considered. This aspect adds credibility, as it reflects clinical routine care as closely as possible.

Future Considerations

Particularly for this younger, low-risk patient population, long-term data will be essential. We will need to examine five-year and ten-year timeframes to draw final conclusions about whether TAVI or SAVR is more appropriate for this patient population. This ongoing trial will continue to provide important data."