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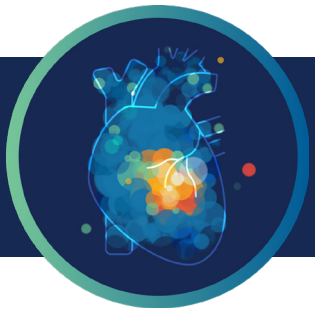
EXPERT INSIGHTS: Q&A WITH PROF. THOMAS PILGRIM



Professor Thomas Pilgrim, MD, FESC

Deputy Physician-in-Chief, Department of Cardiology,

Inselspital, Bern University Hospital,

Bern, Switzerland

Access the full publication: **Transcatheter or Surgical Treatment of Aortic Valve Stenosis**

To those unfamiliar with the term "Heart Team", could you explain what this is and what are, in your opinion, the qualities intrinsic to a well-performing heart team that makes decisions in the very best interests of the patients they serve with structural heart disease?

The Heart Team amalgamates clinical, anatomical and procedural characteristics and the patient's informed choices on treatment, to make evidence-based decisions on the management approach for an individual patient. Intrinsic to the Heart Team is a collaborative group of specialists with expertise in interventional structural heart disease, cardiac surgery and imaging, and additional specialists including nursing. Smooth operation requires the Heart Team to meet frequently, with systematic recording of decisions made and patient outcomes.

In plain language, how would you explain the results of the DEDICATE trial to a young symptomatic patient with severe aortic stenosis at low surgical risk, as you discuss treatment options with them in your hospital clinic?

We know from the DEDICATE trial that for people with severe aortic stenosis, low or intermediate surgical risk and an average age of 74 years the combined risk of death or stroke was not worse 1 year after undergoing TAVI compared to surgery. The risk of death was in fact lower in the short-term following TAVI compared to surgery, 3% versus 6% retrospectively. That said, there is still uncertainty about how these two treatment strategies compare long-term. This is especially relevant for young people who are expected to outlive the durability of the valve replacement, and so could need a redo valve replacement during their lifetime.

The choice of TAVR valve prosthesis, vascular access and surgical technique were left to the discretion of the heart team at each participating site in the DEDICATE trial. Is there a danger of introducing selection and operator bias which may be detrimental to the validity of the trial's outcomes with this type of study design?

The randomization removed treatment allocation bias, and so is an important step in guaranteeing the validity of the statistical comparisons between TAVI and SAVR. Even though operators selected the type of replacement valve to use and followed their own center's standard procedural practices, the Heart Team was central to making decisions on device selection, and the multicenter design (38 sites) further helps reduce selection and operator bias. In fact, selecting the TAVI device most suitable for the patient based on their anatomy reflects real-world clinical practice and should be considered a strength of the study.

How generalizable are the results of this study globally, given that it was performed at multiple sites in Germany alone, and therefore as the authors describe, in line with standard clinical practice of many "Western" countries?

Even though the breadth of TAVI devices and surgical approaches used may differ globally, the findings from DEDICATE agree with other trials that found similar or superior clinical outcomes with TAVI compared to SAVR in different low-surgical risk populations (PARTNER 3, EVOLUT low-risk, NOTION), thereby increasing confidence in generalizability of the findings. Of note, the DEDICATE trial population contained a higher proportion of women (43%) than some of the other trials, which better reflects the population encountered in the real world.

The evidence demonstrating the safety and efficacy of TAVI for severe AS in those at high, intermediate and low surgical risk appears to be overwhelming. Do you see a future where the implementation of TAVI extends to those with moderate, symptomatic calcific aortic valve stenosis?

Retrospective observational studies showed that early aortic valve replacement reduces mortality in patients with moderate aortic stenosis. However, these data are limited by the confounding effects of comorbidities and potential selection bias resulting in preferential adoption of aortic valve replacement in patients with fewer comorbidities. We have to wait for the results from ongoing randomized trials (TAVR-UNLOAD, PROGRESS, EXPAND TAVR II) for clearer insights into the management of patients with moderate aortic stenosis.