

# Cost-Effectiveness of Transcatheter Aortic Valve Implantation in Low Surgical Risk Patients With Severe Symptomatic Aortic Stenosis in Germany

**Objective:**

To demonstrate the cost-effectiveness of TAVI using the SAPIEN 3™ device versus SAVR in low surgical risk patients with severe symptomatic aortic stenosis in Germany.

**Key Points for Decision Makers:**

These results from the first cost-effectiveness study of TAVI in Germany are informative for policy makers as treatment with TAVI versus SAVR in low risk sSAS patients yields an attractive cost per QALY ratio.

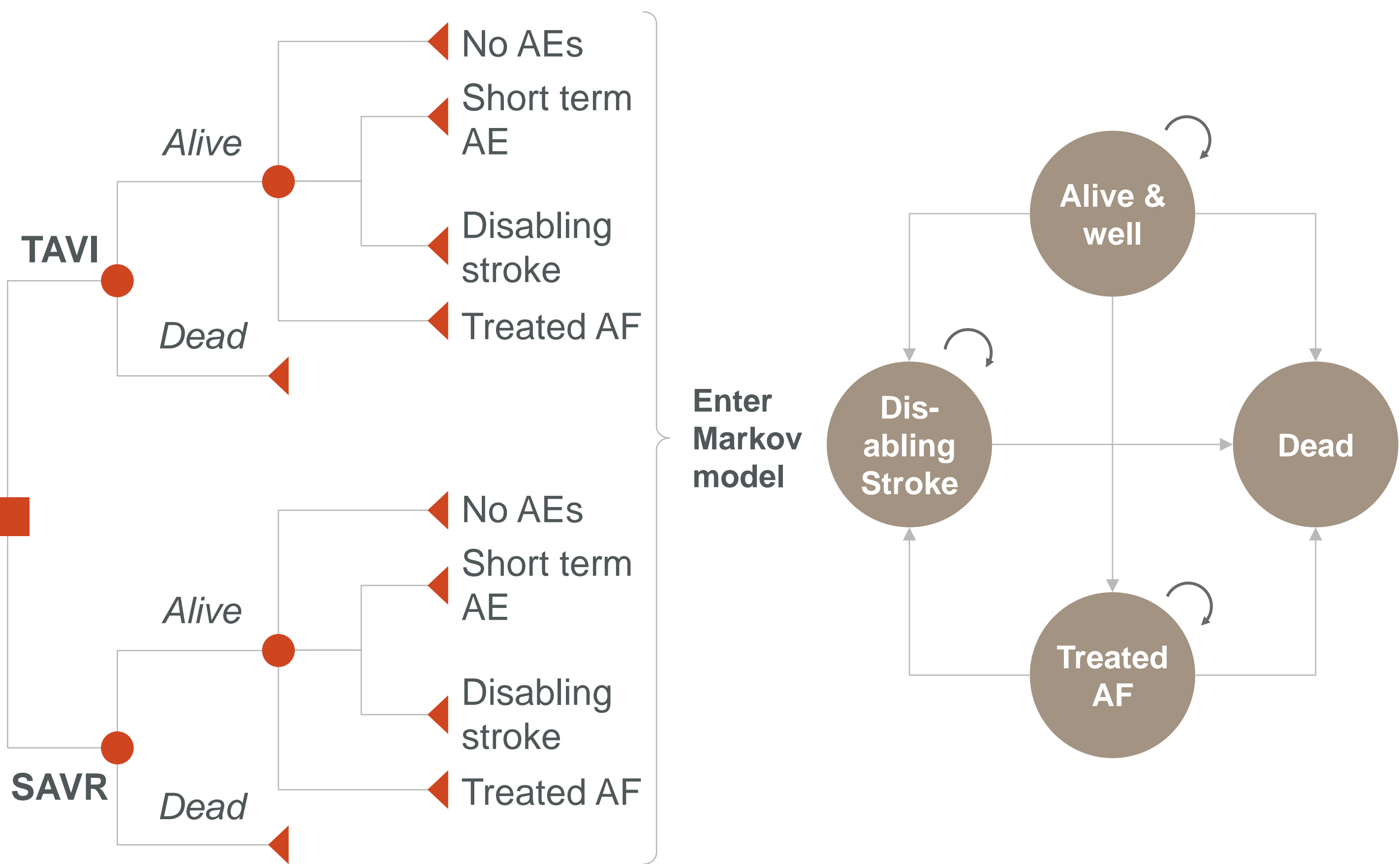
## INTRODUCTION

- Severe symptomatic aortic stenosis (sSAS) is a condition characterized by narrowing of the aortic valve opening, progressive obstruction of left ventricular outflow tract, increased likelihood of mortality, and reductions in quality of life<sup>1</sup>.
- Historically, sSAS was managed by surgical aortic valve replacement (SAVR). However, in the last 20 years, transcatheter aortic valve implantation (TAVI) has become increasingly established as a treatment option<sup>1,2</sup>.
- In a recent multicenter, randomized controlled trial (PARTNER 3) performed in sSAS patients at low risk (LR) of surgical mortality, TAVI using the latest-generation SAPIEN 3™ (Edwards Lifesciences) showed an improved survival, reduced complications, shorter hospital lengths of stay, and improved quality of life<sup>3,4</sup>.

## METHODS

- A published 2-stage Markov-based model<sup>5</sup> to assess changes in costs and HRQOL following a TAVI and a SAVR intervention was adapted for the German context using the German Statutory Health Insurance perspective.
- Early adverse events (AE) associated with the TAVI procedure using the SAPIEN 3™ device were captured mainly from the 30-days AE dataset of the PARTNER 3 trial in a decision tree. These data were then fed into a Markov model that included the following health states to capture longer-term outcomes post-TAVI and post-SAVR: ‘alive and well’; ‘treated atrial fibrillation (AF)’; ‘disabling stroke’, and ‘dead’ (figure 1).
- Monthly transition probabilities between health states and utilities were estimated based on data from PARTNER 3 or other literature sources where there were too few events in PARTNER 3 for reliable estimates. A lifetime time horizon (50 years) was chosen to reflect all potential consequences to people with sSAS over their lifetime.
- The cost perspective was informed by the German-Diagnostic Related Groups (G-DRGs) and from published literature. Costs were measured in 2021 Euros and benefits in QALYs gained using the EQ5D-5L and a preference-based German value set.

Figure 1: Cost effectiveness model



## RESULTS

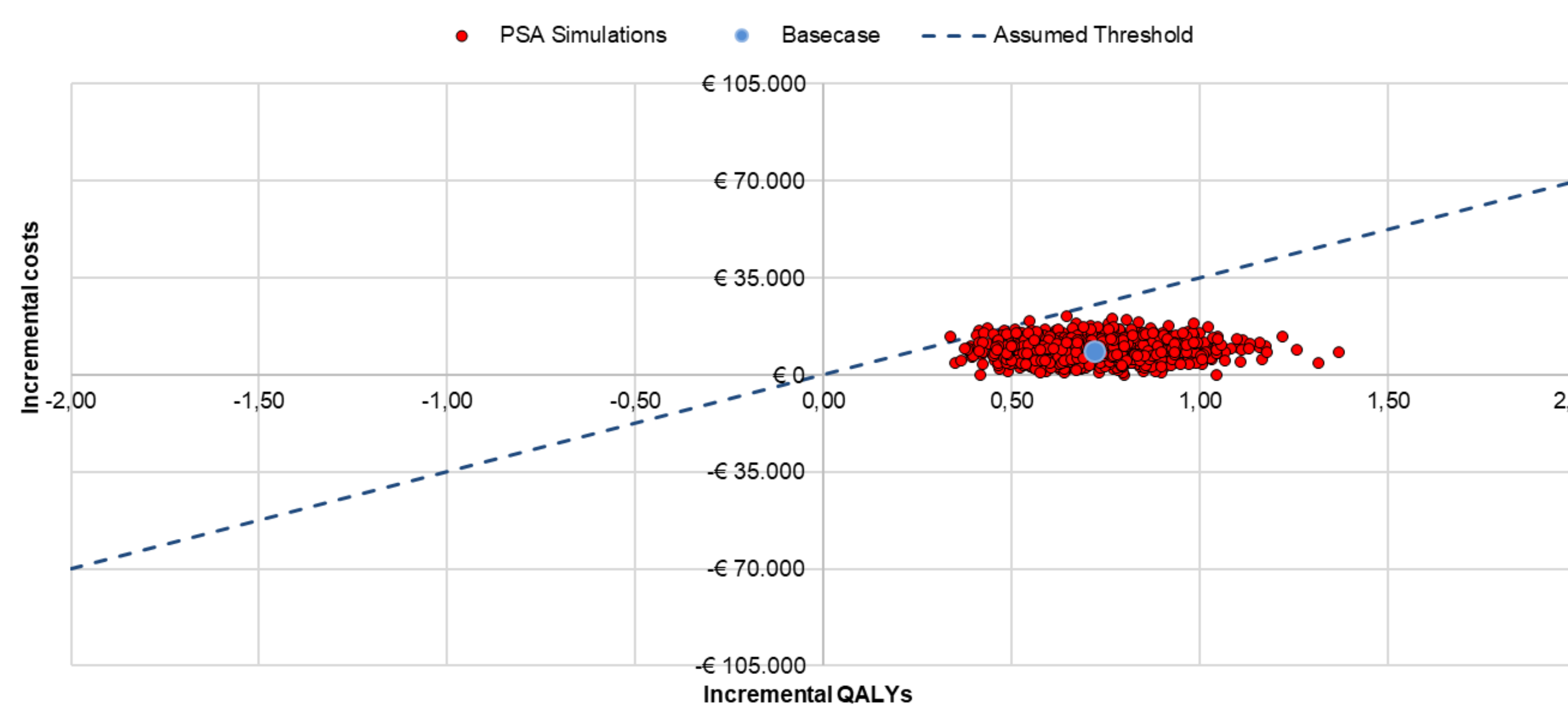
- TAVI with SAPIEN 3™ increased quality-adjusted life years (QALYs) by +0,72 with an increased cost of € 8.664 per patient, leading to an incremental cost-effectiveness ratio of € 12.037 / QALY.
- Assuming a hypothetical willingness to pay (WTP) threshold of € 35.000/QALY, SAPIEN 3™ is a cost-effective option (figure 2).

Figure 2: Base case results – lifetime horizon (50 years)

Summary results	TAVI with SAPIEN 3™	SAVR	Incremental
Cost per patient	€ 37.542	€ 28.878	€ 8.664
Life year gained (undiscounted)	12,83	12,38	0,45
Median survival (years)	15,00	13,17	1,83
QALYs per patient	8,56	7,84	0,72
Incremental Cost Effectiveness Ratio (ICER)	€ 12.037 / QALY		
Incremental Net Monetary Benefit	€ 16.529		
Incremental Net Health Benefit	0,47		

- A cost breakdown revealed higher initial procedure costs with TAVI compared with SAVR, but lower long-term costs related to hospitalizations, treated AF and disabling stroke.
- The deterministic sensitivity analysis showed that TAVI with SAPIEN 3™ remains cost-effective regardless of changes in individual model parameters with patient age, procedure costs and transition probabilities toward treated AF being the parameters that most influence the model.
- The probabilistic sensitivity analysis corroborate the base case results as TAVI remained cost-effective in 99,6% of cases compared with SAVR at the assumed WTP threshold (figure 3).

Figure 3: Cost-effectiveness scatter plot



TAVI with SAPIEN 3™ appears to be a clinically meaningful, cost-effective treatment option over SAVR for patients with severe symptomatic aortic stenosis and low risk for surgical mortality in Germany

Frankenstein L<sup>1</sup>, Leidl R<sup>2</sup>, Kuck KH<sup>3</sup>, Wahlers T<sup>4</sup>, Sarmah A<sup>5</sup>, Candolfi P<sup>5</sup>, Shore J<sup>6</sup>, Green M<sup>7</sup>  
<sup>1</sup>University Hospital Heidelberg, Heidelberg, Germany, <sup>2</sup>Helmholtz Zentrum München, Munich, BY, Germany, <sup>3</sup>University Heart Center, Lübeck, Germany, <sup>4</sup>University Hospital of Cologne, Cologne, Germany, <sup>5</sup>Edwards Lifesciences SA, Nyon, VD, Switzerland, <sup>6</sup>York Health Economics Consortium (YHEC), York University, UK, <sup>7</sup>York Health Economics Consortium (YHEC), York University, UK

**References**

- Boskovski MT, et al. Circulation Research. 2021;128(9):1398-417.
- Vahanian A, et al. EJCTS.2021;60(4): 727-800.
- Mack MJ, et al. NEJM. 2019;380 (18): 1695-705.
- Leon MB, et al. JACC. 2021;77(9):1149-61.
- Gilard M, et al. ViH. 2022;25(4):605-13.



Publication downloadable on <https://doi.org/10.1016/j.jacc.2020.12.052>

