Cost-effectiveness of transcatheter aortic valve intervention (TAVI) as compared with surgical aortic valve replacement (SAVR) in Swedish low risk aortic stenosis patients: Evidence using SWEDEHEART registry data (2018-2020)

Objective:

To demonstrate the costeffectiveness of TAVI using the SAPIEN 3[™] device versus SAVR in low surgical risk patients with severe symptomatic aortic stenosis in Sweden.

Key Points for Decision Makers:

These results leveraging data from the SWEDEHEART registry (2018-2020) are informative for policy makers as treatment with TAVI versus SAVR in low risk sSAS patients yields an attractive cost per QALY ratio.

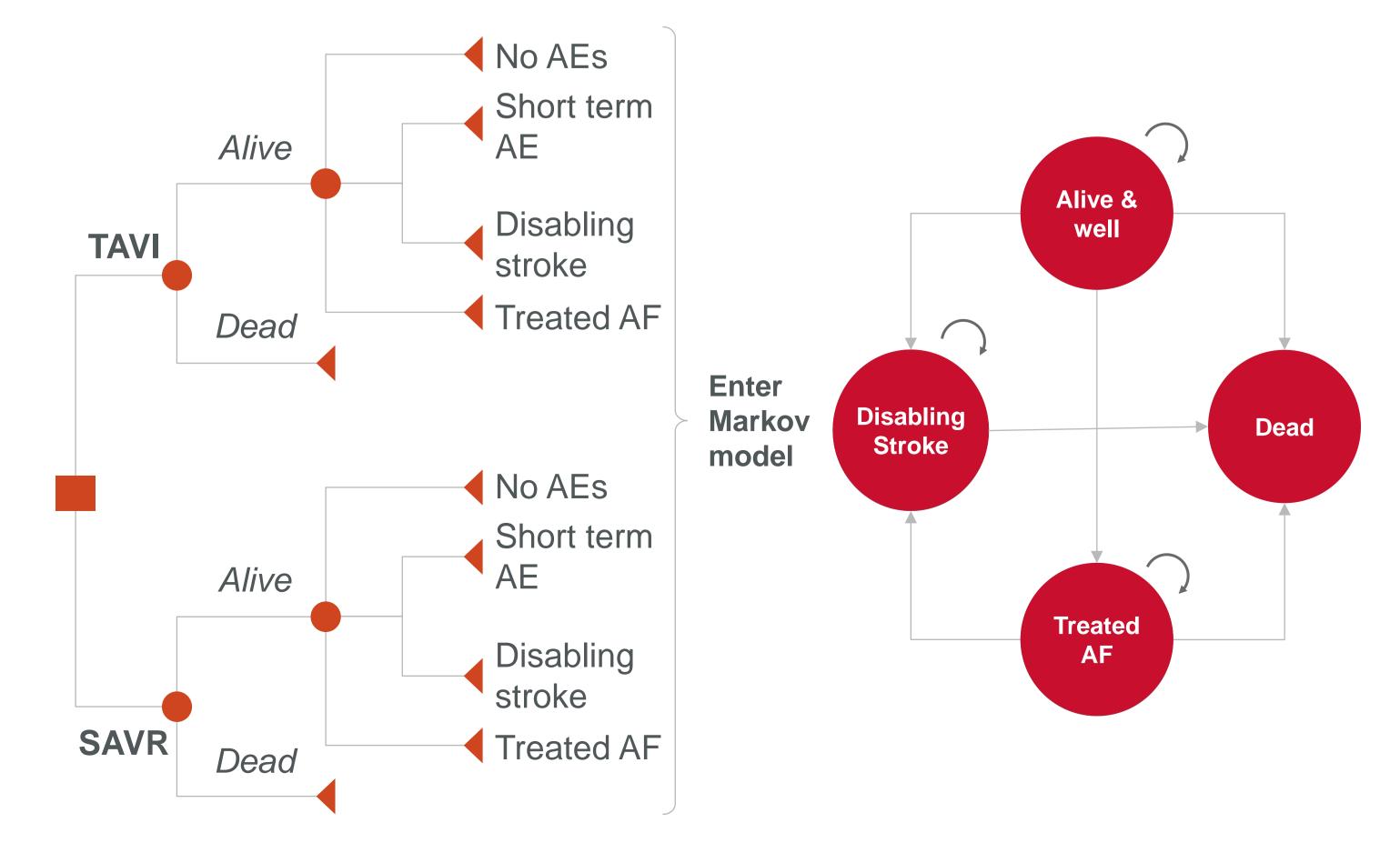
INTRODUCTION

- 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 life¹.
- 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 across all surgical risk groups 1,2.
- Beyond the evidence on clinical benefits, there exists an extensive volume of economic evaluations of TAVI³.
- Recently, several studies have established the cost-effectiveness of TAVI vs. SAVR in the low surgical risk population across several countries.^{4,5,6}

METHODS

- A previously published 2-stage cost-utility model⁴ with a decision tree and a subsequent Markov model structure with four health states (Figure 1) was adapted for the Swedish context using the Swedish Healthcare perspective.
- Data on short and long-term clinical outcomes as well as the health states monthly transition probabilities were extracted for the SAPIEN 3 (n=204) and the SAVR (n=1375) arms from the SWENTRY registry, the SWEDEHEART sub-registry for TAVI⁷ (2018-2020). For TAVI, data were additionally extracted for the pooled SAPIEN 3 and SAPIEN 3 Ultra sample (n= 373).
- For a few outcomes not covered by the registry, data were collected from the National Patient Registry using the ICD-10 codes. For the remaining 4 outcomes (one for TAVI and 3 for SAVR), where data was not available in either of the registries, PARTNER 38 outcomes were used.
- 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 Swedish DRG system and published literature. Costs were measured in 2022 Swedish Kronas (SEK) and benefits in QALYs gained.

Figure 1: Cost effectiveness model



RESULTS

- TAVI with SAPIEN 3[™] increased quality-adjusted life years (QALYs) by +0.35 with an increased cost of 119 161 SEK per patient, leading to an incremental cost-effectiveness ratio of 343 918 SEK / QALY.
- Assuming a hypothetical willingness to pay (WTP) threshold of 1 000 000 SEK /QALY, SAPIEN 3™ is a cost-effective option (Table 2).

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

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Summary results	TAVI with SAPIEN 3	SAVR	Incremental
Cost per patient	940 541 SEK	821 380 SEK	119 161 SEK
Life year gained (undiscounted)	11.79	11.36	0.43
Median survival (years)	13.75	12.00	1.75
QALYs per patient	7.16	6.81	0.35
Incremental Cost Effectiveness Ratio (ICER)	343 918 SEK / QALY		
Incremental Net Monetary Benefit	277 320 SEK		
Incremental Net Health Benefit		0.23	

- The deterministic sensitivity analysis showed that TAVI with SAPIEN 3[™] remains cost-effective regardless of changes in individual model parameters with alive and well health state costs and procedure costs being the parameters that most influence the model (Figure 3).
- The probabilistic sensitivity analysis corroborate the base case results as TAVI with SAPIEN 3™ remained cost-effective in 95.5% of cases compared with SAVR at the assumed WTP threshold (Figure 4).
- TAVI with SAPIEN 3TM remained cost-effective in the various scenario analyses, including in the one that used clinical inputs from SWEDEHEART registry data (2018-2020) for SAPIEN 3 & SAPIEN 3 Ultra pooled sample.

Figure 4: Tornado diagram

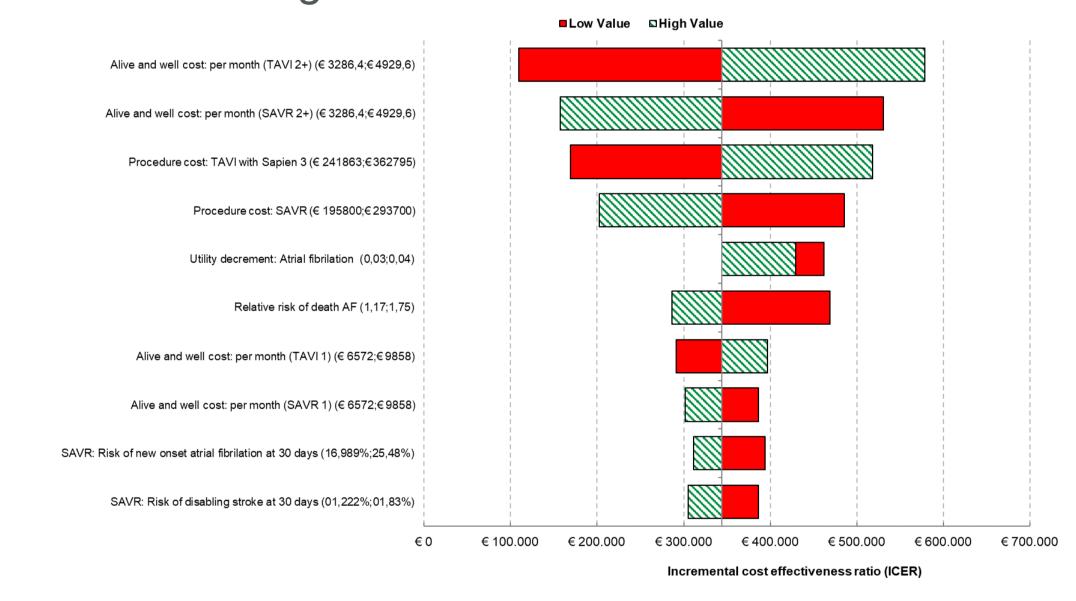
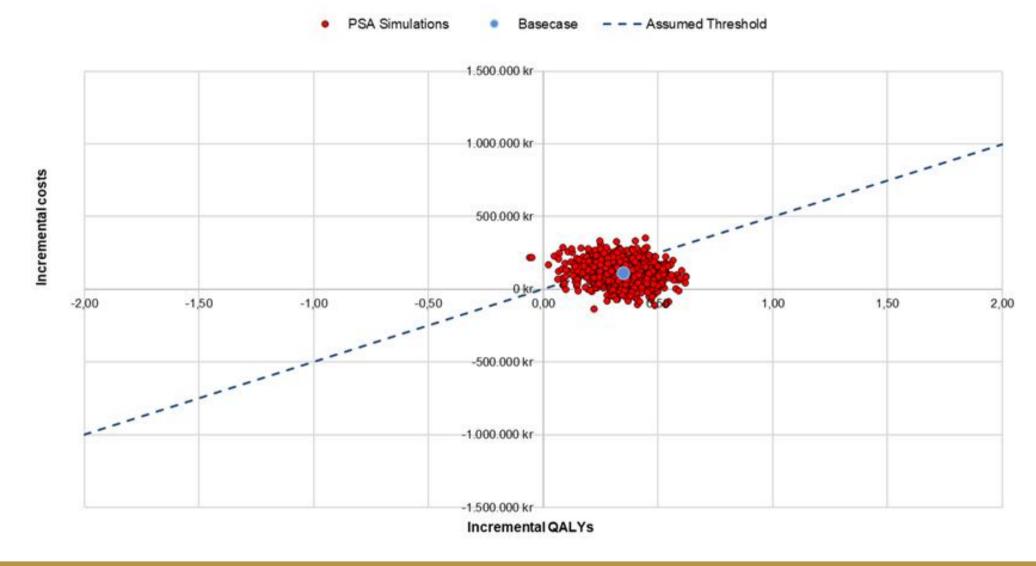


Figure 4: Cost-effectiveness scatter plot



TAVI with the latest generation balloon-expandable devices improves outcomes in Swedish low risk sSAS patients and slightly increases costs.

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