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Transcatheter aortic valve implantation vs surgery in symptomatic severe aortic stenosis patients at low surgical mortality risk in Belgium: an updated cost-utility analysis based on the 5-year data from the PARTNER 3 trial

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Objective:

To demonstrate the cost-effectiveness of TAVI with SAPIEN 3™ versus SAVR in low surgical risk patients with severe symptomatic aortic stenosis in Belgium, using the 5-year PARTNER 3 trial data.

Key Points for Decision Makers:

These results are consistent with those reported in the previously published cost-effectiveness study of TAVI with SAPIEN 3™ in Belgium and are informative for clinicians, policymakers, and budget holders.

INTRODUCTION

- Severe symptomatic aortic stenosis (sSAS) is a condition characterized by the narrowing of the aortic valve opening, leading to progressive obstruction of the left ventricular outflow tract, increased likelihood of mortality, and reductions in quality of life[1].
- Growing evidence supports transcatheter aortic valve implantation (TAVI) over surgical aortic valve replacement (SAVR) for patients with symptomatic severe aortic stenosis (sSAS)[1,2].
- The 5-year PARTNER 3 trial data confirms benefits of TAVI with SAPIEN 3 compared to SAVR in low-risk sSAS patients[3].
- Previous cost-utility analyses based on 2-year outcomes found that TAVI with SAPIEN 3 was cost-effective versus SAVR in several European countries, including in Belgium where it was dominant over a lifetime horizon[4].

METHODS

- A cost-utility analysis was conducted using methodology validated in previously published studies[4-9] to assess changes in both direct healthcare costs and health-related quality of life following a TAVI or a SAVR intervention from the perspective of the Belgian National Healthcare Payer (RIZIV/INAMI+patient).
- A two-stage model structure was used to form the basis of the cost-utility analysis, details of which have been published previously[5].
- Early adverse events (AE) associated with the TAVI procedure using the SAPIEN 3™ device, and the SAVR procedure, 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 the 5-year outcomes from PARTNER 3 or other literature sources where there were too few events in PARTNER 3 for reliable estimates. A lifetime time horizon was chosen to reflect all potential consequences to people with sSAS over their lifetime.
- The cost perspective was based on information from the Belgian All Patient Refined-Diagnosis Related Groups (APR-DRGs) and from published literature. Costs were indexed to 2022 unless otherwise stated.

RESULTS

- TAVI with SAPIEN 3™ is estimated to offer an incremental health benefit of +0.46 QALYs per patient compared with SAVR at a reduced cost of -€ 4 107 per patient over a lifetime horizon. As such, TAVI with SAPIEN 3 was determined to be dominant over SAVR in Belgium (Table 1).

Figure 1: Cost effectiveness model

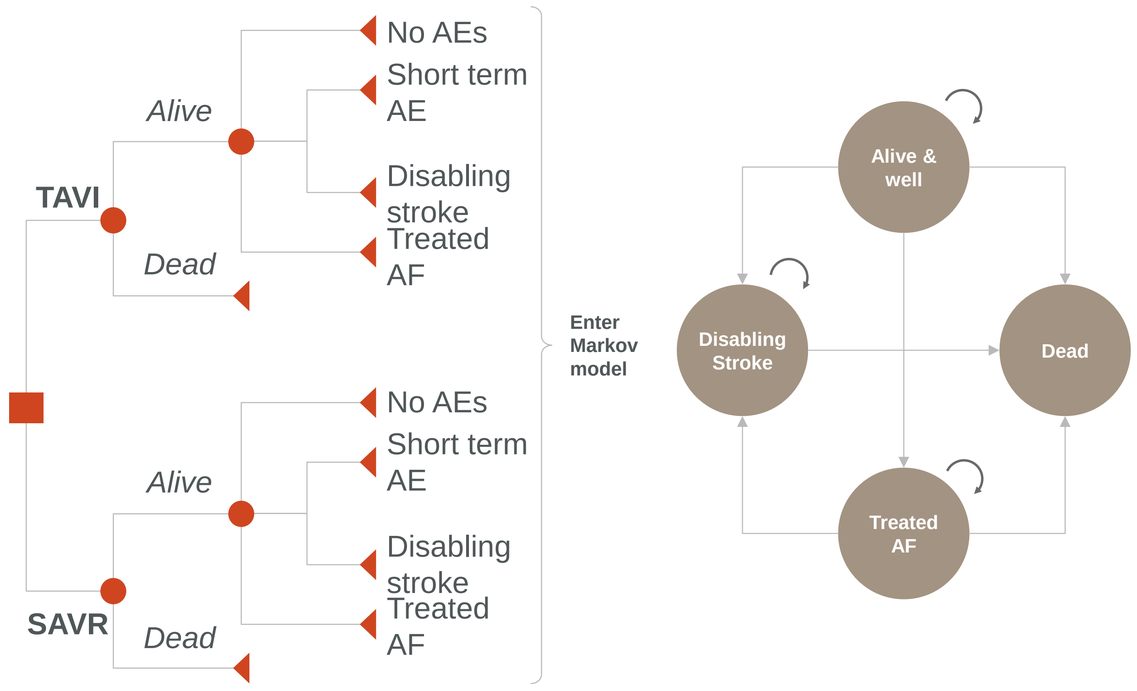

Table 1: Base case results – lifetime horizon

Summary results	TAVI with SAPIEN 3™	SAVR	Incremental
Cost per patient	€ 44 065	€ 48 171	- € 4 107
QALYs per patient	9.03	8.57	0.46
Incremental Cost Effectiveness Ratio (ICER)	Dominant		

- The deterministic sensitivity analysis showed that TAVI with SAPIEN 3™ remains cost-effective regardless of changes in individual model parameters. The procedure costs of TAVI with SAPIEN 3 and SAVR, and the starting age of the cohort, were the parameters that most influence the model.
- The probabilistic sensitivity analysis corroborated the deterministic results. In addition, TAVI was dominant over SAVR in 56.9% of simulations. At the assumed willingness-to-pay (WTP) threshold of € 30 000/QALY or higher, TAVI with SAPIEN 3 was cost-effective over SAVR in 99.1% of simulations.
- TAVI with SAPIEN 3 was dominant or cost-effective compared with SAVR across a wide range of scenarios conducted to assess the impact of changing various assumptions, including the scenario limiting the time horizon to 5 years. These findings demonstrate the comparative robustness of the base case results.

CONCLUSION

- The analysis with 5-year data from the PARTNER 3 trial confirms that TAVI with SAPIEN 3™ is a dominant alternative to SAVR for Belgian sSAS patients at low risk of surgical mortality.
- These results provide valuable insights for clinicians, policymakers, and budget holders in optimizing patient outcomes and healthcare resource allocation.

References

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