Acta Cardiologica

ISSN: (Print) (Online) Journal homepage: https://www.tandfonline.com/loi/tacd20

Is transcatheter aortic valve implantation for aortic stenosis cost-effective?

Patrizio Lancellotti, Khalil Fattouch & Thomas Modine

To cite this article: Patrizio Lancellotti, Khalil Fattouch & Thomas Modine (14 Nov 2023): Is transcatheter aortic valve implantation for aortic stenosis cost-effective?, Acta Cardiologica, DOI: 10.1080/00015385.2023.2281110

To link to this article: https://doi.org/10.1080/00015385.2023.2281110

Published online: 14 Nov 2023.

ACTA CARDIOLOGICA
https://doi.org/10.1080/00015385.2023.2281110

LETTER TO THE EDITOR

Is transcatheter aortic valve implantation for aortic stenosis cost-effective?

Transcatheter aortic valve implantation (TAVI) is becoming a standard treatment option for patients with severe symptomatic aortic stenosis (sSAS). As the comparative clinical evidence for TAVI vs SAVR is growing, cost effectiveness analysis (CEA) could be of supportive value for the treatment choice of sSAS patients in the Belgian clinical practice [1]. Since 2021, the ESC/EACTS guidelines for the management of valvular heart disease has recommended TAVI in older patients ($\geq$75 years), or in those who are at high-risk (STS-PROM/EuroSCORE II >8%) or unsuitable for surgery [2]. However, uptake of these guidelines and TAVI implantation rates vary substantially between European countries with Belgium having lower rates than many (Figure 1) [3].

The reimbursement and budgetary status of TAVI procedures is likely a contributory factor towards this variation [4]. In most Western European countries, we observe a trend towards funding and/or reimbursement access to TAVI for low-risk patients in line with the ESC/EACTs guidelines [5,6]. Although the reimbursement of TAVI procedures in Belgium recently expanded from 500 to 1500 patients in May 2023 [7], this is limited to high-risk and inoperable patients and so Belgium, along with the Netherlands [8], remains one of the most restrictive countries in Western Europe in terms of payer policies.

What is cost-effectiveness analysis?

Cost effectiveness analysis (CEA) is one type of health-economic evaluation that compares the costs and effects of alternative health interventions, thus providing important information from which budgetary and reimbursement decisions can be made [9]. Effectiveness is measured using the quality-adjusted life year (QALY), whilst costs include only those which are directly related to the perspective of the relevant decision-making body. Incremental analysis is carried out between treatment options, and some treatments are found to be both more effective and less costly vs the comparator, known as a 'dominant' treatment option. Where dominance is not resultant, incremental cost-effectiveness ratios (ICERs) are calculated and compared against a pre-determined threshold known as the willingness to pay (WTP) threshold. The most cost-effective treatment option is that which offers the greatest effectiveness, whilst remaining below the WTP threshold. This CEA is the first published comparing TAVI vs SAVR in low-risk patients in Belgium and therefore is a welcome, informative, and important addition to the economic evidence base that should be seriously considered by policy makers [1]. The results found that TAVI dominated SAVR in terms of an increase in QALYs of 0.94 and cost saving of €3013 per patient, thus providing meaningful clinical and cost benefits over SAVR. The result is aligned with a range of published CEAs for other European countries, with the exception of England (Figure 2) [10–16].

Model parameters or assumptions

CEA requires data inputs to inform the clinical event probabilities and associated cost parameters that form the basis of the economic model [17]. For the clinical assumptions, Dubois et al. used PARTNER 3 data to inform the adverse event rates and clinical parameters up to 2 years and a variety of data sources beyond 2 years [1,18]. The cost parameters were based on information from the Belgian All Patient Refined-Diagnosis Related Groups (APR-DRGs) and other published literature (Dubois et al. Table 1) and so, by design, were not specific to patients treated with Sapien 3.

Sensitivity & scenario analysis

Within their model, Dubois et al. performed in-depth sensitivity and scenario analysis, with TAVI remaining cost-effective in every instance of plausible change and in 100% of simulations [1]. This demonstrates that the results are robust and likely to hold true in scenarios where clinical outcomes may vary slightly from PARTNER 3, for instance with other RCTs comparing TAVI vs SAVR in low-risk patients, such as the EVOLUT Low Risk Trial, which has demonstrated excellent results out to 4 years [19]. Therefore, it is likely that a TAVI platform with such evidence would accrue at least similar QALYs and so it appears feasible to assume that a cost-effective outcome would result for Evolut TAVI valves also.

TAVI valve cost

The cost of the balloon-expandable (BE) Sapien 3 valve assumed in the model is €19,610, which appears high in comparison to self-expanding (SE) valves available in Belgium [1], and certainly much higher than the reimbursement level for inoperable and high-risk patients of €11,818 (big lump sum). Therefore, assuming similar adverse event profiles, the ICER and budget impact of TAVI vs SAVR in Belgium will likely be positively impacted

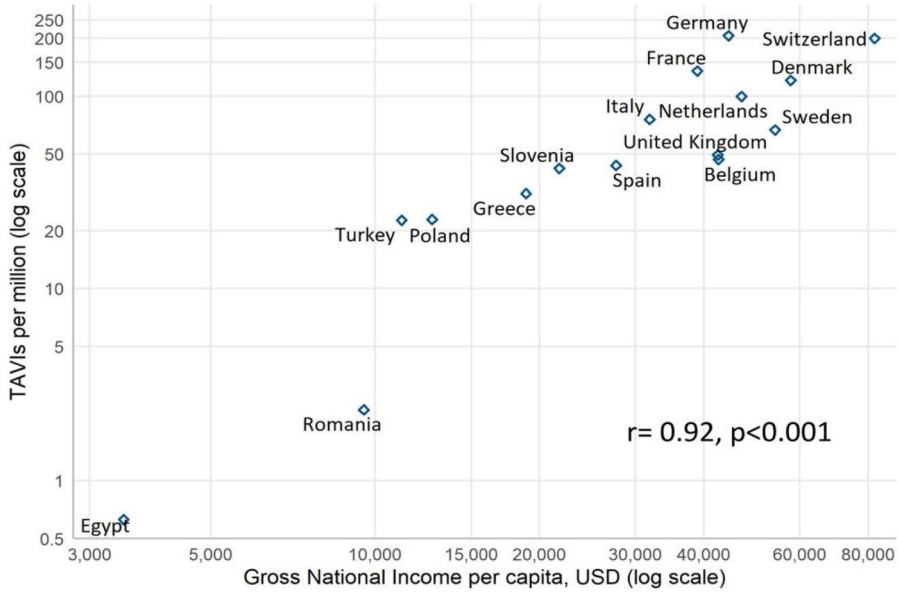

Figure 1. Transcatheter aortic valve implantations per million people by gross national income (GNI) per capita (2016 or latest available year) (from reference [3]).

Figure 2. Summary of published cost-effectiveness analyses comparing TAVI vs SAVR in low-risk patients for European countries (from references [10–16]).

with SE valves, further reducing the financial burden for Belgian hospitals and the wider health-system.

Modelling long-term survival and durability

Low-risk patients are likely to survive longer vs higher risk patients and thus durability, longer term reinterventions and long-term survival will play a key role in this patient population, thus impacting the costs and QALYs accrued in CEA models over the lifetime horizon. In this CEA, the probability of aortic reintervention was based on PARTNER 3 data up to 2 years and then a SAVR durability study thereafter and survival was projected from the 2-year PARTNER III data [1,18]. 5-year data from the PARTNER 3 study was recently published and showed equivalent reintervention rates for Sapien 3 vs SAVR (3.0% and 2.6%, $p = 0.72$, respectively), indicating that the model assumptions appear appropriate given the available data [20]. Similar results regarding reintervention are also observed for CoreValve and Evolut valves as demonstrated by the NOTION trial at 8-year [21] and the Evolut Low Risk trial at 4 years [19].

Conclusion

With pressure growing on healthcare expenditure, cost-effectiveness data comparing TAVI vs SAVR and comparing available TAVI valves will continue to provide important supportive evidence in guiding policy decisions for the treatment of sSAS in wider patient indications. Like Sapien, Evolut TAVI platforms are likely to demonstrate cost-effectiveness in low-risk patients in Belgium with procedural complications, valve cost, durability and survival having variable impact on the ICER. However short-

and long- term patient outcomes will remain the most important parameters for the patients, their caregivers, and the cardiologists.

ORCID

Patrizio Lancellotti http://orcid.org/0000-0002-0804-8194

References

[1] Dubois C, Adriaenssens T, Annemans L, et al. Transcatheter aortic valve implantation versus surgical aortic valve replacement in severe aortic stenosis patients at low surgical mortality risk: a cost-effectiveness analysis in Belgium. Acta Cardiol. 2023; in press.

[2] Vahanian A, Beyersdorf F, Praz F, et al. 2021 ESC/EACTS guidelines for the management of valvular heart disease. Eur Heart J. 2022;43(7):561–632. doi:10.1093/eurheartj/ehab395.

[3] Barbato E, Noc M, Baumbach A, et al. Mapping interventional cardiology in Europe: the European Association of Percutaneous Cardiovascular Interventions (EAPCI) atlas project. Eur Heart J. 202;41(27):2579–2588. doi:10.1093/eurheartj/ehaa475.

[4] Mylotte D, Osnabrugge TLJ, Martucci G, et al. Adoption of transcatheter aortic valve implantation in Western Europe. Interv Cardiol. 2011;9(1):37–40. doi:10.15420/icr.2011.9.1.37.

[5] Auffret V, Lefevre T, Van Belle E, et al. Temporal trends in transcatheter aortic valve replacement in France: France 2 to France TAVI. J Am Coll Cardiol. 2017;70(1):42–55. doi:10.1016/j.jacc.2017.04.053.

[6] Mauri V, Abdel-Wahab M, Bleiziffer S, et al. Temporal trends of TAVI treatment characteristics in high volume centers in Germany 2013-2020. Clin Res Cardiol. 2022;111(8):881–888. doi:10.1007/s00392-021-01963-3.

[7] Implantaten en invasieve medische hulpmiddelen : Lijst van de verstrekkingen en nominatieve lijsten van de individuele hulpmiddelen. Rijksinstituut voor ziekte- en invaliditeitsverzekering. https://www.riziv.fgov.be/nl/professionals/individuele-zorgverleners/verstrekkers-van-implantaten/Paginas/implantaten-lijst-verstrekkingen-nominatieve.aspx.

[8] Standpunt transcatheter aortaklepimplantatie (TAVI) bij patiënten met symptomatische ernstige aortaklepstenose (update). https://www.zorginstituutnederland.nl/publicaties/standpunten/2020/09/30/standpunt-tavi-bij-ernstige-aortaklepstenose.

[9] Russell LB, Gold MR, Siegel JE, et al. The role of cost-effectiveness analysis in health and medicine. JAMA. 1996;276(14):1172–1177.

[10] Gilard M, Eltchaninoff H, Iung B, et al. Cost effectiveness analysis of SAPIEN 3 transcatheter aortic valve implantation procedure compared with surgery in patients with severe aortic stenosis at low risk of surgical mortality in France. Value Health. 2022;25(4):605–613. doi:10.1016/j.jval.2021.10.003.

[11] Mennini FS, Meucci F, Pesarini G, et al. Cost-effectiveness of transcatheter aortic valve implantation versus surgical aortic valve replacement in low surgical risk aortic stenosis patients. Int J Cardiol. 2022;357:26–32. doi:10.1016/j.ijcard.2022.03.034.

[12] Kuck KH, Leidl R, Frankenstein L, et al. Cost-effectiveness of SAPIEN 3 transcatheter aortic valve implantation versus surgical aortic valve replacement in German severe aortic stenosis patients at low surgical mortality risk. Adv Ther. 2023;40(3):1031–1046. doi:10.1007/s12325-022-02392-y.

[13] Tchétché D, de Gennes CD, Cormerais Q, et al. Cost-effectiveness of transcatheter aortic valve implantation in patients at low surgical risk in France: a model-based analysis of the Evolut LR trial. Eur J Health Econ. 2023. doi:10.1007/s10198-023-01590-x.

[14] NICE: Cost-utility analysis: Transcatheter intervention for patients who have operable aortic stenosis NICE guideline NG208. 2021. https://www.nice.org.uk/guidance/ng208/evidence/tavi-economic-analysis-pdf-10890776557.

[15] Health Information & Quality Authority (HIQA), Ireland. https://www.hiqa.ie/sites/default/files/2019-12/TAVI_HTA.pdf.

[16] NIPH: Norwegian Institute of Public Health (NIPH). https://www.fhi.no/en/publ/2021/TAVI-vs-SAVR-for-patients-with-severe-aortic-stenosis-and-low-surgical-risk-and-across-surgical-risk-groups/.

[17] Gupta N, Verma R, Dhiman RK, et al. Cost-Effectiveness analysis and decision modelling: a tutorial for clinicians. J Clin Exp Hepatol. 2020;10(2):177–184. doi:10.1016/j.jceh.2019.11.001.

[18] Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 years after transcatheter aortic valve replacement in patients at low surgical risk. J Am Coll Cardiol. 2021;77(9):1149–1161. doi:10.1016/j.jacc.2020.12.052.

[19] Forrest JK, Deeb GM, Yakubov SJ, et al. 4-Year outcomes of patients with aortic stenosis in the evolut low risk trial. J Am Coll Cardiol. 2023:S0735-1097(23)07628-3. doi:10.1016/j.jacc.2023.09.813.

[20] Mack MJ, Leon MB, Thourani VH, et al. Transcatheter aortic-valve replacement in low-risk patients at five years. N Engl J Med. 2023. doi:10.1056/NEJMoa2307447.

[21] Jørgensen TH, Thyregod HGH, Ihlemann N, et al. Eight-year outcomes for patients with aortic valve stenosis at low surgical risk randomized to transcatheter vs. surgical aortic valve replacement. Eur Heart J. 2021;42(30):2912–2919. doi:10.1093/eurheartj/ehab375.

Patrizio Lancellotti*
Department of Cardiology, CHU SartTilman, University of Liège Hospital, GIGA Cardiovascular Sciences, Liège, Belgium
plancellotti@chuliege.be

Khalil Fattouch
Department of Cardiovascular surgery, GVM Care and Research, Maria Eleonora Hospital and Dichirinos University, Palermo, Italy

Thomas Modine
CHU de Bordeaux, Bordeaux, France

Received 29 October 2023; Accepted 5 November 2023