

**OPTAR Study: Transcatheter Aortic Valve Implantation (TAVI) vs Optimal Medical Treatment (OMT) in prohibitive surgical Risk patients with severe Aortic Stenosis – An exploratory Cost-Effectiveness Analysis**

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Objectivos (Objectives): Aortic valve stenosis, a chronic and progressive valvular heart disease, is a severe cardiovascular condition. The standard treatment of this condition involves a major open surgical procedure of aortic valve replacement. For patients currently ineligible for surgery, medical management is the only treatment option available. Transcatheter aortic valve implantation (TAVI) devices are a less invasive technique that more recently appeared as new treatment option for these high risk, inoperable patients. The objective of this study was to develop an exploratory cost-effectiveness analysis of TAVI in comparison with Optimal Medical Treatment (OMT) in the Portuguese Setting, using a Markov Model developed by Oxford Outcomes in the UK.

Metodologia (Methodology): The underlying model used in this analysis is a 10 year probabilistic model, with separate but linked Markov sub-models, to assess costs and benefits of TAVI vs. OMT. The short term sub-model represents the first 30 days after TAVI considering a cycle length of one day, whereas in the long term model the cycle length is one month for a time horizon of ten years. Health states were based on location of care and progression of health status. For TAVI group patients, the starting point for the model is immediately following the initial implant operation and the Health States considered are: ICU, General Wards, Home, Re-operation and Death. OMT patients are in either home or dead health states. These individuals continue to receive medication until death and are at risk of co-morbidity-related hospitalisations. Portuguese NHS healthcare resource consumption was retrospectively collected at Hospital de Santa Cruz in Lisbon, for a cohort of 43 high risk patients with severe aortic valve stenosis requiring treatment (20 TAVI group; 23 OMT group) followed over an average period of 11 months and implanted with a Medtronic CoreValve System. Clinical parameters, transition probabilities and utility values were derived from published relevant literature. Costs were taken from the most recent official Portuguese published cost tables and hospital reports. All costs and benefits were discounted at 5% p.a. Extensive probabilistic and one-way sensitivity analysis was performed to identify key cost-effectiveness drivers and the relationships between key parameters.

Resultados (Results): Treatment with TAVI compared to standard care increased life years by 1,7 (3,13 vs. 1,46) and quality-adjusted life years (QALYs) by 1,4 (2,23 vs. 0,80). Direct costs were projected to be 32.067 € with TAVI and 4.662 € with OMT. These results corresponded to Incremental Cost Effectiveness Ratio (ICERs) of 16.375 € per LYG and 19.180 € per QALY.

Conclusões (Conclusions): TAVI is highly likely to be a cost-effective intervention for the treatment of AS in patients who are currently ineligible for surgery, in the Portuguese setting.