

Código: 27088

Chave: 00067EC574

Especialidade: Heart Team

Tipo de Apresentação: Comunicação Oral

Título: Cost-effectiveness of transcatheter aortic valve implantation versus surgical aortic valve replacement in patients with severe aortic stenosis

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Palavras-chave: severe aortic stenosis, transcatheter aortic valve implantation, transfemoral approach, surgical aortic valve replacement, cost-effectiveness, QALY

Background: Transcatheter aortic valve implantation (TAVI) has emerged as a new treatment option for patients with severe aortic stenosis. Despite its low periprocedural risk profile in comparison to surgical aortic valve replacement (SAVR), the high device costs might impact their implementation in budget-constrained countries.

Objective: To evaluate cost-effectiveness of transfemoral TAVI versus SAVR in patients with severe aortic stenosis.

Methods: Retrospective single-center cohort including a group of consecutive patients undergoing transfemoral TAVI between January 2015 and December 2017, and a group of patients undergoing isolated SAVR in the same time horizon and selected according to gender and age. Follow-up information (New York Heart Association class and all-cause mortality) was consulted after 1, 6 and 12 months of the procedure and the multiple imputation method was used to treat the missing data. Costs were determined from the perspective of the Health Care Provider. The effectiveness was measured in Quality Adjusted Life Years (QALY). The Incremental Cost Effectiveness Ratio (ICER) was calculated and a willingness to pay threshold of 30.000 €/QALY was considered. Appropriate statistical tests were used to compare two independent groups, multivariable Cox Regression was applied to survival analysis and the bootstrap resampling method with 1000 simulations was used to represent the cost-effectiveness plan.

Results: We included 112 individuals in each group. Mean patient's age was 81 ± 5 and 60,7% were female. Time to discharge was $8,7 \pm 8,2$ days for TAVI and $13,5 \pm 22,8$ days for SAVR ($p=0,042$). Median Society of Thoracic Surgeons (STS) score was 4,55% and 3,49% in TAVI and SAVR groups, respectively ($p<0,001$). After adjusting for STS score, no difference in 1-year all-cause mortality as found between the two groups (HR: 1,652; 95%CI: 0,487-5,607). Costs related to human resources, drugs and hospitalization were lower in TAVI (3.577 € vs 6.313 €), but those concerning materials, diagnostic tests and use of the cardiac catheterization laboratory were higher (20.857 € vs 3.196 €). The ICER was 465.874 €/QALY. Subgroup and sensitivity analysis showed nevertheless that patients with STS > 8% had an ICER of 36.988 €/QALY and the scenario of 90% off on percutaneous valve prosthesis cost of 30.547 €/QALY.

Conclusion: In this single-center retrospective study TAVI, compared to SAVR, was not considered cost-effective. However, in the two previous scenarios (high STS score and low percutaneous valve prosthesis cost) it may be closer to being cost-effective. Further prospective and multi-center studies are needed to provide an extensive estimation of cost-effectiveness of TAVI in Portugal.