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Title Sutureless aortic valve replacement

Agency avalia-t. Axencia de Avaliación de Tecnoloxías Sanitarias de Galicia
Edificio Administrativo San Lázaro · 15781 Santiago de Compostela
Telf.: 881 541 831 · Fax: 881 542 854 · e–mail: avalia–t@sergas.es ·
http://avalia–t.serg

Reference avalia-t2013/03, http://www.sergas.es/Docs/Avalia-t/avaliat201303Protesis_Sin_Sutura.pdf

Aim

The main objective is to assess effectiveness, safety and economic impact of sutureless aortic valve replacement. The specific objectives are: 1) assess the potential benefit-risk balance in comparison to surgical aortic valve replacement; 2) assess the potential benefit-risk balance against transcatheter aortic-valve implantation (TAVI).

Conclusions and results

Evidence comes from 14 low quality studies. All are case series; eight focus on prosthesis ATS 3f EnableTM , five on Perceval S™ and one on the INTUITY™ valve sytem. Regardless of the type of valve, all show good haemodynamic and clinical results. For ATS 3f Enable™, studies showed a highly variable procedural success rate. In the small case series, between 11-17% of the prosthesis had to be replaced at implantation due to inappropriate sizing; 14-33% due to incorrect positioning. Median aortic cross clamp time ranged from 40 to 66 minutes and CPB time from 58 to 85 minutes. Hospital mortality varied from 0% to 11%. Paravalvular leakages were the main complications (2.1%-33%), followed by heart blocks that required definitive pacemaker implantation (0-18,5%), and ventricular arrhythmias (0%-17%). Between 2.2% and 17% of the paravalvular leaks were major and required for a reoperation. In the Perceval S™ studies, procedural success rate varied from 95,6%-100% and mean CPB time for isolated replacement between 35 to 73 minutes. The frequency of major paravalvular leakages, ventricular arrhythmias, definitive pacemaker implantation and thromboembolisms amounted to 2.4%, 7%, 42.5% and 4.8% in some of the studies. Hospital mortality ranged from 0% to 3.3%. The procedural success achieved with the INTUITY™ valve system was 97.3%. The valve was explanted in 3.1% of the cases and 2.3% of the patients experienced paravalvular leaks >1+. Tromboembolic events occurred in 4.6% of the cases and 8.9% required definitive pacemakers. Hospital mortality was 2.1%. No major hemolysis, structural deterioration or migration was observed in any of the studies.

In conclusion, studies on Perceval S™ and INTUITY™ valve system suggest that these prosthesis might be able to reduce cross clamp and CPB times in relation to aortic valve replacement. However, evidence points to the possibility of a higher rate of major paravalvular leaks and reoperations, even though lower than with TAVI. The fact that studies do not report specific criteria for patient recruitment or the criteria which determined the use of different approaches, raises major concerns regarding reproducibility and applicability of results. Follow-up time is less than two years and this is a limitation to assess long-term safety or durability of the prosthesis.

Recommendations

Given the good results of aortic valve replacement and the lack of high quality comparative studies, it is recommended that these valves should not be considered for low surgical risk patients.

Methods

A systematic search was carried out in the main literature and clinical research databases (PubMed, Embase, Cochrane, ISI Web of Knowledge, Centre for Reviews and Recommendations, Cochrane, etc.). Internet was scanned and manufactures contacted to recover non published information. The studies were selected by two independent reviewers based on a set of predefined selection criteria. There were no restrictions regarding study design or publication status. Individual case reports were excluded. Data was extracted using a data extraction form and synthesized qualitatively in the form of evidence tables. The methodological quality of the studies was assessed using the SIGN scale.

Further research/reviews required

Randomized clinical trials comparing sutureless aortic valves with surgical replacement and TAVI in different risk subgroups are recommended before definitive conclusions regarding indications can be established.

Written by

Leonor, Galician Agency for Health Technology assessment (avalia-t), Spain