Editorial

Transapical aortic valve implantation - What have we learnt? Quo vadis?

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After Alain Cribier pioneered in 2002 the transfemoral approach to transcutaneous aortic valve implantation (TAVI) (1), the Leipzig Heart Center was the first to perform a transapical TAVI in December 2004. TAVI is now a treatment for patients with severe aortic stenosis, that had previously been refused for surgery due to prohibitively high surgical risk (2,3). This year we celebrate the 10-year anniversary of this technology, which was inevitably highly controversial in the beginning. The number of TAVI procedures has increased worldwide drastically and in particular in Germany, where now they account for one-third of all isolated aortic valve operations.

Holzhey *et al.* from Leipzig Heart Center have recently published one of the largest experiences with transapical aortic valve implantation using the Sapien valve and its various iterations (Cribier-Edwards, Edwards Sapien THV, Edwards Sapien XT; Edwards Lifesciences, Irvine, CA) (4). Outcome data of this five-year single centre series were presented according to the Valve Academic Research Consortium (VARC) criteria (5). From 2006 to 2011, 439 patients with a mean logistic EuroSCORE of 29.7%±17.7% and STS risk of mortality of 11.4%±7.6% were included. It is of interest to note that during the study period the number of conventional aortic valve replacements also increased slightly, probably because after implement the TAVI program more high-risk patients were referred and secondary reflecting the increasing age of the general population. Due to the early involvement of Leipzig Heart Center in the development of the transapical approach the number of transapical cases was high and not only patients without femoral access were included, as reflected by prevalence of peripheral artery disease in only 18% of cases. Procedural success was 90.2%, stroke occurred in 2.1% of patients intraoperatively and a further 2.1% of patients had a stroke during their hospital stay. Moderate or greater aortic insufficiency due to paravalvular leak was present in 5.7% of patients and in 34.3% of patients mild aortic insufficiency was observed. Overall survival was 90% at 30days, 73% at 1 year , 68% at 2 years and 44% at 5 years (4). The overall results of this study are very good, however, it is noteworthy that a clear learning curve could be demonstrated with statistically significant improvement after 150 procedures. This emphasizes the role of proctoring during the early phase of program development and the use of simulation tools may be helpful to shorten the observed learning curve for transapical aortic valve implantation.

The reported 30-day mortality in the Leipzig series (4) was similar to that reported in previous registries: Canadian registry, 10.4% (6); SOURCE registry, 8.5% (7); FRANCE registry, 12.7% (8); German registry, 8.2% (9) and Italian registry, 5.4% (10). However, despite the high procedural success and good 30-day survival after transapical TAVI, recent studies showed significant differences of one year survival according to logistic EuroSCORE (with best results <15% and <20%, respectively) and no significant difference in mortality regarding transfemoral versus transapical approach (11,12). Similar findings were observed in a multimorbid, higly selected transapical patient collective, when a "groin first" strategy for TAVI was followed (13). These issues may be important for reimbursement in the future due to limited financial resources. Recommendations for TAVI in elderly patients must be based as well on quality of life outcomes, implementation of frailty scoring may be useful to identify patients, who are able to gain a functional

benefit after TAVI (14).

Paravalvular leakage is so far the Achilles' heel of TAVI and recent studies clearly demonstrated the negative impact of moderate to severe aortic regurgitation (AR) on survival (15), even in cases of mild aortic regurgitation an AR-index <25 {AR-index = [(diastolic blood pressure - left ventricular end-diastolic pressure)/ systolic blood pressure] ×100} was associated with an increased risk for one year mortality (16). Aortic valve calcium scoring may be useful to predict the risk of paravalvular leakage after TAVI (17) and detection of severe calcifications in the left ventricular outflow tract may be helpful to prevent annular tear, a rare, but devastating complication after TAVI. Modifications of the valve design, especially the "skirts", may be useful to limit paravalvular leakage in the future. At the moment, paravalvular leakage and so far missing long-term results on hemodynamic performance and longevity of leaflets after crimping may prohibit the use of TAVI in younger patients and in patients with low surgical risk. However, only the currently ongoing randomized clinical trials will provide possible answers for or against the use of TAVI in lower risk patients.

The transapical approach for TAVI, at least not inferior to the transfemoral approach, may be even superior in the long-term with decreased rates of stroke and potentially better durability of leaflets due to less crimping. The use of apical closure devices may reduce bleeding complications, allow reaccess and may shift the transapical approach with minithoracotomy to a complete percutaneous procedure. The transapical approach, due to greater level of control for valve deployment, may be more and more used for treatment of high-risk patients with failing bioprostheses (18) and may facilitate new techniques of valvular therapy (19): beating heart mitral valve repair with neochordae (20) and deployment of ascending aortic stent grafts for aortic dissections and pseudoaneurysms (21,22) are on the horizon. However, only time will tell.

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