Editorial

Transapical transcatheter aortic valve implantation: the front door approach captures the world

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Since the first-in-man procedure in 2002 transcatheter aortic valve implantation (TAVI) has emerged as a novel less invasive treatment option for high-risk patients with severe symptomatic aortic stenosis (1,2). Transcatheter aortic valve implantation has evolved impressively in recent years. The technique is feasible and safe, hemodynamic results after TAVI are excellent and its prognostic impact has been proven in several randomized clinical trials (3-5). Conceptually, two different approaches are applied: the "front door" and the "back door" approach, namely implantation by transapical - "front door" - access or by retrograde - "back door" - access via the arterial system including transfemoral, axillary or subclavian access routes.

The Leipzig Heart Center was one of the first centers worldwide to perform transapical TAVI, and has gathered large experience to date with this innovative technology. Since the beginning of their TAVI program, the number of patients treated annually in their center imcreased rapidly reaching more than 350 patients in 2011. The authors have already reported their experience and practice including comprehensive short- and midterm outcome analyses of their patient cohort (6-9). They further implemented different novel transcatheter valve systems (10,11). In this issue of the journal, Holzey *et al*. now present one of the largest single-center experiences for transapical TAVI worldwide.

Comprehensive clinical testing and outcome assessment is a key issue in interventional cardiology and the basis for evidence-based medicine in the field. Both, reporting complications and outcome as well as discussing difficulties and worries of novel technologies between centers, are important to improve techniques and device design and thereby to optimize the treatment of our patients. Holzhey *et al*. report impressive 5 year experience based on their large prospective transapical TAVI database including over 400 patients. With their report the authors underline the success of TAVI in the longer term. They provide a comprehensive and detailed analysis of their patients undergoing transapical TAVI with the Edwards SAPIEN valve from 2006 to 2011 at their institution, and provide outcome reporting in line with the Valve Academic Research Consortium (VARC) standardized endpoint definitions (12,13).

The authors report a high procedural device success rate of 90.2%. Similar device success rates reported according to the VARC standardized endpoint definitions have previously been published (14-16). In their patient cohort, peri-procedural stroke occurred in 2.1% of patients and a further 2.1% suffered stroke during their hospital stay. Comparable low stroke rates have indeed been observed in transapically treated patients as manipulation of the aortic arch can be avoided by this access route (17-20). Major vascular complications were observed in 3.4% of patients, life-threatening or disabling bleeding occurred in 6.2%, and acute kidney injury in 27.9%, respectively. Overall survival was 90% at 30 days, 73% at 1 year, 68% at 2 years, and 44% at 5 years. These results are completely in line with previous reports of outcomes and overall short- and midterm survival after transapical TAVI (20-22). Four years' experience with the Edwards SAPIEN prosthesis was evaluated by Litzler *et al*., they reported a survival rate of 74% at 1 and 41% at 4 years, respectively (23). To our knowledge, however, the article published in this issue of the journal, is the first outcome report comprising 5 years of post-procedural

follow-up.

In addition to a detailed outcome analysis, Holzhey *et al*. give us a comprehensive assessment of their learning curve by calculation of descriptive statistics and cumulative sum (CUSUM) failure analysis. The learning curve of this center is of great interest as these operators were pioneers in the field and did not have experience of other centers to benefit from. Their wide-ranging analyses include different aspects of the procedure including patient selection and indications as well as adoption of wire skills, fluoroscopic imaging, or postoperative care. Furthermore the individual learning curve from each of the 4 surgeons participating in the program was integrated. The overcoming of the learning curve has been confirmed by a marked improvement of 1 year survival as depicted in the Kaplan-Meier survival curves of the first and second 120 TAVI patients. As the authors state, mainly improvements in postoperative monitoring and complication management lead to the increased survival observed. They provide us an interesting CUSUM failure analysis of all major complications including conversion to sternotomy, stroke, dialysis, low cardiac output, reoperation for bleeding or valve dysfunction, long term dependency on respirator, and death. A significant improvement in performance was observed after 150 TAVI procedures, and a downward slope of the curve was seen after 200 TAVI procedures indicating that the learning phase has been overcome with continuous improvement of the procedure. Impressive learning curves and improved TAVI outcome with increasing experience and device development have previously been reported (24). However, to our knowledge, this analysis represents the first implementation of a CUSUM failure analysis in the field of transcatheter valves, and of interventional cardiology, too. The CUSUM failure analysis is an interesting tool which allows to investigate learning effects and changes in outcome rates over time (25), and this analysis has recently been proposed as appropriate statistical tool for visualizing the performance of TAVI teams (26). We fully agree with the authors that shortening the learning curve of centers just embarking on transapical TAVI is essential, and that structured training including simulator training and visits to experienced centers contributes to an improved patient outcome during the early learning phase.

We congratulate Holzey *et al*. as forerunners for transapical TAVI procedures for this comprehensive report of long term follow-up after transapical TAVI. These data give to the evidence that TAVI with the balloon-expandable Edwards SAPIEN valve has become a routine procedure with good results, and that the "front door" approach is safe and feasible. As the authors state, further long term outcomes are intently awaited for the future decision of whether or not to extend TAVI to younger lower-risk patients.

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