Beyond the short-term: Clinical outcome and valve performance 2 years after transcatheter aortic valve implantation in 227 patients

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Objective: Although the procedural feasibility of transcatheter aortic valve implantation has been shown by multiple groups, longer-term data are rare. We report on 2-year follow-up clinical and echocardiographic results after transcatheter aortic valve implantation in 227 patients.

Methods: Patients' mean age was 81 ± 7 years, 59% were female, mean European System for Cardiac Operative Risk Evaluation was 21% ± 14%, mean Society of Thoracic Surgeons score was 7% ± 5%, and access routes were transfemoral (n = 164), transapical (n = 54), axillary (n = 5), or transaortic (n = 4). A CoreValve (Medtronic Inc, Minneapolis, Minn) prosthesis was implanted in 174 patients, and a SAPIEN prosthesis (Edwards Lifesciences, Irvine, Calif) was implanted in 53 patients. Clinical and echocardiographic investigations were performed at 6 months, 1 year, and 2 years.

Results: Survival was 88.5% at 30 days, 75.9% at 6 months, 74.5% at 1 year, and 64.4% at 2 years. Patients improved significantly in New York Heart Association class after 6 months (from 3.2 ± 0.5 to 1.7 ± 0.7, $P < .001$) and up to 2 years (1.9 ± 0.7). Cumulative incidences of myocardial infarction, stroke, and life-threatening or major bleeding were 2.7%, 6.2%, and 16.2% at 2 years, respectively. The postprocedural mean transprosthetic gradient was 12 ± 4 mm Hg for all valves and did not change up to 2 years, and the effective orifice area was 1.5 ± 0.4 cm^2 with no change over 2 years of follow-up. Moderate or severe prosthetic regurgitation was present in 8% of patients at 2 years. In 6% of patients, the paravalvular or valvular regurgitation grade increased significantly over time.

Conclusions: With excellent functional recovery of the patients, good systolic valve function, and overall low morbidity at 2 years, transcatheter aortic valve implantation may be considered the treatment of choice for aortic valve stenosis in elderly patients with an increased risk for surgery with a heart–lung machine. (J Thorac Cardiovasc Surg 2012;143:310-7)

A growing elderly population has resulted in an increase of the number of patients with severe aortic valve stenosis. Surgical aortic valve replacement (SAVR) is the gold standard to treat severe aortic stenosis with proven effectiveness and long-term results. However, a significant number of elderly patients are not treated surgically for increased operative risk.[1] Advancements in transcatheter technology have led to the innovation of transcatheter aortic valve implantation (TAVI), with the first patient treated in 2002 by Cribier and colleagues.[2] With its less-invasive character by avoiding cardiopulmonary bypass and median sternotomy, TAVI is supposed to allow treatment of candidates at high surgical risk and improve the usually poor prognosis of the natural history of severe aortic stenosis.

Data from the randomized PARTNER trial cohort A[3] recently demonstrated noninferiority of TAVI compared with SAVR treatment with a 1-year follow-up. The most recent publications of several registry studies demonstrated reproducible results up to 1 year.[4-6] These findings may lead to a broader application of TAVI in elderly patients. The next step must be to collect longer-term data to prove the effectiveness and durability of this new treatment option.

At the German Heart Center Munich, a transcatheter valve program was initiated in 2007. A total of 580 patients who were considered at high operative risk by clinical judgment and clinical scores (European System for Cardiac Operative Risk Evaluation and Society of Thoracic Surgeons score) have been treated with catheter-based aortic valve implantation by transfemoral, transapical, transsubclavian, or direct ascending aortic access since then.

A total of 227 patients have completed 2 years of follow-up and form the study population, which is, to the best of our knowledge, the largest series from a single center with 2 years of data. The goals of this article are therefore to assess mortality, morbidity, and valve function beyond the

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Abbreviations and Acronyms
EOA = effective orifice area
LVOT = left ventricular outflow tract
NS = not significant
SAVR = surgical aortic valve replacement
TAVI = transcatheter aortic valve implantation
VARC = Valve Academic Research Consortium

short-term in a large number of patients in an all-comers situation. To achieve comparability to other reports, the data were prepared according to the end point definitions recently published by the Valve Academic Research Consortium (VARC).[7]

MATERIALS AND METHODS

Patients and Aortic Valve Implantation Technique

Between June 2007 and March 2009, 227 patients underwent TAVI for severe aortic stenosis. Since the introduction of the TAVI program at the German Heart Center Munich in 2007, all patients with severe aortic stenosis at high risk for conventional cardiac surgery with sternotomy and cardiopulmonary bypass are referred to a TAVI multidisciplinary team discussion by cardiac surgeons, interventional cardiologists, and cardioanesthesiologists. The baseline patient characteristics of the study group are summarized in Table 1. Choice of access site (transfemoral, subclavian, transapical, transaortic) was based on a ''transfemoral first'' approach.[8,9] If a transfemoral access was not feasible because of diseased peripheral vessels, a subclavian artery or transapical implantation was considered. The transaortic approach was used as a bail-out in selected patients. In this early-experience population, we mainly used the CoreValve prosthesis (Medtronic Inc, Minneapolis, Minn) if a transfemoral access was eligible, because the smaller introduction sheaths (22F) for the SAPIEN (Edwards Lifesciences, Irvine, Calif) prosthesis were not yet available. The logistic European System for Cardiac Operative Risk Evaluation and Society of Thoracic Surgeons score were not different among patients treated with a CoreValve or a SAPIEN prosthesis. Decisions were based on preprocedural imaging diagnostics (computed tomography scan, angiography, and transesophageal and transthoracic echocardiography) performed in all patients.

All implantations were performed in a hybrid theater. Patients were treated under general anesthesia in the study population. Transfemoral TAVI was carried out with the use of percutaneous closure devices or after surgical cut-down of the femoral artery in case of vessel calcifications or severe obesity. The subclavian artery was dissected free for access through a 4- to 5-cm left or right infraclavicular incision. Transapical valve implantation was performed via a left anterolateral minithoracotomy. For transaortic access, an upper median ministernotomy was performed. After balloon valvuloplasty during rapid ventricular pacing, valve deployment was performed under fluoroscopy on the beating heart in case of the self-expanding CoreValve implantation and during an episode of rapid ventricular pacing in case of the balloon-expanding SAPIEN implantation.

After TAVI, all patients were referred to an intensive care unit and monitored for at least 1 day. Heart rate monitoring was continued until discharge. Platelet inhibition was performed by the application of aspirin 100 mg per day lifelong in all patients. After retrograde TAVI, an additional dose of 75 mg clopidogrel was administered for 6 months postprocedurally. Patients with an indication for warfarin therapy received aspirin and warfarin without clopidogrel.

TABLE 1. Patient baseline characteristics (n = 227)

Parameter	Mean ± SD, or n (%)
Mean age, y	81 ± 7
Female	134 (59%)
Logistic euroSCORE	21% ± 14%
STS score	7% ± 5%
BNP value	7100 ± 14,000 U/L
Mean annulus diameter	23 ± 2 mm
Mean aortic valve area	0.6 ± 0.2 cm^2
Mean aortic gradient	48 ± 17 mm Hg
Implanted valve	
CoreValve (Medtronic Inc, Minneapolis, Minn)	174 (77%)
SAPIEN (Edwards Lifesciences, Irvine, Calif)	53 (23%)
Access site	
Transfemoral	164 (72%)
Transapical	54 (24%)
Subclavian artery	5 (2%)
Ascending aorta	4 (2%)
Coronary heart disease	118 (52%)
Peripheral vessel disease	61 (27%)
Cerebrovascular disease	41 (18%)
Previous stroke	26 (11%)
Pulmonary hypertension > 60 mm Hg	53 (23%)
Previous cardiac surgery	42 (19%)
Atrioventricular valve disease	44 (19%)
Lung disease	52 (23%)
Porcelain aorta	15 (7%)
Atrial fibrillation	51 (22%)
NYHA class III or IV	218 (96%)
Ejection fraction < 35%	42 (19%)
Renal insufficiency (creatinine > 1.5 mg/dL)	48 (21%)

SD, Standard deviation; *STS,* Society of Thoracic Surgeons; *BNP,* brain natriuretic peptide; *euroSCORE,* European System for Cardiac Operative Risk Evaluation.

Follow-up

Clinical and echocardiographic follow-up data were collected at discharge, 6 months, 1 year, and 2 years after the procedure.

Echocardiographic investigations were performed by an experienced echocardiographer with an HP Sonos 5500 and HP Sonos 7500 (Hewlett Packard, Palo Alto, Calif). Peak and mean systolic pressure gradients in the left ventricular outflow tract (LVOT) 1 cm below the valve and across the valve were measured in an apical 3- or 5-chamber view using pulsed-wave Doppler for the LVOT measurements and continuous-wave Doppler for the valve measurements, respectively. The LVOT diameter was measured 1 cm below hinge points of the visible prosthetic leaflets from the inner edges of the stent in a parasternal long-axis zoom view. In patients with sinus rhythm, 3 of the best available signals were averaged. If atrial fibrillation was present, a minimum of 5 measurements was averaged. Effective orifice area (EOA) was obtained by using the continuity equation.[10] Prosthetic regurgitation was assessed by a semiquantitative approach using the extent of the regurgitant jet length (color Doppler), pressure half-time measurement (continuous-wave Doppler), in case of transvalvular regurgitation vena contracta measurement, and in case of paravalvular leakage estimation of percentage of circumference. The severity of regurgitation was graded as none, mild, mild–moderate, moderate, moderate–severe, and severe.

Echocardiographic data were available in 203 of 203 living patients (100%) at discharge, 132 of 159 living patients (83%) at 6 months, 119 of 157 living patients (76%) at 1 year, and 90 of 140 living patients (64%) at 2 years.