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Transapical Versus Transfemoral Aortic Valve Implantation: A Multicenter Collaborative Study

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Background. There are no direct comparisons between transapical aortic valve implantation (TA-AVI) and transfemoral aortic valve implantation (TF-AVI). Therefore, the aim of this study was to compare the short-term and midterm outcomes of TA-AVI versus TF-AVI.

Methods. Data from four European centers were pooled and analyzed. To minimize differences between TA-AVI and TF-AVI multivariable analysis was used. Study endpoints were defined according to the Valve Academic Research Consortium-I criteria at 30 days and 1 year. Primary endpoints of this study were 30-day all-cause mortality and mortality during follow-up.

Results. A total of 882 patients underwent TAVI, of whom 793 (89.9%) underwent TF-AVI and 89 (10.1%) underwent TA-AVI. Patients undergoing TA-AVI had a higher estimated risk of mortality as defined by the logistic European System for Cardiac Operative Risk Evaluation score (median 27.0, interquartile range [IQR]: 20.2 to 33.8 versus median 20.0, IQR: 12.3 to 27.7; $p < 0.001$) and The Society of Thoracic Surgeons Score (median 10.2, IQR: 5.3 to 9.9 versus median 6.7, IQR: 3.5 to 9.9; $p < 0.001$) and had more comorbidities. At 30 days, there was an increased risk of all-cause mortality in the TA-AVI group (odds ratio [OR] 3.12, 95% confidence interval [CI]: 1.43 to 6.82; $p = 0.004$). TF-AVI was associated with a higher frequency of major (OR 0.33, 95% CI: 0.12 to 0.90; $p = 0.031$) and minor vascular complications (OR 0.17, 95% CI: 0.04 to 0.71; $p = 0.0015$). In-hospital stay was significantly longer among patients undergoing TA-AVI (OR 2.29, 95% CI: 1.28 to 4.09; $p = 0.05$). During a median follow-up of 365 days (IQR: 174 to 557), TA-AVI was associated with an increased risk of all-cause mortality (hazard ratio 1.88, 95% CI: 1.23 to 2.87; $p = 0.004$).

Conclusions. In institutions performing a low volume of TA-AVI, the technique is associated with an increased risk of all-cause mortality and longer hospital stay but less vascular complications in comparison with TF-AVI. The interaction between experience and type of treatment on outcome requires further investigation before advocating one treatment over the other.

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Transcatheter aortic valve implantation (TAVI) has emerged as a viable alternative to surgical aortic valve replacement (SAVR) for patients with symptomatic aortic stenosis at high operative risk [1–4]. In case of suitable peripheral arterial anatomy, transfemoral aortic valve implantation (TF-AVI) is generally considered the access site of choice. However, bleeding and vascular complications frequently occur and are associated with increased risk of perioperative morbidity and long-term mortality [5–7]. Transapical aortic valve implantation (TA-AVI) entails catheter-based access closer to the valve landing zone with potentially superior control of valve positioning, potential reduction of stroke due to absence of retrograde crossing of the aortic valve, in addition to lesser access site complications [8]. However, TA-AVI is considered a more invasive and complex procedure when compared with TF-AVI, which can be performed completely percutaneous under general or local anesthesia [9]. Furthermore, recovery of patients undergoing TA-AVI tends to be longer [10].

Little information is available on the direct comparison of TF-AVI and TA-AVI. Therefore, the aim of this study was to compare the short-term and midterm outcomes of

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Abbreviations and Acronyms

CI = confidence interval
ESV = Edwards SAPIEN valve
IQR = interquartile range
MCS = Medtronic CoreValve system
OR = odds ratio
STS = The Society of Thoracic Surgeons
TA-AVI = transapical aortic valve implantation
TAVI = transcatheter aortic valve implantation
TF-AVI = transfemoral aortic valve implantation
VARC = Valve Academic Research Consortium

TA-AVI versus TF-AVI in a population from the Pooled Rotterdam-Milano-Toulouse in Collaboration (PRAGMATIC) registry [11].

Patients and Methods

Patients

The PRAGMATIC initiative is a collaboration of four European institutions with established TAVI experience. The baseline patient characteristics, procedural details, and clinical outcome data from a series of 944 consecutive patients who underwent TAVI were collected since the introduction of the respective local TAVI program until July 2011: (1) San Raffaele Scientific Institute, Milan (n = 330); (2) Clinique Pasteur, Toulouse (n = 224); (3) Thoraxcenter, Erasmus Medical Center, Rotterdam (n = 206); and (4) Hôpital Rangueil, Toulouse (n = 184). After the Valve Academic Research Consortium (VARC)-I consensus document was made public, the proposed endpoint definitions were adopted and the respective local databases were modified accordingly [12]. All data were then pooled into a dedicated global multicenter database. Patient eligibility for TAVI at each center was described previously [13–15]. This study was approved by the Institutional Review Board/Ethics Committee of each hospital. All patients provided written informed consent for the procedure and data collection according to the policy of each hospital.

Imaging, Access Strategy, and Device Choice

In all patients, multimodality imaging (transthoracic or transesophageal echocardiography or both, and angiography or multislice computed tomography or both) was performed to assess anatomic suitability for TAVI and determine the optimal access strategy. The transfemoral approach was the access route of first choice in all participating centers. When transfemoral access was deemed inappropriate, a transapical, a transaxillary/subclavian, or a transaortic approach was considered. Final access strategy was decided upon by the treating physician or heart team decision. Both TAVI technologies with CE mark approval were used dependent on the access used. For the TF approach, the Edwards SAPIEN THV (ESV [Edwards Lifesciences, Irvine, CA]) and Medtronic CoreValve System (MCS [Medtronic, Minneapolis, MN]) were used. With respect to the ESV, the Retroflex delivery catheter and a 22F or 24F sheath size was used until mid 2010, and was then replaced by the SAPIEN XT THV (SXT) and uses the Novaflex (Edwards Lifesciences) delivery catheter, which goes through an 18F or 19F sheath. With respect to the MCS, a 21F sheath was used until 2006 and was then replaced by an 18F compatible system. In the TA-AVI group, the Ascendra I and II (Edwards Lifesciences) were used to deliver the ESV and the SXT since mid 2010.

Study Endpoints and Definitions

The primary endpoints of this study were 30-day all-cause mortality and mortality during follow-up. All endpoints were defined using the VARC-I recommendations [12]. After hospital discharge, mortality data were collected by contacting the civil registries, referring physician or general practitioner. Follow-up data was completed in 99.7% of the patients who survived the first 30 days.

Statistical Analysis

Categorical variables are presented as frequencies and percentages and, compared with the use of the Pearson χ^2 or Fisher's exact test, as appropriate. Continuous variables are presented as means (±SD) in case of a normal distribution, or medians (interquartile range [IQR]) in case of a skewed distribution, and compared with the use of Student's *t* test or the Mann-Whitney *U* test. Normality of the distributions was assessed using the Shapiro-Wilks test.

Univariable and multivariable logistic regression was used to assess the effect of access approach on short- and long-term outcome. Cox proportional hazard regression analysis was performed to determine the relation between transapical access and mortality during follow-up. Multivariable analysis was adjusted for all differences in baseline characteristics. Results of these analyses are reported as odds ratios (OR) and hazard ratios with 95% confidence intervals (CI), as appropriate. Survival curves for time-to-event variables were constructed on the basis of all available follow-up data with the use of Kaplan-Meier estimates and were compared with the log rank test. A two-sided alpha level of 0.05 was used for all superiority testing. All statistical analyses were performed using SPSS version 20.0 (SPSS Inc, Chicago, IL).

Results

During the study period, 944 patients underwent TAVI, of which 793 were transfemoral (84.0%), 89 transapical (9.4%), 58 subclavian (6.1%), and 4 direct transaortic valve implantation. The baseline characteristics of the 882 patients undergoing either TF-AVI or TA-AVI are depicted in Table 1. Patients undergoing TA-AVI had a higher prevalence of a history of coronary artery bypass graft, coronary artery disease, hypertension, and a glomerular filtration rate less than 60 mL/min (79.3% vs 61.2%, $p = 0.001$). As expected, the frequency of peripheral vascular disease was higher in the TA-AVI population (67.4% versus 17.7%, $p < 0.001$). This was reflected in a significantly higher logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) and The