Transapical aortic valve implantation in patients with poor left ventricular function and cardiogenic shock

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Objectives: In line with our institutional no exclusion policy we accept patients with very poor left ventricular performance and cardiogenic shock for transcatheter aortic valve implantation (TAVI). The purpose of our study was to analyze outcome in these patients and to identify what happens to the left ventricular function after TAVI in patients with failing ventricles.

Methods: Between April 2008 and August 2013, 730 patients underwent transapical TAVI at our institution. The study group consisted of all 104 patients who presented with severely depressed left ventricular function, defined as left ventricular ejection fraction (LVEF) $\leq 30\%$. Based on the Society of Thoracic Surgeons predicted risk of mortality, the arithmetic risk for surgery in the study cohort was $23\% \pm 19\%$ (2%-90%), and 23 patients (22%) were in cardiogenic shock.

Results: Excluding patients in cardiogenic shock, the survival rates in the study group at 1, 2, and 4 years were $81\% \pm 5\%$, $65\% \pm 6\%$, and $45\% \pm 8\%$, respectively. Patients in cardiogenic shock showed significantly worse outcome ($P = .048$). Improvement in LVEF of 50% or more was found in 74 patients (71%) and 100% or more improvement in 45 patients (43%). Early improvement in LVEF was significantly ($P = .049$) greater in patients with preoperative values of LVEF $\leq 20\%$.

Conclusions: In the majority of patients with failing ventricles, left ventricular function is quickly restored after TAVI and elimination of aortic stenosis. Without the additional trauma of cardioplegic arrest, TAVI is the potentially superior treatment option in patients with poor and very poor left ventricular performance. (J Thorac Cardiovasc Surg 2014;148:2877-82)

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According to recently reported registry data,[1,2] 7% to 9% of patients referred for transcatheter aortic valve implantation (TAVI) present with left ventricular ejection fraction (LVEF) below 30%. In view of the higher operative mortality rate[3] and the grave prognosis if the aortic valve pathology is left untreated,[4] TAVI has already been performed as an alternative treatment in these patients but it is still the subject of controversial discussion or has even been considered by recent guidelines to be contraindicated.[5]

In line with our institutional no exclusion policy[6] we accept patients with very poor left ventricular performance[7] and cardiogenic shock[8] for TAVI. The purpose of our study was to analyze outcomes in these patients and to identify what happens to the left ventricular function after TAVI in patients with failing ventricles. This study represents an update of our preliminary report in this field.[7]

PATIENTS AND METHODS

Patients and Study Design

This was a retrospective, observational, single-center, cohort study of prospectively and retrospectively collected data. The institutional review board at our institution approved the study and all patients or their representatives gave informed consent.

Between April 16, 2008, and August 1, 2013, 730 consecutive patients underwent a planned transapical TAVI procedure at our institution with a balloon-expandable prosthesis (Sapien THV or XT type; Edwards Lifesciences, LLC, Irvine, Calif). The whole institutional process of patient selection, the inclusion and exclusion criteria, the diagnostic workup, and the selection of the access site have been described in detail in previous publications.[6,9] All patients were evaluated by the institutional TAVI team and accepted for the procedure according to the team consensus. Patients with an extreme risk profile or cardiogenic shock were not excluded. The only exclusion criteria for TAVI were signs of active aortic valve endocarditis or too large an annulus. All patients completed at least the 30-day follow-up period.

Study Cohort

The study cohort included all 104 consecutive patients of this institutional cohort (14.2%) who presented with LVEF between 10% and 30%. The preoperative characteristics of the study cohort are given in Table 1.

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Abbreviations and Acronyms

BAV = balloon aortic valvuloplasty
CPB = cardiopulmonary bypass
LVEDD = left ventricular end diastolic diameter
LVEF = left ventricular ejection fraction
TAVI = transcatheter aortic valve implantation

Cardiogenic Shock

As we explained in a previous report,[8] cardiogenic shock was diagnosed only if all the following criteria were present: unstable hemodynamic condition and requirement of increasing doses of adrenaline and upcoming or evident multiorgan failure, including oligoanuria and pulmonary congestion at chest radiography. Based on this definition, cardiogenic shock was diagnosed in 23 patients of the study cohort (22.1%). In patients with cardiogenic shock, the median Society of Thoracic Surgeons predicted risk of mortality was 38.7% (interquartile range [IQR], 22.2%-62.1%; range, 8.1%-89.5%). Stages III to V of renal failure (ie, glomerular filtration rate 0-59 mL/min) were present in 18 patients with cardiogenic shock (78.3%). Seven patients with shock (30.4%) needed respirator support preoperatively. An intra-aortic balloon pump was preoperatively present or its intraoperative implantation was electively planned in 8 patients (34.8%). The median N-terminal probrain natriuretic peptide level was 1.7 10^4 pg/mL (IQR, 11,345-28,416 pg/mL; range, 1323-77,019 pg/mL).

Implantation Procedure and Elective Use of Cardiopulmonary Bypass (CPB)

All TAVI procedures were performed in our hybrid operating room by a consistent heart team using a principal surgical technique[10] with some modifications.[11] A monoplane angiographic system (Artis zee, Siemens AG, Munich, Germany) was used. The whole procedure was guided by transesophageal echocardiography.

In accordance with our institutional policy, the elective use of CPB was considered in patients with cardiogenic shock, very poor left ventricular function (LVEF < 20%), enlarged right ventricles related to severe pulmonary hypertension, and in patients with planned combined surgical intervention.[6] For cannulation, the femoral vessels were exposed surgically.[12] The final decision about the use of CPB was made in the operating room after review of all aspects of preoperative diagnostics by the members of the implanting team and after meticulous evaluation of heart function by means of intraoperative transesophageal echocardiography. Our institutional strategy has been described in detail elsewhere.[6-9,12]

Selection of the Prosthesis Size and Treatment of Intraprocedural Regurgitation

The recommendations of the valve manufacturer were in general applied: a 23-mm prosthesis was used for aortic annulus diameter—as assessed by transesophageal echocardiography—of between 18 and 22 mm, a 26-mm prosthesis for annulus diameter of between 21 and 25 mm, and a 29-mm prosthesis (after introduction of the Sapien XT type) for annulus diameter of between 24 and 27 mm. In borderline cases, multislice computed tomography measurements in multiple planes influenced valve size selection. Intraprocedural regurgitation was precisely graded according to the guidelines and treated according to our institutional policies.[6] In the presence of relevant regurgitation, additional curative measures (such as redilation or implantation of a second prosthesis) were taken.

Evaluation of Left Ventricular Function

Left ventricular function was assessed preoperatively by means of transthoracic echocardiography or transesophageal echocardiography. Left ventricular end diastolic diameter (LVEDD) and LVEF were measured and prospectively stored in the institutional TAVI database. Postoperatively, transthoracic echocardiography measurements were performed-—usually within the first postoperative week—on a routine basis. Postoperative values of LVEF and LVEDD were collected retrospectively. Differences to preoperative values in absolute numbers and as a percentage of preoperative values were calculated.

Follow-up

The follow-up regarding death or survival was 100%. Official information regarding death was also obtained from the state administrative office. For all patients domiciled in Germany, information was obtained from the German Register of Residents. All patients from foreign countries were contacted via telephone, E-mail, or letter. The date of the last contact was recognized. This study is reported according to the updated standardized end point definitions of the Valve Academic Research Consortium-2.[13]

Statistical Analysis

Continuous variables are presented as mean ± standard deviation or medians, IQR, and minimum-maximum range. Categorical variables are described as numbers and percentages. Several parameters of left ventricular function are presented as box-whisker plots. Differences in LVEF and LVEDD before and after the procedure were analyzed using the Wilcoxon signed-rank test. Differences between patients with very poor LVEF (10%-20%) and patients with poor LVEF (21%-30%) were analyzed using the Mann-Whitney *U* test, Fisher exact test, or the McNemar test. The Kaplan-Meier survival functions were calculated. A log-rank test was performed to analyze differences between subgroups. A Cox proportional hazards model was used to investigate possible risk factors for mortality. A univariable approach for all possible risk factors was evaluated. Proportional hazard assumptions were checked. For several parameters, multivariable Cox proportional hazards models with all combinations were performed. The best model was chosen according to Akaike's information criterion. The data were evaluated using IBM SPSS Statistics software, version 19 (IBM SPSS Inc, Armonk, NY) and R 2.15 statistics software (R Foundation for Statistical Computing, Vienna, Austria).

RESULTS

Intraprocedural Course in Study Cohort

A balloon-expandable prosthesis was implanted in all patients; 46 patients (44.2%) received the Sapien XT type prosthesis and 58 patients (55.8%) received the THV type prosthesis. A 23-mm prosthesis was implanted in 18 patients (17.3%), a 26-mm prosthesis was implanted in 55 patients (52.9%), and a 29-mm prosthesis was implanted in 31 patients (29.8%). To reduce or eliminate relevant intraprocedural regurgitation, redilation was performed in 5 patients (4.8%) and a second TAVI prosthesis was implanted in 3 patients (2.9%). There was no severe postprocedural regurgitation and in no case was there the need to convert to conventional surgery because of untreatable regurgitation.

Valve deployment was performed with elective use of CPB in 30 patients (28.8%). The median radiation time was 6.0 minutes (IQR, 4.5-9.7 minutes; range, 2.1-65.3 minutes). Simultaneous elective percutaneous coronary artery stenting was performed in 14 patients (13.5%) with