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

TABLE 1. Preoperative characteristics of study cohort (N = 104)

Characteristic	Median/n	Interquartile range/ ratio (%)	Minimum-maximum
Male/female	63/41	60.6/39.4	—
Age (y)	79	73-84	29-93
Height (cm)	170	164-175	145-187
weight (kg)	74	64-85	42-119
Body mass index	25	23-28	19-43
Body surface area (m^2)	1.87	1.71-2.01	1.32-2.38
Additive EuroSCORE	15	13-18	5-25
Logistic EuroSCORE (%)	60	39-80	4-97
EuroSCORE II (%)	33	18-52	2-95
STS PROM score (%)	17	10-26	2-90
STS MoM score (%)	54	39-69	19-97
NYHA class IV	68	65.4	—
Cardiogenic shock	23	22.1	—
NT-proBNP (pg/mL)	10,758	4268-17,941	1064-93,605
Troponin I (μg/mL)	0.06	0.02-0.10	0.00-83.00
FEV1 (L)	1.6	1.2-2.3	0.6-3.3
IVC (L)	1.9	1.5-2.5	0.7-3.6
Diabetes mellitus	34	32.7	—
PAD	72	69.2	—
s/p stroke, neurologic disease	29	27.9	—
Creatinine clearance (mL/min)	51	33-62	0-175
Dialysis	6	5.8	—
Systolic PAP > 50 mm Hg	66	63.5	—
Atrial fibrillation	38	36.5	—
Coronary artery disease	68	65.4	—
s/p PCI	25	24.0	—
s/p CABG	27	26.0	—
s/p AVR	7	6.7	—
s/p MVR	2	1.9	—
Pacemaker/ICD	21	20.2	—
LVEF (%)	25	20-30	10-30
LVEF $\leq$ 20%	42	40.4	—
LVEDD (mm)	57	51-63	38-80
MR moderate/severe	36	34.6	—
TR moderate/severe	19	18.3	—
Aortic calcification moderate/severe	36	41.3	—

EuroSCORE, European System for Cardiac Operative Risk Evaluation; *STS PROM*, Society of Thoracic Surgeons predicted risk of mortality; *STS MoM*, Society of Thoracic Surgeons predicted risk of morbidity or mortality; *NYHA*, New York Heart Association; *NT-proBNP*, N-terminal probrain natriuretic peptide; *FEV1*, forced expiratory volume in 1 second in liters (L); *IVC*, inspiratory vital capacity in liters (L); *PAD*, peripheral arterial disease; *s/p*, status post; *PCI*, percutaneous coronary intervention; *CABG*, coronary artery bypass grafting; *AVR*, aortic valve replacement; *MVR*, mitral valve repair/replacement; *ICD*, implantable cardioverter defibrillator; *LVEF*, left ventricular ejection fraction; *LVEDD*, left ventricular end-diastolic diameter; *MR*, mitral regurgitation; *TR*, tricuspid regurgitation; *PAP*, pulmonary artery pressure.

concomitant coronary artery disease. Excluding patients with simultaneous coronary artery stenting, the median amount of contrast agent was 86 mL (IQR, 70-115 mL; range, 40-260 mL). Including patients with combined planned surgical interventions, the median procedural time was 105 minutes (IQR, 85-145 minutes; range, 30-415 minutes).

Echocardiographic Parameters and Myocardial Recovery

Median LVEF increased significantly ($P < .001$) from 25% (IQR, 20%-30%; range, 10%-30%) to 40% (IQR, 30%-50%; range, 20%-65%). In relation to the preoperative value, a 50% increase or more in LVEF was observed in 74 patients (71.2%) and a 100% increase or more in 45 patients (43.3%) (Figure 1). Median LVEDD decreased significantly ($P < .001$) from 57 mm (IQR, 51-63 mm; range, 38-80 mm) to 54 mm (IQR, 51-60 mm; range, 35-73 mm). There was significantly ($P = .049$) more increase in LVEF in patients with very poor LVEF (Figures E1 and E2). Median effective orifice area increased significantly ($P < .001$) after valve deployment from 0.6 cm^2 (IQR, 0.6-0.8 cm^2; range, 0.5-1.8 cm^2) to 2.3 cm^2 (IQR, 1.8-2.6 cm^2; range, 0.8-3.7 cm^2).

Thirty-Day Outcome in Study Cohort

The overall 30-day mortality rate in patients with LVEF of 10%-30% was 5.8%; 6 patients died during the first 30 days after the TAVI procedure. Excluding the 23 patients in cardiogenic shock, the 30-day mortality rate was 3.7%; 3 of 81 patients died during the first 30 days. Aspects related to 30-day outcome and complication rates according to the Valve Academic Research Consortium-2 criteria[13] are summarized in Table 2.

Survival in Study Cohort

The overall survival rates at 1, 2, and 4 years were 72.9% $\pm$ 4.6%, 60.5% $\pm$ 5.4%, and 41.8% $\pm$ 6.8%, respectively. Excluding the 23 patients in cardiogenic shock, the survival rates at 1, 2, and 4 years were 81.0% $\pm$ 4.6%, 65.1% $\pm$ 6.1%, and 45.0% $\pm$ 7.8%, respectively. Patients without cardiogenic shock showed better ($P = .047$) survival than patients in cardiogenic shock. The preoperative status of very poor LVEF (10%-20%) failed to be predictive for follow-up mortality (hazard ratio, 1.02; 95% confidence interval, 0.55-1.87; $P = .959$). The Kaplan-Meier survival functions are shown in Figure 2. Significant predictors of follow-up mortality in univariable and multivariable analysis are given in Table 3.

DISCUSSION

Outcome After TAVI in Patients With Poor Left Ventricular Performance

Despite the fact of very low early mortality, we observed an overall 1-year survival rate of 73% in our study cohort of 104 patients with an LVEF 10% to 30%. The observed mortality during the first year was mainly governed by cardiogenic shock, with the better 1-year survival rate of 81% in nonshock patients. Control group patients with an

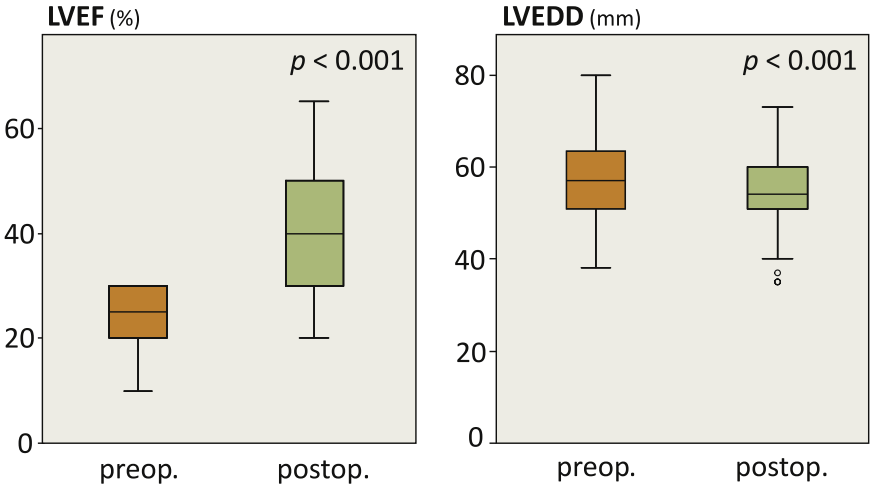

FIGURE 1. Left ventricular ejection fraction (*LVEF*) and left ventricular end diastolic diameter (*LVEDD*) preoperatively and before discharge from hospital as assessed by echocardiography. *preop*, Preoperatively; *postop*, postoperatively.

LVEF > 30% showed better survival but not until after about 1.5 years. Based on the known desperate prognosis if only medical management is offered, with <50% 1-year survival in patients with LVEF ≤ 40%,[4] a clear benefit of a TAVI strategy in nonsurgically managed patients becomes evident. Furthermore and despite a tremendously higher risk profile in our study cohort, we observed better outcome than in cohorts with LVEF ≤ 40% treated with surgical valve replacement, which had 1-year survival of about 60% to 70%.[3,14] On that account and further based on our no exclusion policy, TAVI became our primary choice of treatment in these patients soon after its introduction at our institution.[6,7]

TABLE 2. Procedural, periprocedural, and 30-day outcome in the study cohort (N = 104), according to Valve Academic Research Consortium criteria[13]

Outcome	N	Ratio (%)
Conversion to surgical AVR	0	0.0
Unplanned use of CPB	1	1.0
TAV-in-TAV deployment	3	2.9
Moderate PPM	6	5.8
Severe PPM	2	1.9
TAV moderate regurgitation	1	1.0
TAV severe regurgitation	0	0.0
Periprocedural/spontaneous MI	0	0.0
Disabling stroke	0	0.0
Nondisabling stroke	2	1.9
Life-threatening/disabling bleeding	5	4.8
Major bleeding	9	8.7
AKI stage I	13	12.5
AKI stage II/III	7	6.7
Renal replacement therapy	6	5.8
Major access-related complications	4	3.8
Minor access-related complications	3	2.9
New pacemaker implantation	6	5.8
Device success criterion (success; 30-d)	96	92.3
Early safety criterion (failure; 30-d)	16	15.4
All-cause mortality (30-d)	6	5.8
All-cause mortality (excluding shock; 30-d)	3	3.7

AVR, Aortic valve replacement; *CPB*, cardiopulmonary bypass; *TAV*, transcatheter aortic valve; *PPM*, prosthesis-patient mismatch; *MI*, myocardial infarction; *AKI*, acute kidney injury.

In recent studies, the important prognostic value of a low flow state (defined as stroke volume index ≤35 mL/m^2) rather than LVEF alone has been shown.[15-17] Although our study design did not consider stroke volume index, significant similarities in several patients' characteristics exist: mean LVEF 23% ± 6%, indexed effective orifice area ≤0.6 cm^2/m^2 in 99 patients (95.2%), and low gradient with mean gradient ≤40 mm Hg in 65 patients (62.5%) and mean gradient ≤20 mm Hg in 20 patients (19.2%) of our study cohort. O'Sullivan and colleagues[15] observed in 61 patients with low gradient aortic stenosis and LVEF ≤ 40% a 1-year mortality rate of 24.5%. The pioneering Canadian group described a 1-year mortality of about 35% in 90 patients with low-flow-low gradient aortic stenosis and LVEF < 50%.[16] Among 225 patients from the Placement of Aortic Transcatheter Valves trial with low flow aortic stenosis and LVEF < 50% (excluding patients with LVEF < 20%), a 2-year mortality rate of 48.7% was found.[17] Because of the prognostic value, we fully agree with all these groups that a measure of stroke volume index should be included in the evaluation of TAVI candidates. Despite higher mortality rates in low-flow patients, one may summarize these studies and conclude that especially critical patients profit most from a comprehensive therapeutic strategy. Otherwise, if they are left untreated, their prognosis is grave.

Our study cohort contained a high proportion of patients with acute decompensation, catecholamine dependence, and cardiogenic shock. Therefore, we observed a higher

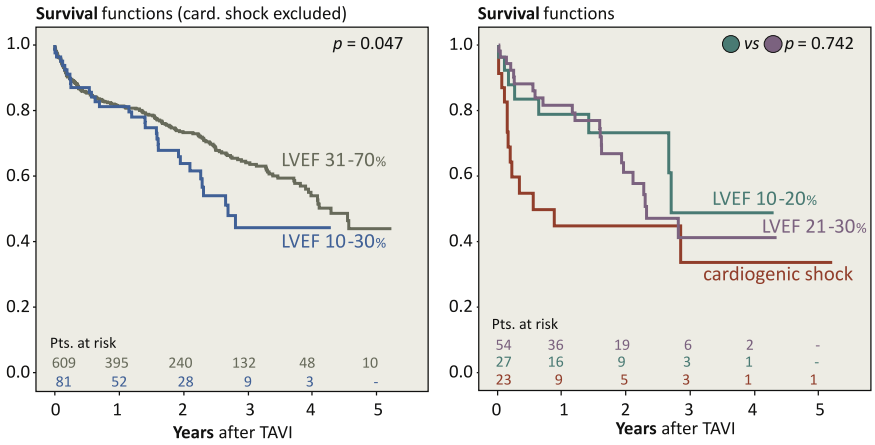

FIGURE 2. Kaplan-Meier survival functions in patients with different preoperative left ventricular ejection fraction (*LVEF*). *TAVI*, Transcatheter aortic valve implantation.

arithmetic risk profile, more patients in New York Heart Association functional class IV, and significantly more patients with severe pulmonary hypertension. Decompensation in aortic stenosis is a potentially fast, ongoing process. Therefore, almost all our patients were treated with an urgent indication and often with an emergency indication.

Cardiogenic Shock

Treatment of patients with severe aortic stenosis and cardiogenic shock remains a medical and surgical challenge. As we have already stated, TAVI is a realistic lifesaving option for these patients who would otherwise die.[8] On the other hand, one may criticize the large amount of resources used and the fact that more than half of patients were lost within the first year. Our ethos is to concentrate on the >40% of patients who survive the first year with relatively good further prognosis. Saving these patients' lives can succeed only if there is no fear of recruiting all efforts. Of course, a tailored strategy and a multidisciplinary approach are mandatory to achieve satisfactory results.[8]

TABLE 3. Predictors of follow-up mortality

	Hazard ratio	95% Confidence interval	*P* value
Univariable analysis			
Additive EuroSCORE	1.12	1.03-1.22	.010
Logistic EuroSCORE	1.02	1.00-1.03	.021
EuroSCORE II	1.02	1.01-1.03	.003
STS PROM score	1.03	1.01-1.04	.001
Cardiogenic shock	1.91	1.99-3.67	.052
s/p CABG	1.86	0.98-3.55	.060
Absence of AKI	0.52	0.27-1.02	.056
Multivariable analysis			
s/p CABG	2.11	1.09-4.09	.027
Cardiogenic shock	2.17	1.11-4.22	.023

EuroSCORE, European System for Cardiac Operative Risk Evaluation; *STS PROM*, Society of Thoracic Surgeons predicted risk of mortality; *s/p*, status post; *CABG*, coronary artery bypass graft; *AKI*, acute kidney injury.

Role of CPB

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] Under these critical circumstances, we consider the elective application of CPB a useful tool to prevent resuscitation because of ventricular fibrillation and to allow myocardial recovery.[12] Among patients with elective use of CPB, we did not observe a negative effect on procedural or postprocedural variables. Furthermore, the emergency use of CPB with known worse outcome was rare (1%) in our study cohort of patients with LVEF between 10% and 30%.

Instant Myocardial Recovery Following TAVI

We observed an effect of instant myocardial recovery in the majority of our patients, with a more pronounced increase in LVEF in patients with very poor left ventricular performance. Clavel and colleagues[18] described better myocardial recovery at discharge and at 1 year in the TAVI cohort with LVEF ≤ 50% compared with patients treated with surgical valve replacement. Their study found female gender, absence of atrial fibrillation, baseline LVEF, TAVI therapy, increase in aortic valve area, and absence of need for coronary revascularization to be independent predictors of LVEF recovery, whereas myocardial contractile reserve failed to be predictive for recovery. We fully agree with the philosophy behind their concept: Avoiding the additional trauma of cardioplegic arrest is beneficial for myocardial recovery in patients with significantly impaired LVEF.

Clinical Implications

Based on our no exclusion policy, we do not refuse TAVI to patients with high comorbidity status or profound shock.[6] Soon after the introduction of TAVI at our institution, it became our primary choice of treatment in patients with poor or very poor left ventricular performance.[7] Unlike solely palliative balloon aortic valvuloplasty (BAV), TAVI eliminates aortic valve stenosis completely (instead of only partially) and without significant additional trauma. We consider complete elimination of stenosis (without residual regurgitation) a prerequisite to allow early myocardial recovery followed by restoration of dependent organ function. Because BAV also requires rapid pacing, we are convinced that the trauma to critical patients is not significantly reduced by using solely palliative BAV. In addition, BAV only reduces aortic valve stenosis instead of completely eliminating it. Furthermore, it carries the risk of relevant aortic valve insufficiency remaining after BAV. Both factors could complicate myocardial recovery. Since the introduction of TAVI at our institution, we have never favored BAV instead of TAVI. Contrary to surgical valve replacement under these circumstances, TAVI allows elimination of aortic valve stenosis without aortic crossclamping and cardioplegic arrest—a more gentle concept for a stressed myocardium and for patients with a relatively high operative mortality.

Study Limitations

Our study has 3 major limitations: it is based only on transapical TAVI and is further limited to 1 type of balloon-expandable prostheses. On the other hand, a major benefit of our study design is the consistent dataset and the large number of patients treated with 1 identical strategy by a permanent team. Out of clinical concerns in critical patients, we waived any preoperative evaluation of myocardial contractile reserve. Also, our analysis of postoperative myocardial recovery solely focused on the early postoperative period and did not consider long-term changes of parameters of left ventricular performance.

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.

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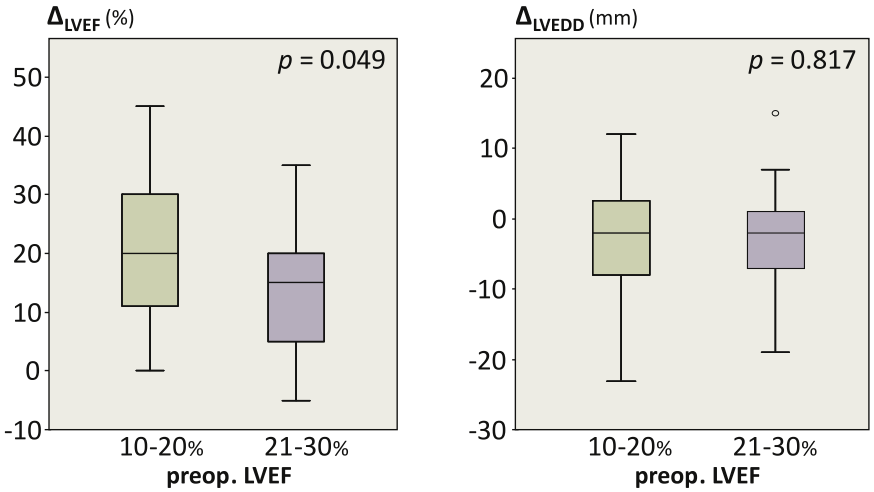

FIGURE E1. Postoperative changes in left ventricular ejection fraction (Δ_{LVEF}) and left ventricular end diastolic diameter (Δ_{LVEDD}) in patients with poor and very poor preoperative (*preop*) left ventricular performance.

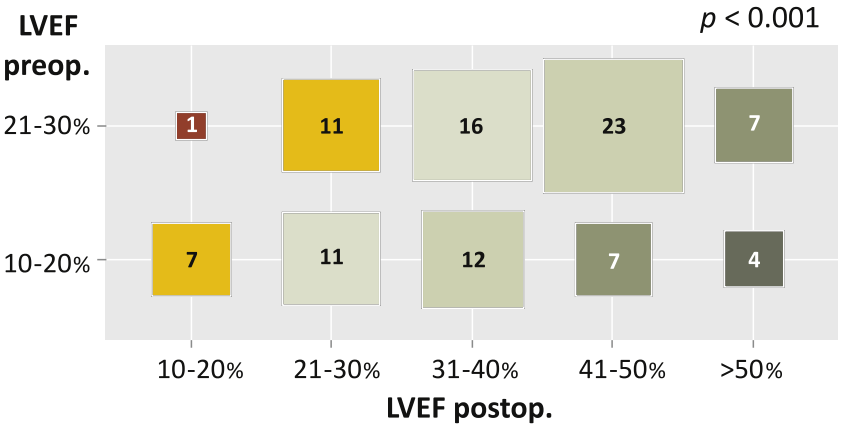

FIGURE E2. Fluctuation plot of postoperative changes in left ventricular ejection fraction (*LVEF*) in patients with poor and very poor preoperative left ventricular performance. Absolute numbers of patients are given (difference to study cohort numbers caused by in-hospital mortality). *preop*, Preoperatively; *postop*, postoperatively.