Journal of the American College of Cardiology
© 2010 by the American College of Cardiology Foundation
Published by Elsevier Inc.

Vol. 56, No. 10, 2010
ISSN 0735-1097/$36.00
doi:10.1016/j.jacc.2010.02.065

CATHETER AORTIC VALVE IMPLANTATION

Transapical Aortic Valve Implantation in 175 Consecutive Patients

Excellent Outcome in Very High-Risk Patients

Miralem Pasic, MD, PHD, Axel Unbehaun, MD, Stephan Dreysse, MD, Thorsten Drews, MD, Semih Buz, MD, Marian Kukucka, MD, Alexander Mladenow, MD, Tom Gromann, MD, Roland Hetzer, MD, PHD

Berlin, Germany

Objectives The aim of this study was to evaluate the outcome of transapical aortic valve implantation in a single center with expanded procedural experience and to compare it with predicted risk for conventional aortic valve surgery.

Background Transapical aortic valve implantation is a new approach for high-risk patients with severe aortic stenosis. There are only limited single-center experiences with very small numbers of patients.

Methods Since April 2008, transapical aortic valve implantation was performed in 175 consecutive patients. The mean patient age was 79.8 ± 9 years, with a range of 36 to 97 years. The mean Society of Thoracic Surgeons score was 23.5 ± 19.4% (range 2.7% to 89.5%); 98.3% of patients were in New York Heart Association functional class III or IV. Ten patients were in cardiogenic shock.

Results Technical success of the procedure was 100%. There was no conversion to conventional surgery. Cardiopulmonary bypass was used in 8 patients (6 elective, 2 emergency). The 30-day mortality was 5.1% for the entire group, 3.6% for all patients without cardiogenic shock, and 30% for the patients with cardiogenic shock. Survival at 1, 6, and 12 months was 94.9%, 85.5%, and 82.6%, respectively.

Conclusions The outcome of transapical aortic valve implantation was very favorable and already reproducible during the learning curve. The method has become de facto our institutional primary choice for treatment of high-risk patients with severe aortic valve stenosis. (J Am Coll Cardiol 2010;56:813–20) © 2010 by the American College of Cardiology Foundation

Transapical aortic valve implantation is a new therapeutic approach in high-risk patients with severe aortic valve stenosis (1–8). It is necessary for this new procedure to match the results of the established method, and then to exceed them. It should be proved as a safe and reliable procedure to be applied in all high-risk patients. Therefore, the institutional learning curve for the new treatment is a very sensitive phase. However, transapical aortic valve implantation departs from standard surgical policies and requires new ways of thinking. The team approach with cooperation between surgeons, cardiologists, and anesthesiologists means that responsibilities in the team must be defined very precisely and must be well coordinated. It also needs a special hybrid operating room that combines a catheter laboratory with the preconditions necessary to perform surgery and sterile valve preparation before implantation, anesthesiologic equipment, appropriate lighting, and the heart-lung machine. Until optimal organization is achieved, the results of the new procedure during the learning curve may be affected negatively by procedural questions. We report our initial experience with the first 175 patients during the learning curve for establishing this new method.

From the Deutsches Herzzentrum Berlin, Berlin, Germany. Prof. Pasic and Drs. Unbehaun, Dreysse, Drews, and Buz have been proctors to Edwards Lifesciences since July 2009. All other authors report that they have no relationships to disclose.

Manuscript received January 4, 2010; revised manuscript received February 11, 2010, accepted February 15, 2010.

Methods

Patients. Between April 27, 2008, and October 16, 2009, transapical aortic valve implantation was performed in 175 consecutive high-risk patients with aortic valve stenosis. Patients were considered for the procedure if the Society of Thoracic Surgeons (STS) score was 10% or higher. The only exclusion criteria were active valve endocarditis or an aortic annulus diameter of more than 24 mm. Severe comorbidity was not considered a contraindication. The study was approved by our institutional review committee. Written informed consent was obtained from all patients or

Abbreviations and Acronyms

CABG = coronary artery bypass grafting
CT = computed tomography
LVEF = left ventricular ejection fraction
NYHA = New York Heart Association
TEE = transesophageal echocardiography

their representatives. The mean follow-up was 6 months, with a range from 1 to 18 months.

Patient baseline characteristics. The mean age of patients was 79.8 ± 9 years (range 36 to 97 years). The baseline demographic factors, risk factors, hemodynamic measurements, and laboratory values of the patients are shown in Table 1. There were 120 women and 55 men. The mean STS score for the entire group was 23.5 ± 19.4% (range 2.7% to 89.5%). Ten patients had an STS score of <10% but were considered high-risk candidates for conventional surgery and also were treated by transapical aortic valve implantation. The main pathologic features giving rise to this decision were severe to complete circular calcification of the ascending aorta (so-called porcelain aorta) in 4 patients, severe pulmonary hypertension in 2 patients, long-term immunosuppressive therapy in 2 patients, lever cirrhosis in 1 patient, and malignancy in 1 patient. Ten patients were in cardiogenic shock with a mean STS score of 67.1 ± 29.0% (range 14.7% to 89.5%). Twelve patients had degeneration of previously implanted biologic aortic valve prostheses. One hundred seventy-two patients (98.3%) were in New York Heart Association functional class III or IV.

Table 1 Pre-Operative Characteristics in 175 Patients

Characteristic	Value	Range	%
Age (yrs)	79.8 ± 9.0	36–97	—
Female	120	—	70
Body mass index (kg/m^2)	26.6 ± 4.7	17.1–45.0	—
STS score	23.5 ± 19.4	2.7–89.5	—
Logistic EuroSCORE (%)	38.3 ± 19.7	6.3–96.7	—
Mean aortic valve area (cm^2)	0.57 ± 0.22	0.22–1.16	—
Mean dP (mm Hg)	46.5 ± 13.9	11.8–97.5	—
Aortic annulus diameter (mm)	22.1 ± 1.3	19–24	—
NYHA functional class III or IV	172	—	98.3
Cardiogenic shock	10	—	5.7
Coronary artery disease	66	—	37.7
Mitral regurgitation grade 3 or 4	12	—	6.8
Tricuspid regurgitation grade 3 or 4	6	—	3.4
Pulmonary hypertension	66	—	37.7
Porcelain aorta	8	—	4.5
Mean LVEF (%)	52 ± 18	10–83	—
LVEF <35%	40	—	22.8
Previous CABG	18	—	10.2
Previous aortic valve replacement	12	—	6.9
Previous mitral valve surgery	4	—	2.3
Atrial fibrillation	65	—	37
Pre-operative IABP	2	—	1.1
Pacemaker	31	—	17.7
Creatinine (mg/dl)	1.3 ± 0.7	0.5–6.3	—
Cancer or other malignancy	10	—	5.7
Liver cirrhosis	4	—	2.3

CABG = coronary artery bypass grafting; dP = mean transvalvular gradient; IABP = intraaortic balloon pump; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

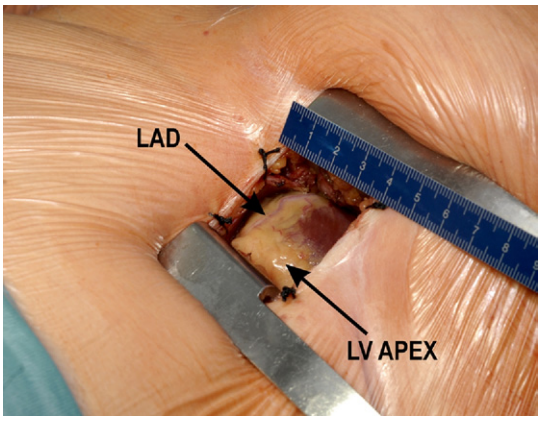

Figure 1 Approach

Excellent access to the apex of the heart through the left mini anterior thoracotomy. LAD = left anterior descending artery; LV = left ventricular.

Pre-operative examinations. The pre-operative examinations included clinical and blood examinations, electrocardiography, chest X-ray, coronary angiography, transthoracic echocardiography, cranial computed tomography (CT), CT of the chest and pelvis, and ultrasound examinations (Doppler) of the arteries and veins of the lower extremities and of the carotid arteries. Physical examination, neurologic clinical findings, transthoracic echocardiography, cranial and chest CT, and the battery of blood examinations were repeated during the first week after surgery.

Education of the team and team building. We educated a team consisting of 5 surgeons, 2 cardiologists, and 2 anesthesiologists with expertise in echocardiography dedicated to this program to be able to run it at our institution 24 h/day. The team was trained by theoretical procedural preparation, followed by training on a computer simulator and by dry runs to practice handling the equipment and to improve coordination between the members of the team. Part of the training consisted of visits to teaching centers in Leipzig, Germany, and Rouen, France, with procedural life-case demonstrations. The first 2 procedures at our institution were proctored by Prof. Thomas Walther from Leipzig, Germany.

Surgical technique. Aortic valve implantation was performed through a mini left anterior thoracotomy (Fig. 1) via the transapical route with a balloon-expandable transcatheter stent-prosthetic xenograft valve (Edwards SAPIEN THV, Edwards Lifesciences, Irvine, California) of 23 or 26 mm diameter. Implantations were performed in our hybrid operating room (Fig. 2) with a monoplane angiography system by our team of cardiac surgeons, a cardiologist, and anesthesiologists. A perfusionist and a heart-lung machine were present in the operating room. The procedure was

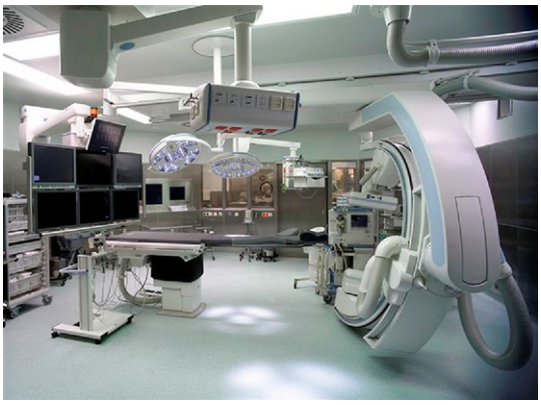

Figure 2 The Hybrid Operating Room

A special operating room that combines a catheter laboratory with the preconditions necessary to perform surgery and sterile valve preparation before implantation, anesthesiologic equipment, appropriate lighting, and the heart-lung machine.

divided into a series of sequences performed step by step. The principal surgical technique, as described in detail by Walther et al. (1), was used in the first 20 patients and later with several of our modifications. The most important modification of the technique was angiographic visualization of the aortic root while the prosthetic valve was being deployed slowly. It enabled easy correction of the position of the valve with perfect presentation of the relationships between the prosthetic valve, aortic valve annulus, aortic cusps, and the coronary arteries (Fig. 3). The procedure was monitored by fluoroscopy, angiography, and intraoperative transesophageal echocardiography (TEE). Our anesthesiologists with expertise in echocardiography performed continuous TEE during the procedure. Transcranial Doppler ultrasound monitoring for cerebral embolism also was performed.

Choice of valve size. The size of the valve used was determined according to the diameter of the native aortic valve annulus measured by intraoperative TEE. We chose a valve size of 23 mm for aortic valve annuli smaller than 21 mm and a 26-mm prosthesis for annulus diameter of 21 mm or more. Annulus diameter of 24 mm was the upper limit for the 26-mm valve. The orientation value for the lower limit for the 23-mm valve was a diameter of the native aortic annulus of 19 mm. In borderline cases, the decision was made on an individual basis, taking into account additional factors such as the distances from the annulus to the coronary artery ostia, the shape of the annulus (oval versus circular), the amount of material in the leaflets, aortic diameters at the level of the sinuses of Valsalva, the sinotubular junction and ascending aorta, and the amount of calcification in the left ventricular outflow tract, anterior mitral leaflet, and aortic valve leaflets themselves.

Institutional procedural polices. We have established institutional policies concerning the procedure that have evolved according to our own experience. These contain our guidelines on how to act in particular situations with regard to patient selection, procedural steps, and complications. The most important 7 principles are:

1. "No exclusion" policy: all patients with STS score of 10% or higher are evaluated as candidates for treatment regardless of comorbidities and clinical status, for example, profound shock (except patients with active endocarditis), if it is technically possible to perform the procedure in terms of the annular size.
2. Elective femoro-femoral cardiopulmonary bypass is considered in patients with severe cardiogenic shock, poor left ventricular function (left ventricular ejection fraction [LVEF] 10% to 20%), or both.
3. Intra-aortic balloon pump was applied prophylactically in very high-risk patients (only at the beginning of the study; later, the decision was based only on the patient's hemodynamic condition).
4. Concomitant mitral or tricuspid valve pathologic features are not treated simultaneously, but later on by surgery, if necessary.
5. Simultaneous elective coronary artery stent implantation is considered in patients with concomitant coronary artery disease. Only the most relevant coronary artery stenosis is treated (not applied in the first 25 patients but introduced later, after post-operative myocardial infarction occurred in 1 patient).
6. Intraoperative valve regurgitation (central, paravalvular, or both): aortic regurgitation after valve implantation of grade 1 to 2 should be treated by additional balloon dilation of the valve and, if necessary, by implantation of

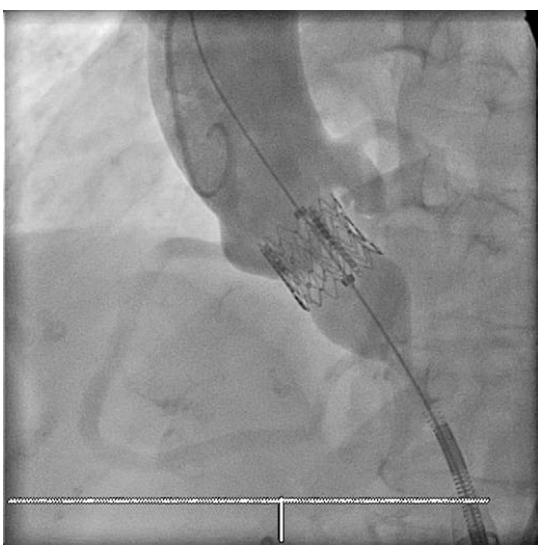

Figure 3 Valve Deployment

Our modification of the procedure performing intraoperative angiography during slow and gradual valve deployment. If the position is not ideal, it can be corrected easily by pushing or pulling the catheter with the mounted prosthetic valve.

a second valve. If it is not correctable, conventional surgical aortic valve replacement should be performed.

7. Special situations: Patients with STS score lower than 10% are not considered for transapical valve implantation, except for clear surgical reasons, for example, porcelain aorta. Patients with a very high STS score but with a contraindication for transcatheter procedure (e.g., patients with previous mitral valve replacement) may be evaluated for transapical valve implantation.

Statistical analysis. Continuous variables are expressed as mean ± SD and maximal and minimal absolute numbers. Statistical analyses were carried out with the Student *t* test, the chi-square test, or the Fisher exact test. The paired *t* test was used for pre- and post-operative comparisons, and the unpaired *t* test was used for comparisons between the 23- and 26-mm prostheses. Univariate logistic regression was applied to identify predictors for post-operative survival. The data were evaluated by SPSS software version 17.0 for Windows (SPSS, Inc., Chicago, Illinois). A p value <0.05 was considered to be significant.

Results

Early outcome. Technical procedural success was 100%. There was no conversion to open heart surgery. The 30-day mortality was 5.1% (9 patients died after surgery) for the entire group. It was 8% (n = 4) in the first 50 patients, 4% (n = 2) in the second 50 patients, and 4% (n = 3) in the last 75 patients. In the subgroup of 165 patients without cardiogenic shock, the 30-day mortality was 3.6% (6 patients died). Of 10 patients with cardiogenic shock, 3 died (30%). The mean STS score of all patients who died during the first month was 19.9 ± 10.2% (range 5.8% to 32.4%). The causes of early deaths were septicemia in 1 patient with pre-operative methycillin-resistant *Staphylococcus aureus*, acute myocardial failure in 1 patient, multiorgan failure in 4 patients, basilar vein thrombosis in 1 patient, and abdominal complications in 2 patients.

Procedural course. The 26-mm valves were implanted in 107 patients, and 23-mm valves were implanted in 68 patients. During the same procedure, 5 patients received a second valve implanted within the first valve (valve in valve) after redilation of the first valve because of a paravalvular leak and relevant regurgitation. The implantation of valves in patients with degeneration of previously implanted biologic aortic valve prostheses (valve in an old valve) was entirely uneventful in all 12 patients. Concomitantly to aortic valve implantation, additional elective procedures were performed in 29 (16.6%) patients (Table 2). Elective femoro-femoral cardiopulmonary bypass was applied in 6 (3.4%) patients with severe cardiogenic shock, poor left ventricular function (LVEF 10% to 20%), or both. The mean cardiopulmonary bypass time was 12 min (range 5 to 25 min). An intra-aortic balloon pump was inserted electively during the procedure in 2 patients with pre-operative poor LVEF.

Table 2 Elective Procedures Combined With Transapical Implantation

Procedure	No. of Patients
Coronary artery stenting (elective)	22
ASD II closure with an occlusion device	1
Dilation of the stenotic pulmonary valve	1
LV aneurysmectomy	2
Renal artery stenting	1
Off-pump CABG	1
Permanent caval filter*	1
Closure of a groin arteriovenous fistula*	1

*The same patient.
ASD II = secundum atrial septal defect; LV = left ventricle; other abbreviation as in Table 1.

Intraoperative echocardiographic data. The mean pre-operative transvalvular gradient was 46.5 ± 13.9 mm Hg (range 11.8 to 97.5 mm Hg), and the mean aortic valve area was 0.57 ± 0.22 cm^2 (range 0.22 to 1.16 cm^2). The mean post-operative transvalvular gradient was 6.28 ± 2.94 mm Hg (range 1.19 to 15.56 mm Hg), and the mean aortic valve area was 1.88 ± 0.51 cm^2 (range 0.85 to 3.37 cm^2) (Fig. 4A). According to the size of the implanted valves (23 or 26 mm), the mean transvalvular gradient for the 23-mm valves was 6.37 ± 2.4 mm Hg (range 1.8 to 11.7 mm Hg), and for the 26-mm valves, it was 6.17 ± 3.35 mm Hg (range 1.19 to 15.56 mm Hg) (Fig. 4B). There was no statistically significance difference between the transvalvular gradients in the subgroup of patients with 23-mm valves and the patients with 26-mm valves (p = 0.76) (Fig. 4C). However, there was a significant difference (p = 0.001) in the mean aortic area between the 2 subgroups. The mean aortic valve area of the patients receiving 23-mm valves was 1.69 ± 0.49 cm^2 (range 0.85 to 2.88 cm^2), and in 26-mm valve recipients it was 2.05 ± 0.47 cm^2 (range 1.0 to 3.37 cm^2) (Fig. 4D).

Procedural and post-operative complications. In 2 (1.1%) patients, cardiopulmonary bypass was used on an emergency basis because of inadequate hemodynamic recovery immediately after valve deployment. In one of them, the cause was obstruction of the left coronary ostium after deployment of the valve. Emergency femoro-femoral cardiopulmonary bypass was established to stabilize the hemodynamic situation during successful implantation of a stent, and for additional myocardial reperfusion (total cardiopulmonary bypass time, 56 min). An intra-aortic balloon pump also was implanted. The further post-operative course of the patient was uneventful. She was weaned from the ventilator and the intra-aortic balloon pump was explanted on the first post-operative day. In 3 patients, there were intraoperative problems with bleeding from the apex of the heart. All patients with intraoperative hemostatic problems had received clopidogrel before surgery. There was no aortic dissection, no new or increased mitral valve incompetence, and no valve dislocation or dysfunction.

There were 2 cases of post-operative surgical revision through the same mini anterior thoracotomy because of

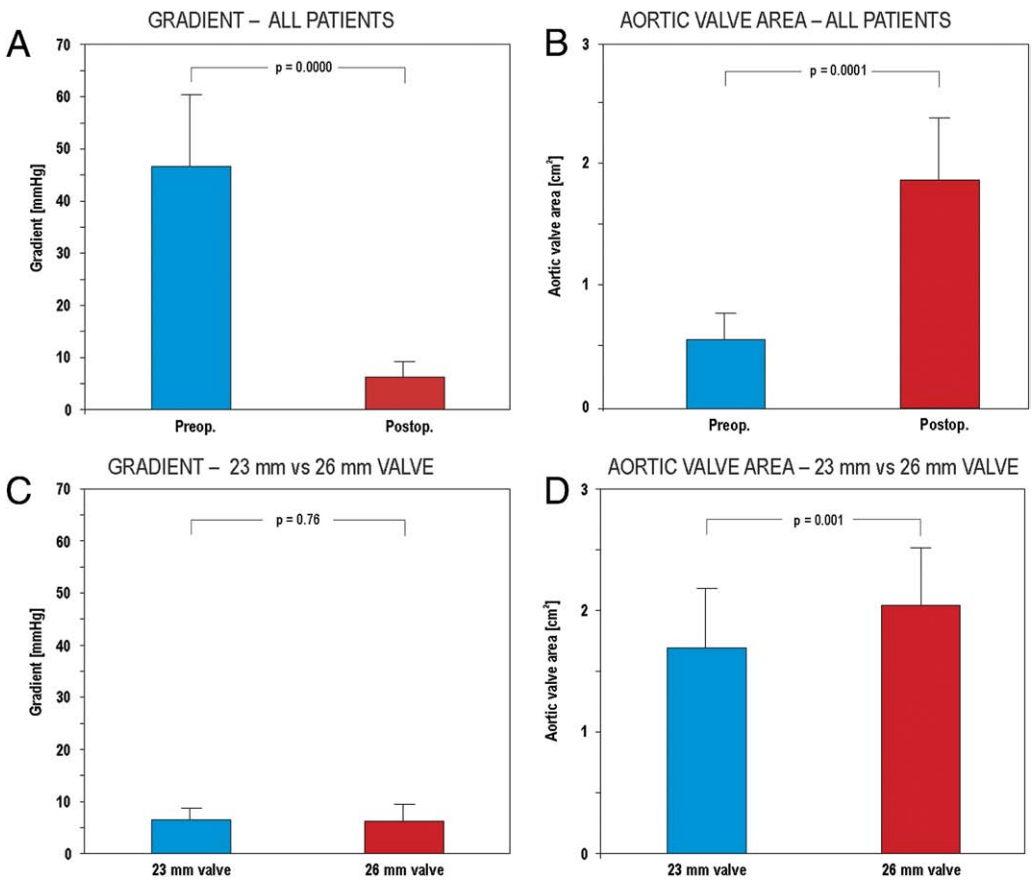

Figure 4 **Intraoperative Transesophageal Echocardiography Data**

(A to D) Bar graphs showing that transapical aortic valve implantation significantly reduced the mean pre-operative transvalvular gradient and improved the mean aortic valve area. Preop. = before surgery; Postop. = after surgery.

post-operative bleeding. These patients also had been treated with clopidogrel before surgery. Ten patients (5.7%) required pacemaker implantation because of higher-grade aortic valve block after surgery. In 1 patient, a 1-cm apical pseudoaneurysm was seen in the post-operative CT. The apex of the heart was explored on the seventh post-operative day, and the pseudoaneurysm was closed uneventfully through the previous mini anterior left thoracotomy and without need for cardiopulmonary bypass. In 1 patient with coronary artery disease, myocardial infarction occurred on the first post-operative day. He immediately received an intra-aortic balloon pump, and then 3 stents were placed in the diseased right coronary artery. He recovered well, but the post-operative course was prolonged. There were 2 cases of post-operative wound problems: in 1 patient who had had methycillin-resistant *Staphylococcus aureus* before surgery, thoracotomy wound secretion developed. She died after surgery of septicemia. Another patient with shock, anasarca, and severe ascites had an inguinal lymph fistula followed by inguinal wound infection after femoro-femoral cardiopulmonary bypass. The patient additionally had ileus and died of multiorgan failure. Thrombosis of the common femoral artery at the puncture site occurred in 1 patient with peripheral arterial disease, and abdominal complications needed surgical revision in 3 patients.

One patient experienced a new clinical neurologic deficit after surgery. One patient had severe central valvular regurgitation during the follow-up. She was treated successfully again with transapical implantation 10 months after the primary procedure. Prosthetic valve endocarditis occurred in 1 patient after urinary tract infection, 4 months after transapical valve implantation. The stent valve was replaced with a standard biological valve. After an initial uneventful course, this patient had abdominal complications (gastrointestinal bleeding) and died.

Late survival and predictors of survival. The survival at 1, 6, and 12 months was 94.9 ± 1.9%, 85.5 ± 3.0%, and 82.6 ± 3.6%, respectively. The mean STS score of all patients who died during the follow-up was 38.4 ± 27.1% (range 5.1% to 89.5%). Univariate analysis of more than 30 pre-operative variables indicated cardiogenic shock, body mass index, and maximal oxygen uptake as predictors for early death during the first 30 post-operative days (Table 3).

Table 3 Predictive Factors of 30-Day Mortality

Parameter	Odds Ratio	95% Confidence Interval	p Value
Age	1.01	0.93–1.10	0.838
Sex	—	—	—
Body mass index	1.13	1.00–1.26	0.043
Logistic EuroSCORE	1.00	0.97–1.04	0.989
STS score	0.98	0.94–1.03	0.591
NYHA functional class	2.75	0.71–10.65	0.144
Cardiogenic shock	4.46	0.82–24.31	0.044
Pro-BNP	1.00	1.00–1.00	0.517
$VO2_{max}$	0.45	0.24–0.83	0.011
Previous CABG	—	—	—
Previous AVR	—	—	—
Previous MVR	—	—	—
Pulmonary hypertension	2.33	0.60–9.01	0.221
COPD	1.21	0.31–4.68	0.780
FEV1	0.52	0.09–3.01	0.465
Diabetes mellitus	—	—	—
Renal insufficiency	1.00	0.20–5.00	0.996
Serum creatinine	0.67	0.19–2.41	0.537
Coronary artery disease	0.68	0.18–2.61	0.569
Calcification of ascending aorta	0.22	0.03–1.69	0.221
Ischemic cerebral lesion(s)	1.13	0.29–4.38	0.859
Peripheral arterial disease	0.52	0.13–1.99	0.336
Aortic valve regurgitation	0.70	0.21–2.34	0.559
Mitral valve regurgitation	1.26	0.41–3.87	0.691
Tricuspid valve regurgitation	1.04	0.24–4.45	0.961
LVEF	1.01	0.96–1.07	0.616
LVEDD	0.93	0.84–1.03	0.183
dP max	0.98	0.95–1.02	0.290
dP mean	0.97	0.93–1.02	0.264
AVA	0.67	0.01–38.25	0.844
Annulus size	0.84	0.47–1.50	0.562

AVA = aortic valve area; AVR = aortic valve replacement; BNP = brain natriuretic peptide; COPD = chronic obstructive pulmonary disease; dP max/mean = maximum/mean transvalvular gradient; FEV1 = forced expiratory volume in 1 s; LVEDD = left ventricular end diastolic diameter; MVR = mitral valve repair/replacement; $VO2_{max}$ = maximal oxygen uptake; other abbreviations as in Table 1.

Univariate analyses at 12 months showed 10 independent predictors for late survival (Table 4).

Discussion

Outcome. Our results of transapical valve implantation in 175 high-risk patients proved that this method can achieve better results than those of conventional surgery as predicted by risk factors. The success rate improved with our increasing experience, with the mortality rate falling from 8% in the first 50 patients to 4% later on. The main consequence of our favorable results is that transapical valve implantation has gradually become de facto the primary choice for treatment of high-risk patients with severe aortic valve stenosis.

Transapical approach needs longer learning curve. The importance of the learning curve was demonstrated clearly in the published experience (3–8). Procedural success improved from the initial 78% to 96% (5,6), followed by improvement in the early survival rate (4). In contrast to the transfemoral way of implantation (4,7,8), the transapical approach needs a longer learning curve because of complexity of the technique, which differs from the standard surgical procedure (4). Webb et al. (4) reported better improvement of the initial results in the transarterial approach (mortality rate reduction from 12.3% in the initial half to 3.6% in the second half of 113 patients) than in the transapical approach (reduction of mortality from 25% to 11.1% in 55 patients).

Training of the team is crucial for excellent initial results. We believe that our favorable results already achieved during the learning curve are mostly the result of the training of the team to work together before we started the clinical program. Coordination between the members of the team (cardiologists, anesthesiologists, surgeons) was made uniform and was standardized for the procedure, with clearly defined roles for each member. Standard commands and also standard steps for new, unexpected situations were established. After rebuilding one of our operating rooms to produce a new hybrid operating room and training the team, we started a program of transfemoral, transaxillary, and transapical treatment of

Table 4 Predictive Factors of Cumulative Late Mortality

Parameter	Hazard Ratio	95% Confidence Interval	p Value
Age	1.03	0.98–1.07	0.270
Sex	1.12	0.56–2.25	0.756
Body mass index	1.03	0.96–1.10	0.389
Logistic EuroSCORE	1.03	1.02–1.05	0.001
STS score	1.02	1.01–1.04	0.008
NYHA functional class	2.11	1.09–4.10	0.027
Cardiogenic shock	5.56	2.52–12.28	0.001
ProBNP	1.00	1.00–1.00	0.001
$VO2_{max}$	0.81	0.68–0.97	0.022
Previous CABG	1.25	0.55–2.88	0.593
Previous AVR	0.81	0.19–3.39	0.773
Previous MVR	1.02	0.14–7.46	0.987
Pulmonary hypertension	1.44	0.73–2.81	0.291
COPD	0.57	0.27–1.21	0.144
FEV1	0.58	0.25–1.36	0.209
Diabetes mellitus	1.28	0.56–2.95	0.557
Renal insufficiency	1.68	0.80–3.52	0.167
Serum creatinine	1.37	1.03–1.82	0.031
Coronary artery disease	0.70	0.36–1.37	0.294
Calcification of ascending aorta	0.82	0.51–1.34	0.433
Ischemic cerebral lesion(s)	1.74	0.87–3.48	0.121
Peripheral arterial disease	0.71	0.37–1.38	0.312
Aortic valve regurgitation	1.07	0.64–1.80	0.796
Mitral valve regurgitation	1.49	0.92–2.39	0.102
Tricuspid valve regurgitation	1.57	0.98–2.53	0.062
LVEF	0.98	0.96–1.00	0.037
LVEDD	0.99	0.95–1.04	0.741
dP max	0.98	0.97–1.00	0.022
dP mean	0.97	0.95–1.00	0.017
AVA	1.23	0.19–7.93	0.825
Annulus size	0.99	0.75–1.31	0.929

Abbreviations as in Tables 1 and 3.

aortic valve stenosis in very high-risk patients using different types of systems and valves. After every implantation, we analyzed the course of the procedure and complications and identified possible weak points of the procedure. This resulted in compilation of our institutional procedural standards toward the beginning of the program. Our modification of the technique by angiographic monitoring during slow and gradual valve deployment significantly improved the crucial part of the transapical aortic valve implantation process. Furthermore, we noted early that higher positioning of the valve than what we had originally been taught reduced or eliminated paravalvular leaks. Last but not least, we have excellent conditions to perform this procedure in our new hybrid operating room that clearly contributed to the favorable initial results.

"A temptingly easy and straightforward procedure." It is necessary to emphasize that the procedure seems—to an inexperienced observer—to be a temptingly easy and straightforward procedure. And it really is one if there are no complications. However, the procedure poses a high risk of possible dangerous and life-threatening complications that can occur at any moment during the procedure. In contrast to a standard surgical procedure, if complications do occur, they are very difficult to control and it is necessary to be aware of that fact.

Elective use of cardiopulmonary bypass. Cardiopulmonary bypass is very rarely necessary for transcatheter aortic valve implantation. Its use during the beginning of our learning curve gave us more safety. Elective cardiopulmonary bypass may be helpful in patients with reduced LVEF and additional severe mitral valve regurgitation, with coronary artery disease, with severe pulmonary hypertension with an enlarged right ventricle, or in unstable hemodynamic situations. These patients might have ventricular fibrillation during or immediately after cessation of rapid pacing for balloon dilatation of the native valve or valve deployment. However, the final decision of whether to use cardiopulmonary bypass was left until intraoperative TEE was performed.

Combined elective coronary artery stenting and transcatheter aortic valve implantation. A significant proportion of patients with severe aortic valve stenosis are older patients with concomitant coronary artery disease. It is not clear whether any other treatment than medical for coronary artery disease is really necessary after severe aortic valve stenosis is eliminated by transcatheter aortic valve implantation. Coronary artery disease can be treated by stent implantation before or after transcatheter aortic valve implantation. However, percutaneous coronary intervention may be technically difficult or impossible later on. The possible alternative is to treat both pathologies simultaneously. The theoretical advantage of this policy is to eliminate completely the risk of complications because of a pathologic feature left untreated during the waiting time for the second procedure. Our decision to use this approach was prompted after one of our patients experienced myocardial infarction on the first post-operative day. We treat only the most significant coronary lesion(s) to keep the procedure as simple as possible.

Risk scores for transcatheter aortic valve implantation. There is no specific risk score to predict early mortality after transcatheter aortic valve implantation. Our multivariate analysis demonstrated that neither the STS score nor the logistic EuroSCORE were predictors for early death, but only for survival later on during the follow-up. Although the EuroSCORE has been used in most publications regarding transcatheter aortic valve implantation, we used the STS score, which is much more valuable. The logistic EuroSCORE overestimates surgical risk in high-risk patients. Recent publications suggest an actual mortality of one third to one half this estimate in high-risk patients in high-volume centers (9,10). The EuroSCORE was developed from surgical data (that are now too old) almost a decade and a half ago, and especially for coronary revascularization procedures, and not specifically for aortic valve replacement (11). Therefore, transcatheter aortic valve implantation required development of its own risk score.

Study limitations. The main limitation is that we have no control group of patients undergoing conventional aortic valve replacement. However, the calculated operative risk for the conventional operation as assessed by the STS score is a valuable method of evaluating the procedural success. Because of a short follow-up, there was a very small number of patients to analyze the late survival. Further multivariate analysis could not be reported because of the low number of end points. Therefore, our data show only a trend, and a study with larger patient numbers is required.

Conclusions

Transapical aortic valve implantation already has proved its qualities during the learning curve in our institution. The operative procedure and the equipment are still being evolved and improved. With increased experience and simplified equipment in the future, it is likely that the procedure will become a real alternative to the standard surgical treatment for all patients with aortic valve stenosis, and not only for high-risk patients.

Acknowledgments

The authors thank Anne Gale for editorial assistance, Rosemarie Günther for secretarial help, and Julia Stein for the statistical analyses.

Reprints requests and correspondence: Prof. Miralem Pasic, Deutsches Herzzentrum Berlin, Augustenburger Platz 1, D-13353 Berlin, Germany. E-mail: pasic@dhzb.de.

REFERENCES

1. Walther T, Dewey T, Borger MA, et al. Transapical aortic valve implantation: step by step. Ann Thorac Surg 2009;87:276–83.
2. Himbert D, Descoutures F, Al-Attar N, et al. Results of transfemoral or transapical aortic valve implantation following a uniform assessment

in high-risk patients with aortic stenosis. J Am Coll Cardiol 2009;54:303–11.
3. Walther T, Simon P, Dewey T, et al. Transapical minimally invasive aortic valve implantation: multicenter experience. Circulation 2007; 116 Suppl II:I240–5.
4. Webb JG, Altwegg L, Boone RH, et al. Transcatheter aortic valve implantation. Impact on clinical and valve-related outcomes. Circulation 2009;119:3009–16.
5. Webb JG, Chandavimol M, Thomspon CR, et al. Percutaneous aortic valve implantation retrograde from the femoral artery. Circulation 2006;113:842–50.
6. Webb JG, Pasupati S, Humphries K, et al. Percutaneous transaterial aortic valve replacement in selected high-risk patients with aortic stenosis. Circulation 2007;116:755–63.
7. Grube E, Schuler G, Buellesfeld L, et al. Percutaneous aortic valve replacement for severe aortic stenosis in high-risk patients using the second- and current third-generation self-expanding CoreValve prosthesis: device success and 30-day clinical outcome. J Am Coll Cardiol 2007;50:69–76.
8. Grube E, Gerckens U, Wenaweser P, Buellesfeld L. Percutaneous aortic valve replacement with CoreValve prosthesis. J Am Coll Cardiol 2008;51:170–1.
9. Dewey TM, Brown D, Ryan WH, Herbert MA, Prince SL, Mack MJ. Reliability of risk algorithms in predicting early and late outcomes in high-risk patients undergoing aortic valve replacement. J Thorac Cardiovasc Surg 2008;135:180–7.
10. Wendt D, Osswald BR, Kayser K, et al. Society of thoracic surgeons score is superior to the EuroSCORE determining mortality in high risk patients undergoing isolated aortic valve replacement. Ann Thorac Surg 2009;88:468–75.
11. Antunes MJ. The EuroSCORE—10 years later. Time to change? Eur J Cardiothorac Surg 2010;37:253–4.

Key Words: transapical ■ valve ■ transcatheter.