Elective femoro-femoral cardiopulmonary bypass during transcatheter aortic valve implantation: A useful tool

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Objective: Transcatheter aortic valve implantation is a new method to treat high-risk patients with aortic valve stenosis. The operative risk can be reduced, especially in patients with severely reduced left ventricular function or cardiogenic shock. Nevertheless, this new procedure has some potential risks, especially during the phases of rapid pacing (valvuloplasty and valve deployment). The use of cardiopulmonary bypass allows the perioperative risk to be reduced.

Method: Between April 2008 and August 2011, 512 consecutive patients underwent transcatheter aortic valve implantation. Cardiopulmonary bypass was used in 35 patients. In this special group, there were 17 men and 18 women with a mean age of 77 ± 12 years (range, 38–92 years). Left ventricular ejection fraction was a mean of $32\% \pm 19\%$ (range, 10%–70%), European System for Cardiac Operative Risk Evaluation was $60\% \pm 27\%$ (range, 13%–97%), and Society of Thoracic Surgeons' mortality score was $35\% \pm 28\%$ (range, 4%–90%).

Results: Cardiopulmonary bypass was used in 13 patients with preoperative cardiogenic shock, 11 patients with impaired heart function during the procedure, 7 patients with severely impaired left ventricular function (left ventricular ejection fraction, $17\% \pm 6\%$; range, 10%–30%), 3 patients with concomitant conventional surgical procedures, and 1 patient with impaired right ventricular function. The technical success rate was 94%, 30-day mortality was 20%, and 1-year survival was 46%.

Conclusions: The use of cardiopulmonary bypass enhances safety in critical transcatheter aortic valve implantation procedures. Furthermore, transcatheter aortic valve implantation with cardiopulmonary bypass seems to provide better results than medical therapy or conventional aortic valve replacement in critically ill patients. The need for cardiopulmonary bypass emphasizes that the procedure should be performed only in cooperation between cardiologists and cardiac surgeons. (*J Thorac Cardiovasc Surg* 2013;145:757-63)

Transcatheter aortic valve implantation (TAVI) has become a standard procedure in multiple centers for high-risk patients with severe aortic stenosis.¹⁻¹⁰ Although Walther and colleagues^{1,2} showed that transapical aortic valve implantation might reduce the risk of conventional surgical aortic valve replacement in high-risk patients, some authors recommend performing this new procedure only in patients with a Society of Thoracic Surgeons' (STS) mortality score less than 20%, a European System for Cardiac Operative Risk Evaluation (euroSCORE) less than 40%, and an expected survival of more than 1 year.¹¹ However, the prognosis is grave for patients who are not candidates for conventional aortic valve replacement or TAVI.¹²

An alternative is to perform TAVI on cardiopulmonary bypass (CPB). This procedure can be performed in patients with severely depressed left ventricular function, an enlarged right ventricle, or in cardiogenic shock. In addition, previous heart surgery in this high-risk patient group will not increase the perioperative risk.¹³ This study examines the surgical procedure and postoperative course of patients undergoing TAVI on CPB.

PATIENTS AND METHODS

Patients

TAVI was performed between April 2008 and August 2011 in 512 patients at the Deutsches Herzzentrum Berlin, Germany. An Edwards SAPIEN valve (Edwards Lifesciences, Irvine, Calif) was implanted in 459 patients, and a CoreValve (Medtronic Inc, Minneapolis, Minn) was implanted in 53 patients. According to the individual patient risk profile, a transapical access was chosen in 441 patients, a transfemoral access was chosen in 56 patients, and a transaxillary access was chosen in 15 patients. The transapical route for aortic valve implantation was chosen especially in patients undergoing reoperation because it enables more precise valve handling and positioning. The group of 512 patients was divided into 2 groups according to whether the procedure was performed on elective CPB or not. Group I consisted of 35 patients in whom the TAVI procedure was performed on elective CPB. Group II served as controls and consisted of 477 patients in whom the TAVI procedure was performed without elective CPB.

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Abbreviations and Acronyms

CPB	= cardiopulmonary bypass
euroSCORE	= European System for Cardiac Operative Risk Evaluation
IABP	= intra-aortic balloon pump
LVEF	= left ventricular ejection fraction
PRIND	= prolonged reversible ischemic neurologic deficit
STS	= Society of Thoracic Surgeons
TAVI	= transcatheter aortic valve implantation

Patient Cohorts

Group I consisted of 35 patients (17 male and 18 female) with a mean age of 77 ± 12 years (range, 38–92 years). The left ventricular ejection fraction (LVEF) was a mean of $32\% \pm 19\%$ (range, 10%–70%), the euroSCORE was $60\% \pm 27\%$ (range, 13%–97%), and the STS mortality score was $35\% \pm 28\%$ (4%–90%). The procedure was performed in all these patients on CPB. CPB was used in 13 patients with preoperative cardiogenic shock, in 11 patients with impaired heart function during the procedure, in 7 patients with severely impaired left ventricular function (LVEF, 17 ± 6 ; range, 10%–30%), in 3 patients with planned concomitant conventional surgical procedures, and in 1 patient with impaired right ventricular function. Group II (control group) consisted of 477 patients in whom the TAVI procedure was performed without the heart-lung machine. In this group, there were 185 men and 292 women with a mean age of 80 ± 8 years (range, 29–99 years). The LVEF was a mean of $51\% \pm 13\%$ (range, 10%–70%), the euroSCORE was $35\% \pm 19\%$ (range, 2%–95%), and the STS mortality score was $16\% \pm 13\%$ (1%–82%). In group I, significantly more patients had pulmonary hypertension, the creatinine and pro-B-type natriuretic peptide levels were significantly higher (Table 1), and the ejection fraction was significantly lower (Table 2). Therefore, the euroSCORE and STS mortality score were significantly higher in group I ($P < .05$) (Table 1).

Preoperative and Postoperative Evaluation

Pre- and postoperative examinations included clinical and laboratory examinations, electrocardiogram, chest x-ray, transesophageal echocardiography, and multislice computed tomography of the chest and pelvis followed by vascular 3-dimensional reconstruction. Preoperative coronary angiography and ultrasound examinations (Doppler) of the arteries and veins of the lower extremities and of the carotid arteries were performed. The Doppler examination allowed the detection of severe peripheral vascular disease. The echocardiographic data, postoperative course, potential complications, and late outcome were followed.

Aims of the Elective Use of Cardiopulmonary Bypass for Transcatheter Aortic Valve Implantation

According to our institutional policies,⁴ the elective use of cardiopulmonary bypass was considered in patients with reduced ejection fraction ($<20\%$), presenting in cardiogenic shock (eg, catecholamine dependence, organ failure, artificial ventilation), with a relevantly enlarged right ventricle with pulmonary hypertension, or with a planned concomitant conventional surgical procedure.⁴ TAVI was performed on elective CPB to increase safety and hemodynamic stability during the procedure, and particularly to prevent manual cardiopulmonary resuscitation if ventricular fibrillation occurred during the TAVI procedure (in patients with poor left ventricular function, enlarged right ventricle with reduced pulmonary

function, or cardiogenic shock). In addition, CPB allowed myocardial recovery of the unloaded heart in patients with shock.

Procedural and Technical Considerations

Immediately before the procedure, the whole team analyzed the diagnostic workup and discussed the possible technical difficulties and complications and means to prevent them. Elective coronary artery stent implantation was considered in patients with concomitant coronary artery disease.^{4,14} Only the most relevant coronary artery stenosis was considered to be a target for stent implantation.^{4,14,15}

The procedures were performed in a hybrid operating room in a completely sterile environment and under fluoroscopic imaging with a mono-plane angiography system. All patients were under general anesthesia. The surgical technique of transcatheter valve implantation was based on the procedure described by several authors,^{1–4} with the modification of transcatheter valve positioning and liberation under simultaneous angiography with contrast medium to find the optimal valve position and reduce the risk of paravalvular leakage.¹⁰ The procedure was monitored by fluoroscopy, angiography, and intraoperative transesophageal echocardiography.

Cannulation for Elective Cardiopulmonary Bypass

The use of normothermic femoro-femoral CPB was routinely considered to provide a higher safety level during the procedure, and especially to prevent manual cardiopulmonary resuscitation if ventricular fibrillation occurred during TAVI. We routinely used an open surgical approach to the femoral vessels, using a 15F cannula to cannulate the common femoral artery and a 23F cannula to cannulate the femoral vein (“as small as possible”) to neutralize the risk of vascular complications. In the case of severe calcification, the axillary artery was cannulated. A small (2–3 cm) incision in the groin, parallel to the ligamentum inguinale Poupart, was chosen (and not a classic vascular access to the femoral vessels). This incision enables easier identification and faster and only limited dissection of the vessels, but special attention was given to the ligation (by metallic clips) of the small lymphatic tracts (to prevent postoperative lymphatic fistula). In the case of the transfemoral approach for TAVI, the artery of better quality was used for the TAVI procedure and the other site was used for CPB cannulation. A fully percutaneous approach was not used to exclude the possible negative aspects of the procedure itself and to achieve optimal access and hemostasis.

Technical Consideration of the Transcatheter Aortic Valve Implantation Procedure During Elective Cardiopulmonary Bypass

The guidewires and introducers were introduced via the left ventricular apex into the left ventricle while a slight filling of the heart was achieved by reducing the CPB drainage to maintain left ventricular ejection and facilitate initial passage of the guidewire through the stenotic aortic valve. If complete unloading of the heart was possible, balloon dilatation of the native valve and valve deployment were performed without rapid pacing to avoid possible ventricular fibrillation. If complete drainage and unloading of the heart were not possible, rapid pacing was used for balloon valvuloplasty and valve release, and the left ventricle was drained as much as possible to prevent heart distension and ventricular fibrillation. Once adequate deployment and function of the prosthesis had been achieved, the left ventricular purse strings were tied and hemostasis was achieved. The prophylactic transfemoral placement of an intra-aortic balloon pump (IABP) was considered in patients with poor LVEF or cardiogenic shock to secure greater safety and hemodynamic stability during the immediate postoperative course.⁴ Then, weaning from CPB was performed.

Statistical Evaluation

All data analyses were performed using PASW Statistics, version 18.0 (SPSS, Inc, Chicago, Ill). The Gaussian distribution of the data was tested by the Kolmogorov-Smirnov test. Depending on the result, the

TABLE 1. Patient data (n/% or mean $\pm$ standard deviation, range)

	Group I	Group II	Test
No. of patients (n)	35	477	
Sex (male/female)	17/18	185/292	$P > .05^*$
Age (y)	78 $\pm$ 12 (38–92)	79.6 $\pm$ 8 (29–99)	$P > .05^\dagger$
Weight (kg)	74 $\pm$ 14 (44–115)	74 $\pm$ 17 (37–147)	$P > .05^\dagger$
Body mass index	27 $\pm$ 4.7 (19–43)	27 $\pm$ 5 (16–59)	$P > .05^\dagger$
Comorbidity			
Coronary heart disease	25 (71%)	282 (59%)	$P > .05^*$
Peripheral vascular disease	24 (69%)	329 (69%)	$P > .05^*$
Pulmonary hypertension (systolic >50 mm Hg)	22 (63%)	131 (27%)	$P = .0001^*$
Chronic obstructive pulmonary disease ‡	15 (43%)	231 (48%)	$P > .05^*$
Diabetes mellitus	8 (23%)	127 (27%)	$P > .05^*$
Previous surgery			
CABG	6 (17%)	77 (16%)	$P > .05^*$
AVR	3 (9%)	21 (4%)	$P > .05^*$
MVS	3 (9%)	11 (2%)	$P > .05^*$
Apical descending conduit	1 (3%) §	0	$P > .05^*$
Previous cerebral ischemia			
Stroke/PRIND/TIA	3 (9%)/1 (3%)/0	47 (10%)/2 (4%)/2 (4%)	$P > .05^*$
Laboratory data			
Creatinine (mg/dL)	1.5 $\pm$ 0.7 (0.7–3.4)	1.2 $\pm$ 0.7 (0.5–8.2)	$P = .016^\dagger$
Pro-BNP (pg/mL)	16,440 $\pm$ 19,050 (687–77,019)	4527 $\pm$ 6621 (10–50,678)	$P = .008^\dagger$
Preoperative risk score			
euroSCORE (logistic, %)	59 $\pm$ 27 (13–97)	35 $\pm$ 19 (12–95)	$P < .05^\dagger$
STS mortality score (%)	35 $\pm$ 28 (4–90)	16 $\pm$ 13 (1–82)	$P < .05^\dagger$

CABG, Coronary artery bypass grafting; AVR, aortic valve replacement; MVS, mitral valve surgery; PRIND, prolonged reversible ischemic neurologic deficit; TIA, transient ischemic attack; BNP, B-type natriuretic peptide; euroSCORE, European System for Cardiac Operative Risk Evaluation; STS, Society of Thoracic Surgeons. *Fisher exact test. † t test. ‡ Long-term use of bronchodilators or steroids for lung disease. § Apico-descendent conduit (21 mm, St Jude Medical Inc, St Paul, Minn) presenting with severe calcification and aortic valve insufficiency.

measurements were analyzed by the Levene test for variance and by the Mann-Whitney U test and the unpaired sample t test to discern significance. The log-rank test was used for survival analysis (Kaplan-Meier curves).

RESULTS

The technical procedure was performed using the standard technique in all patients.¹⁵ CPB was used in 35 cases: in 13 patients with preoperative cardiogenic shock, in 11 patients with impaired heart function during the procedure, in 7 patients with severely impaired left ventricular function (LVEF, 17% $\pm$ 6%; range, 10%–30%), in 3 patients with concomitant surgical procedures, and in 1 patient with impaired right ventricular function.

Echocardiographic Data

Preoperative echocardiographic data showed significant differences in left ventricular function between the 2 groups (Table 2). In group I, the left ventricular end-diastolic diameter was significantly higher than in group II (LV end-diastolic diameter: group I: 56 $\pm$ 10.2 mm [range, 38–80 mm], group II: 49 $\pm$ 7 mm [range, 30–73 mm] [$P < .05$]), and the ejection fraction was significantly lower (group I: 32% $\pm$ 19.1% [range, 10%–70%], group II: 51 $\pm$ 13% [range, 10%–70%] [$P < .05$]). Neither the aortic valve orifice area nor the diameter of the aortic annulus differed

between the groups. The transvalvular aortic valve gradient differed between the groups because in group I the ejection fraction was significantly lower (Table 2). Although the degree of mitral valve insufficiency did not differ, patients with previous heart surgery (group I) more often had pulmonary hypertension and a higher degree of tricuspid valve insufficiency (Tables 1 and 2).

Postoperatively, the transvalvular gradient was low because of the special design of the valve and did not differ between the 2 groups (Table 2). Central and paravalvular regurgitation are special characteristics in transcatheter valve implantation. Therefore, it is not surprising that postoperative echocardiographic examinations showed slight central incompetence in 2 patients in group I (6%) and 50 patients in group II (10%). Minimal paravalvular leakage was seen in 17 patients (49%) in group I and 184 patients (39%) in group II ($P > .05$). The paravalvular regurgitation was mostly of grade I or less; only in a few patients was it between grades I and II. No patients in group I had insufficiency of grade II or more.

Procedural and Postprocedural Course

The technical success rate was 94% (33/35) in group I and 100% (477/477) in group II. One patient in group I developed an annulus rupture during valve liberation, and 1

TABLE 2. Echocardiographic data (mean $\pm$ standard deviation, range)

	Group I	Group II	Test
Preoperative			
Left ventricular end-diastolic diameter (mm)	56 $\pm$ 10.2 (38–80)	49 $\pm$ 7 (30–73)	$P < .05^*$
LVEF (%)	32 $\pm$ 19.1 (10–70)	51 $\pm$ 13 (10–70)	$P < .05^*$
Aortic valve			
Insufficiency (degree)	1.1 $\pm$ 0.7 (0–3)	0.9 $\pm$ 0.7 (0–4)	$P > .05^\dagger$
Orifice area (cm ²)	0.7 $\pm$ 0.3 (0.3–1.8)	0.7 $\pm$ 0.2 (0.3–1.4)	$P > .05^\dagger$
Diameter of aortic annulus (mm)	23 $\pm$ 1.7 (18–26)	23 $\pm$ 1.6 (18–29*)	$P > .05^\dagger$
Gradient max (mm Hg)	53 $\pm$ 23.2 (20–106)	74 $\pm$ 19 (14–159)	$P < .05^*$
Gradient mean (mm Hg)	35 $\pm$ 17.4 (10–84)	49 $\pm$ 14 (7–100)	$P < .05^*$
Mitral valve			
Insufficiency (degree)	1.3 $\pm$ 0.7 (0–3)	1.1 $\pm$ 0.6 (0–3)	$P > .05^\dagger$
Tricuspid valve			
Insufficiency (degree)	1.3 $\pm$ 1.1 (0–4)	0.6 $\pm$ 0.7 (0–3.5)	$P = .008^\dagger$
Postoperative			
Central AVI (degree)	2 (6%)	50 (10%)	$P > .05^\dagger$
Degree 0–I	1	29	$P > .05^\ddagger$
Degree I	1	19	$P > .05^\ddagger$
Degree I–II		2	$P > .05^\ddagger$
Degree II			
Paravalvular AVI (degree)	17 (49%)	184 (39%)	$P > .05^\dagger$
Degree 0–I	7	91	$P > .05^\ddagger$
Degree I	6	68	$P > .05^\ddagger$
Degree I–II	3	21	$P > .05^\ddagger$
Degree II	1	4	$P > .05^\ddagger$
Aortic valve gradient			
Max (mm Hg)	8 $\pm$ 3.4 (4–15)	9 $\pm$ 5 (0–40)	$P > .05^\dagger$
Mean (mm Hg)	4 $\pm$ 1.7 (2–7)	5 $\pm$ 2.5 (1–20)	$P > .05^\dagger$

LVEF, Left ventricular ejection fraction; AVI, aortic valve implantation. *Mann-Whitney U test. † t test. ‡ Fisher exact test.

patient died of apical bleeding in tabula (a 91-year-old patient with reoperation). Even in group II, the success rate was 100%; in addition, 1 patient developed a type A dissection, which was successfully treated by placement of an uncovered aortic endostent.¹⁶ The patient's postoperative course was uneventful. In group I, 3 patients received a CoreValve (26 mm in 1 patient and 29 mm in 2 patients), and 32 patients received an Edwards SAPIEN valve (23 mm in 9 patients, 26 mm in 20 patients, and 29 mm in 3 patients). In group II, 50 patients received a CoreValve (29 mm valve) and 427 patients received an Edwards SAPIEN valve (23 mm in 135 patients, 26 mm in 258 patients, and 29 mm in 34 patients). There were no statistically significant differences.

Peripheral cannulation for CPB was performed in 26 patients. The mean bypass time was 64 $\pm$ 63 minutes (range, 6–257 minutes). However, central cannulation via median sternotomy was performed in 9 patients. In these patients, the mean bypass time was 227 $\pm$ 165 minutes (range, 77–628 minutes). The mean CPB time was 23 $\pm$ 27 minutes (range, 6–83 minutes), significantly lower in patients with elective bypass than in patients with extracorporeal circulation because of impaired heart function during the procedure (154 $\pm$ 91 minutes; range, 26–316 minutes), in patients presenting preoperatively in cardiogenic shock

(111 $\pm$ 61 minutes; range, 43–172 minutes), or in patients with concomitant surgical procedures (121 $\pm$ 173 minutes; range, 12–628 minutes) ($P < .05$). An IABP was placed preoperatively in 2 patients, and an IABP was necessary in 4 patients at the end of the procedure.

Length of Stay

Because of the patients' multimorbidity, they required a long postoperative in-hospital stay. The mean intensive care unit stay was 4.1 $\pm$ 6.7 days (range, 0.2–38 days) in group I and 1.8 $\pm$ 1.7 days (range, 0.6–9.8 days) in group II. The total length of in-hospital stay was 29.6 $\pm$ 19 days (range, 3–134 days) in group I and 10.1 $\pm$ 4 days (range, 4–19 days) in group II. The intensive care unit and in-hospital stays were significantly longer in group I ($P < .05$).

Preoperative and Postoperative Stroke Rate

Preoperatively, in group I, 3 patients had a history of stroke and 1 patient had a prolonged reversible ischemic neurologic deficit (PRIND), whereas in group II, 47 patients had previous stroke, 2 patients had a PRIND, and 2 patients had a transitory ischemic attack. Postoperative clinical examination showed that in group I, 1 patient had a new stroke and that in group II, 2 patients had a stroke, 1 patient presented with a PRIND, and 8 patients had signs of a transient

TABLE 3. Operative data (mean $\pm$ standard deviation, range)

	Group I	Group II	Test
No. of patients (n)	35	477	
Technical success rate	33 (94%)	477 (100%)	$P = .045^*$
On-pump surgery	35 (100%)	—	
CoreValve (Medtronic Inc, Minneapolis, Minn)	3	50	$P > .05^*$
Size: 26/29/31 mm	1/2/—	—/29/—	
Edwards SAPIEN valve (Edwards Lifesciences, Irvine, Calif)	32	427	$P > .05^*$
Size: 23/26/29 mm	9/20/3	135/258/34	
Pacemaker implantation			
DDD/VVI	—/2 (6%)	16 (3%)/22 (5%)	$P > .05^*$
Reason for CPB			
Cardiogenic shock	13 (37%)	—	
Intraprocedural impaired heart function	11 (31%)	—	
Impaired LV function	7 (20%)	—	
Impaired RV function	1 (3%)	—	
Concomitant surgical procedure	3 (9%)	—	
CPB (peripheral)			
No. of patients	26 (74%)	—	
Bypass time	64 $\pm$ 63 (6–257)	—	
CPB (central)			
No. of patients	9 (26%)	—	
Bypass time	227 $\pm$ 165 (77–628)	—	
Time of hospitalization (d)			
Length of stay on ICU	4.1 $\pm$ 6.7 (0.2–38)	1.8 $\pm$ 1.7 (0.6–9.8)	$P < .05^\ddagger$
Total length of stay	29.6 $\pm$ 19 (3–134)	10.1 $\pm$ 4 (4–19)	$P < .05^\ddagger$
Mortality			
30-d mortality	7 (20%)	22 (4.83%)	$P < .05^\ddagger$
Survival			
6-mo survival	54%	87%	$P < .05^\ddagger$
1-y survival	46%	84%	$P < .05^\ddagger$
1.5-y survival	46%	80%	$P < .05^\ddagger$
2-y survival	40%	72%	$P < .05^\ddagger$

CPB, cardiopulmonary bypass; LV, left ventricular; RV, right ventricular; ICU, intensive care unit. *Fisher exact test. ‡ Mann-Whitney U test. ‡ Log-rank test ($P < .05$).

ischemic attack. There was no statistical difference between the 2 groups.

Cardiac Pacemaker

In the case of postoperative atrioventricular block degree III for more than 3 days, a cardiac pacemaker was implanted. In group I, 2 patients (6%) required pacemaker implantation postoperatively (both received an Edwards SAPIEN valve), and in group II, 38 patients (8%) required pacemaker implantation postoperatively (12 patients received a CoreValve and 26 patients received an Edwards SAPIEN valve). Although 24% of patients with a CoreValve required pacemaker implantation, 6% of patients with an Edwards SAPIEN valve required pacemaker implantation. There was no statistically significant difference between groups I and II.

Survival

The 30-day mortality was 20% in group I and 4.8% in group B. The 1-year survival was 46% in group I and 84% in group B. The difference was statistically significant

(Table 3, Figure 1). In group I, during the first 30 days, 7 patients died: myocardial failure in 3 patients, septicemia in 2 patients, and intraoperative death in 2 patients. Five of these 7 patients presented with preoperative cardiogenic shock; 1 patient had severe central aortic prosthesis insufficiency, making a second Edwards SAPIEN valve implantation necessary; and 1 patient had a type A dissection, making sternotomy necessary. No patient with concomitant heart surgery died.

In group II, the reason for early postoperative death was mostly septicemia (7 patients), followed by myocardial failure (4 patients), right-sided heart failure (3 patients), embolism (2 patients), and other reasons, for example, left ventricle perforation and rupture of an abdominal aortic aneurysm (7 patients).

DISCUSSION

In patients with advanced heart failure, the operative risk is elevated during conventional aortic valve replacement. The mortality ranged from 3% to 30%.^{7-9,14} TAVI has been introduced to reduce the surgical risk in patients

FIGURE 1. Survival (Kaplan-Meier curves, log-rank test: $<.05$).

with advanced age. In this article, we show that the use of CPB during TAVI allows the procedure to be performed with greater safety in patients with advanced heart failure.

As presented in an earlier publication,^{14,17,18} TAVI can be performed successfully in patients with advanced heart failure. Our group showed that the postoperative course in patients with left ventricular function less than 25% is prolonged, but the midterm survival is not influenced.¹⁴ In this cohort, an elective femoro-femoral bypass was used in 43% of patients. As reported in 2010,⁴ our standard institutional policy is to consider the use of elective femoro-femoral CPB in patients with severe cardiogenic shock, poor left ventricular function (LVEF, 10%–20%), or both.

Nevertheless, no literature as yet exists presenting experience with the elective and urgent use of CPB during TAVI. CPB is rarely necessary for TAVI, but it is a prerequisite for the procedure to have the heart-lung machine ready to use in the operating room, and it is an important part of the safety net,¹⁷ although not all patients placed on CPB during the procedure need the support. Nevertheless, its elective use increases the safety in critically ill patients to maintain hemodynamic stability during the phases of rapid pacing and to prevent manual cardiopulmonary resuscitation, because the postoperative course of these patients is unfavorable.

We consider the use of the heart-lung machine in the following 3 ways: (1) placement of the connecting tubes on the table, (2) cannulation of the femoral vessels without starting up the heart-lung machine, and (3) valvuloplasty and valve deployment under a short duration of CPB.

The first strategy may save time if complications occur, for example, in patients with a small distance of the coronary ostia to the aortic annulus or in patients with severe

pulmonary hypertension. The second strategy seems to be justified in patients with markedly reduced left ventricular function (ie, LVEF $<25\%$) or severe regurgitation of the atrioventricular valves. If hemodynamic instability (refractory to high-dose catecholamine administration) occurs, the heart-lung machine may be started within 1 second after simply removing the clamps on the connecting tubes. The third strategy is considered at Deutsches Herzzentrum Berlin in patients with poor left ventricular performance (LVEF, 10%–20%), cardiogenic shock, or decompensated right-sided heart failure with an enlarged right ventricle. The progression of rapid pacing into ventricular fibrillation is often difficult to manage. The primary use of CPB instead of its secondary use on an emergency basis may provide superior results.

We have shown that the elective use of extracorporeal circulation (in some cases for several minutes only) allows TAVI to be performed in patients with severely depressed myocardial function (ejection fraction $<20\%$). Patients in cardiogenic shock and with concomitant heart disease can safely undergo operation. Therefore, our guidelines for particular situations with regard to patient selection, use of CPB, and IABP are as follows:

1. “No exclusion” policy: All patients with an STS score of 10 or more 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 CPB is considered in patients with severe cardiogenic shock, poor left ventricular function (LVEF, 10%–20%), or enlarged right ventricle with severe pulmonary hypertension.
3. The IABP is considered in high-risk patients with depressed hemodynamic condition.

CPB is rarely necessary for TAVI. Nevertheless, its use allows the procedure to be performed safely in patients with severely depressed left ventricular function (ejection fraction $<20\%$) with or without additional severe mitral valve regurgitation, coronary artery disease, severe pulmonary hypertension with an enlarged right ventricle, or unstable hemodynamics. These patients might develop ventricular fibrillation during or immediately after the cessation of rapid pacing for balloon dilatation of the native valve or valve deployment.

CONCLUSIONS

From our initial experience, TAVI with CPB seems to provide better results than medical treatment or conventional aortic valve replacement, which carries a relatively high operative mortality in these specific patients.^{7-9,12,14,19,20} In addition, it emphasizes that TAVI should be performed only in cooperation between

cardiologists and cardiac surgeons in a hybrid operating room in a completely sterile environment with potential elective use of the heart–lung machine.

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