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% ± 19% (range, 10%–70%), European System for Cardiac Operative Risk Evaluation was 60% ± 27% (range, 13%–97%), and Society of Thoracic Surgeons' mortality score was 35% ± 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% ± 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% ± 19% (range, 10%–70%), the euroSCORE was 60% ± 27% (range, 13%–97%), and the STS mortality score was 35% ± 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% ± 13% (range, 10%–70%), the euroSCORE was 35% ± 19% (range, 2%–95%), and the STS mortality score was 16% ± 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 monoplane 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