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Results of percutaneous and transapical transcatheter aortic valve implantation performed by a surgical team☆

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Abstract

Objective: Transcatheter aortic valve implantation has been performed by several groups, most of them either specializing on the transapical (surgeons) or the percutaneous femoral transarterial approach (cardiologists). We achieved both transapical and percutaneous transcatheter valve implantation by a surgical team in a hybrid suite. **Methods:** Since June 2007, 137 patients ($n = 78$ female, mean age 81 ± 7 years) underwent transcatheter aortic valve implantation ($n = 109$ transfemoral, $n = 3$ via subclavian artery, $n = 2$ directly through ascending aorta, $n = 23$ transapical) with the CoreValve ($n = 114$) or the Edwards Sapien ($n = 23$) prosthesis. **Results:** Thirty-day mortality was 12.4% in this patient cohort. One hundred and eight patients (78.8%) are alive at a mean follow-up of 97 ± 82 days. Pacemaker implantation due to postoperative AV block was performed in 27 patients (19.7%), and 7 patients (5.1%) sustained neurological events. Patients improved in NYHA class (from 3.1 ± 0.3 to 1.9 ± 0.5, $p < 0.001$) and in self-assessed health state (from 55 ± 17% to 68 ± 16%, $p < 0.001$) at one-month follow-up. Echocardiographic assessment revealed excellent hemodynamic function of the prostheses with a mean aortic gradient (MAG) of 11.9 ± 4.4 mmHg and an effective orifice area (EOA) of 1.6 ± 0.4 cm^2 at discharge and a MAG of 11.0 ± 4.2 mmHg and an EOA of 1.6 ± 0.3 cm^2 at six months FU. **Conclusions:** Transcatheter aortic valve implantation has become an alternative technique for the treatment of aortic stenosis with reasonable short- and mid-term results at our institution. With the opportunity to treat aortic stenosis by conventional surgical valve replacement and transapical and percutaneous transcatheter procedures, the technique of lowest risk for the individual patient can be chosen and performed by one team.

Keywords: Valves; Aortic stenosis; Minimally invasive; Interventional

1. Introduction

The new technology of transcatheter aortic valve implantation has been developed to minimize the operative trauma in high-risk patients with severe symptomatic aortic stenosis who are refused for conventional surgical aortic valve replacement. After the pioneering works of Webb et al. [1], Grube et al. [2] and Walther et al. [3], who demonstrated the technical feasibility, a growing number of centers are introducing the transcatheter aortic valve implantation procedure. Hereby, the teams usually specialize on either the percutaneous transfemoral or the transapical access, depending on their specialization (cardiology or surgery). In contrast, our basic approach to the treatment of severe aortic stenosis is to offer the most adequate treatment for the individual patient. Furthermore, since procedural complications mainly require interventions by surgeons, the entire implantation lies in the hands of one team. Therefore, we established both the transarterial and the transapical implantation technique by a surgical team in a hybrid suite. The aim of the present study was to analyze the clinical outcome of the patients who had undergone transcatheter aortic valve implantation by percutaneous and transapical access. The study presents the experience of a surgical team over one year and discusses the advantages of a surgical environment for transcatheter valve procedures.

2. Methods

2.1. Patient selection, preoperative evaluation and choice of access site

Patients with severe symptomatic aortic stenosis aged >75 years and with a high risk for conventional surgical aortic valve replacement were considered for transcatheter valve implantation. Surgical risk was assessed by the EuroSCORE (expected mortality >20%) and clinical judgement, if risk factors were present, which are not covered by the score

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(such as repeated previous cardiac surgery, liver cirrhosis, porcelain aorta, immobility due to orthopaedic diseases etc.). Patients' characteristics are summarized in Table 1. All patients signed an informed consent. The study was approved by the local ethics committee (2234/08).

In all patients, computed tomography of the thorax, abdomen and pelvis is performed with 3D reconstruction of the complete aorta and specific reconstruction (individual orthogonal angulation) of the aortic root. Coronary artery disease is evaluated by coronary angiography in all patients. If significant stenoses are present, coronary intervention is performed prior to aortic valve implantation. Furthermore, we reassess the severity of the aortic stenosis and the annulus diameter by transthoracic and transesophageal echocardiography.

Table 1
Patient characteristics.

Parameter	
Age at time of operation (years)	81.4 ± 6.7
Gender (female/male)	78/59
Logistic EuroSCORE mortality risk (%)	24.3 ± 14.9
STS score (%)	23.4 ± 10.1
Preoperative pro BNP (ng/l)	7827 ± 17230
Procelain aorta	9/137 (7%)
Cardiac decompensation	32/137 (23%)
Urgent or emergent intervention	17/137 (12%)
Preoperative ejection fraction	
>50%	81/137 (59%)
35–50%	29/137 (21%)
<35%	27/137 (20%)
Coronary artery disease	66/137 (48%)
No intervention	25/66 (38%)
Previous PTCA/stent	23/66 (35%)
Previous coronary artery bypass operation	18/66 (27%)
Pulmonary hypertension (systolic pulmonary artery pressure >60 mmHg)	37/137 (27%)
Previous cardiac surgery	21/137 (15%)
Coronary artery bypass	17/21 (81%)
Mitral/tricuspid valve surgery	2/21 (9.5%)
Combination/other	2/21 (9.5%)
Atrial fibrillation	56/137 (41%)
Diabetes mellitus	34/137 (25%)
Renal insufficiency (creatinine level >1.5 mg/dl)	29/137 (21%)
On dialysis	3/137 (2%)
Significant concomitant valve disease	28/137 (20%)
Mitral insufficiency >grade II	13/28 (46%)
Tricuspid insufficiency >grade II	7/28 (25%)
Mitral and tricuspid insufficiency	7/28 (25%)
Mitral stenosis	1/28 (4%)
COPD	31/137 (23%)
Restrictive lung disease	2/137 (1.5%)
Recent pneumonia	6/137 (4%)
Peripheral vessel disease	36/137 (26%)
Claudication	30/36 (83%)
Previous intervention/stent	1/36 (3%)
Previous peripheral bypass surgery	5/36 (14%)
Cerebral vascular disease	29/137 (21%)
Internal carotid stenosis >70%	20/29 (69%)
Previous stent implantation	4/29 (14%)
Previous carotid surgery	4/29 (14%)
Previous stent and surgery	1/29 (3%)
Previous stroke	11/137 (8%)
Gastrointestinal disease	18/137 (13%)
Orthopedic disease	26/137 (19%)
Liver disease	5/137 (4%)
Hematologic disease or cancer	18/137 (13%)
Psychiatric disease	3/137 (2%)
Parkinson's disease	2/137 (1%)

BNP: brain natriuretic peptide, COPD: chronic obstructive pulmonary disease.

For transfemoral implantation, a minimum diameter of 6.5 mm is required for the CoreValve delivering system, and a 7 mm diameter for the Edwards Sapien system. In our experience, 20% of the patients had contraindications for transfemoral valve implantation, such as peripheral vessel disease with stenosed femoral or iliac vessels, severe kinking, aortic or iliac dissection, or previous peripheral bypass surgery. The subclavian artery was assessed as the access site of second choice in those patients. If the subclavian artery did not reach the diameter requirements as well, we considered transapical valve implantation through a left anterolateral minithoracotomy. In two patients, none of the routine access sites were eligible, and the device was implanted directly through the ascending aorta via a partial upper sternotomy.

2.2. Prostheses

The CoreValve prosthesis (CoreValve, Irvine, CA) and the Edwards Sapien prosthesis (Edwards Lifesciences, Irvine, CA) were implanted in our series. Both received the CE mark in 2007 for transarterial implantation. In addition, the Edwards Sapien prosthesis received the CE mark for transapical implantation in December, 2007. The CoreValve prosthesis, a porcine pericardial valve mounted in a self-expandable nitinol stent, has an 18 French delivery sheath suitable for vessels ≥6.5 mm. Transapical implantation of the CoreValve prosthesis was performed within the context of the approval study ($n = 5$, approved by the institutional ethics committee). The Edwards Sapien prosthesis, a bovine pericardial valve in a balloon-expandable steel stent, is approved for both the transarterial and the transapical access. The transarterial delivery sheath has a size of 22 F for the 23 mm prosthesis (mean vessel size 7 mm), and 24 F size for the 26 mm prosthesis (mean vessel size 8 mm), respectively. It is suitable for native annulus sizes of 17–25 mm, while the CoreValve prosthesis, available in 26 mm and 29 mm sizes, can be implanted in annuli of 19–27 mm.

2.3. Implantation techniques and postoperative management

Preoperatively, a loading dose of 300 mg clopidogrel was administered to patients receiving a CoreValve prosthesis. All patients were operated in a surgical hybrid suite. We opted to perform the procedures under general anesthesia to assure stable hemodynamics and avoid patient movement during valve implantation. Perioperative anticoagulation included administration of 5000 IE heparin. Arterial and venous guide wires for potential femoral cannulation were placed into one groin prior to the procedure. Transfemoral valve implantation was performed by percutaneous punctuation and device closure (ProStar XL, Abbott Vascular, IL; $n = 85$) or by surgical dissection of the femoral artery ($n = 24$). For the subclavian access, the subclavian artery was dissected through a 5 cm subclavicular skin incision ($n = 3$). Antegrade transapical

aortic valve implantation was performed through a left anterolateral minithoracotomy ($n = 23$). In two patients, retrograde implantation directly through the ascending aorta was performed through partial upper ministernotomy. A transient pacemaker wire was placed transvenously for transarterial retrograde implantation, and epicardially for transapical antegrade valve implantation. A balloon valvuloplasty of the stenotic aortic valve was performed under rapid ventricular pacing with 160–180 beats/min in all patients. Under fluoroscopy control, the prosthesis, crimped on the delivery catheter, was placed in the aortic annulus. The CoreValve prosthesis was then gradually released on the beating heart, while the Edwards Sapien prosthesis was deployed by balloon inflation under rapid ventricular pacing. Details of the implantation procedures have been described previously [4–8]. Prosthesis function was assessed by angiography and intraoperative transesophageal echocardiography. In patients with lateral minithoracotomy or ministernotomy, a chest tube was placed before wound closure. After the procedure, the patients were transferred to the intensive care unit and usually extubated within 2–4 h. For postoperative anticoagulation, we administer 75 mg clopidogrel/day for six months and a lifetime dose of 100 mg/day aspirin in patients receiving a CoreValve prosthesis, and a lifetime dose of 100 mg aspirin/day in patients receiving an Edwards Sapien prosthesis. Patients with atrial fibrillation or other indications for coumarin receive coumarin and aspirin without clopidogrel.

2.4. Follow-up echocardiography

All patients undergo echocardiography at rest preoperatively, at discharge, and six months postoperatively. At present, 62 patients have completed six months follow-up.

Echocardiography was carried out using an image Point Hx ultrasound system with a 2.5 MHz transducer (Hewlett Packard, USA). Peak and mean systolic pressure gradients (MPGs) in the left ventricular outflow tract (LVOT) 1 cm below the valve and across the valve were measured in an apical three- or five-chamber view using pulsed wave Doppler for the LVOT measurements and continuous wave Doppler for the valve measurements, respectively. In patients with sinus rhythm, three of the best available signals were averaged. If atrial fibrillation was present, a minimum of five measurements was averaged. Effective orifice area (EOA) was obtained by using the continuity equation [9].

2.5. Statistical analysis

Data are presented as mean ± standard deviation or as percentages. Differences between groups were tested with Student's *t*-test for independent or paired variables, as appropriate. The survival function was illustrated by Kaplan–Meier curves. Survival distributions were compared with the log rank test.

3. Results

Between June 2007 and August 2008, 137 patients underwent catheter-based aortic valve implantation at our institution. One hundred and nine patients had transfemoral valve implantation ($n = 105$ CoreValve, $n = 4$ Edwards Sapien), three patients had the aortic valve prosthesis implanted via the subclavian artery ($n = 3$ CoreValve), and two patients had direct ascending aortic access through an upper ministernotomy ($n = 2$ CoreValve). Twenty-three patients underwent transapical aortic valve implantation ($n = 5$ CoreValve, $n = 18$ Edwards Sapien).

Table 2
Intraoperative data.

Parameter	
Procedural success	135/137 (98.5%)
Conversion to surgical AVR	1/137 (0.7%)
Intraprocedural circulatory depression	29/137 (21.2%)
Catecholamine therapy	15/29 (51%)
Resuscitation	8/29 (28%)
Defibrillation	2/29 (7%)
Extracorporeal circulatory support	4/29 (14%)
Intraprocedural pericardial effusion (>1 cm)	5/137 (3.6%)
Contrast agent (ml)	150 ± 65
Fluoroscopy time (min)	25 ± 11
Dose-area product (μGy cm^2)	30000 ± 18856
Procedure time (min)	80 ± 38

3.1. Intraoperative and early postoperative outcome

Procedural success was 98.5% (135/137). Intraoperative data are summarized in Table 2. Postoperative AV block with the need of pacemaker implantation occurred in 19.7% of the patients (27/137), vascular complications with the need of surgical intervention occurred in 11.7% of the patients (16/137), and 5.1% sustained neurological events (7/137, $n = 1$ cerebellar infarction with no residual symptoms, $n = 2$ cerebral infarction with no awakening after intervention, $n = 4$ middle cerebral artery infarction with persistent hemiparesis).

3.2. Survival

Thirty-day mortality was 12.4% (17/137) in this series. Among our first 62 patients, who completed six months follow-up to date, survival is 77% (48/62). The Kaplan–Meier survival curve is illustrated in Fig. 1a. Survival was not improved in patients with a lower EuroSCORE value (log rank test, $p = 0.566$, Fig. 1b).

3.3. Clinical follow-up and hemodynamics

Patients improved in mean NYHA classification from 3.1 ± 0.3 preoperatively to 1.7 ± 0.6 at 30 days postoperatively and 1.9 ± 0.5 at six months FU ($p < 0.001$) (Fig. 2a). Self-assessed general health state on a scale of 0–100% was 55 ± 17% preoperatively. This improved to 68 ± 16% at 30 days postoperatively ($p < 0.001$), and was 64 ± 21% six months postoperatively ($p = 0.071$) (Fig. 2b). Fig. 3 illustrates the mean aortic gradients and EOAs for the different valve types and sizes. Paravalvular leakage resulting in regurgitation grade II occurred in 12% of the patients at discharge, and in 8% at six months follow-up.

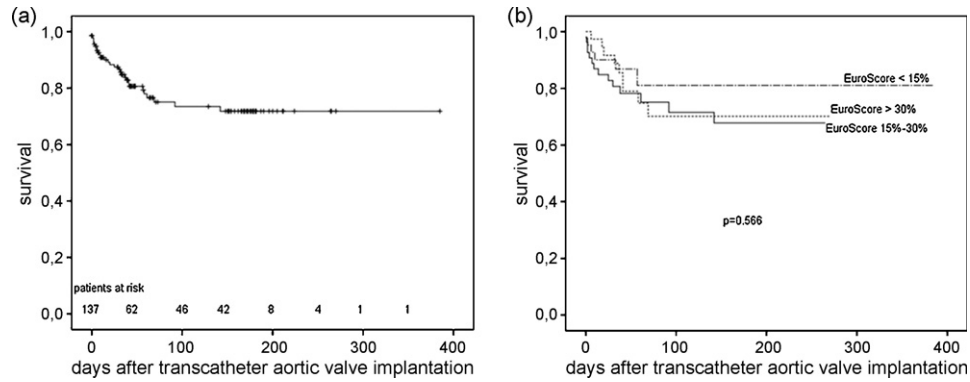

Fig. 1. Survival. (a) Survival curve for 137 patients after transcatheter aortic valve implantation. Follow-up duration is shown in days on the *x*-axis. (b) The survival curves of the 137 patients subdivided into groups of EuroSCORE <15% (n = 44), 15–30% (n = 54), and >30% (n = 39) show no significantly improved survival for patients with lower EuroSCORE values.

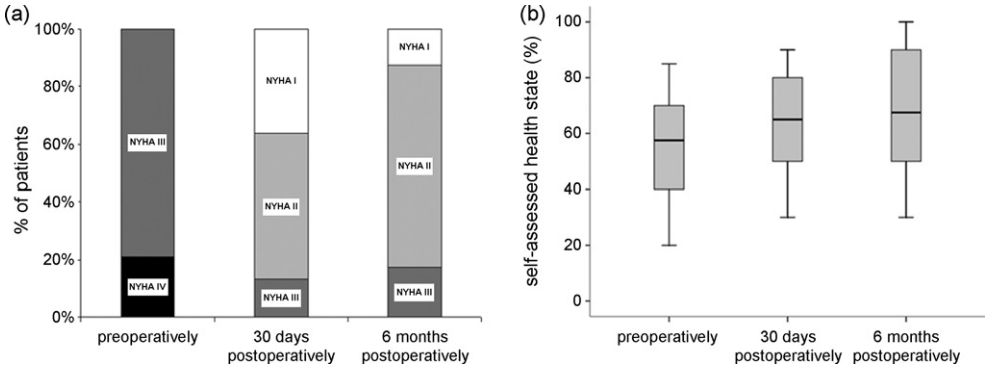

Fig. 2. Clinical data. (a) The proportion of patients being in NYHA class III and IV is 100% preoperatively, and <20% 30 days and six months postoperatively. (b) The boxplot shows the improvement of self-assessed health state on a scale of 0–100% at 30-day and six-month follow-up.

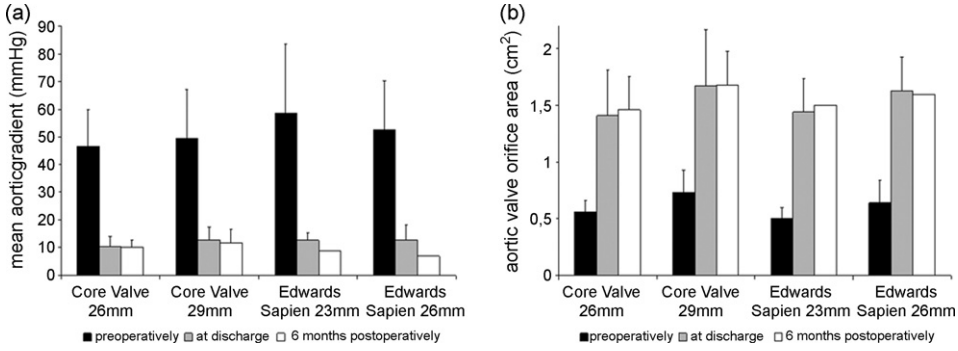

Fig. 3. Hemodynamic data. (a) Mean aortic gradients preoperatively and at 30-day and six-months follow-up for all implanted valve types and sizes. (b) Aortic valve orifice areas preoperatively and at 30-day and six-month follow-up for all implanted valve types and sizes.

4. Discussion

After Cribier's report on the first successful transcatheter aortic valve implantation in a human in 2002 [10], the technique has undergone several modifications. The transvenous antegrade access [11] has been abandoned in favor of the transarterial retrograde access, and the supplementary antegrade transapical access has been established. The transarterial, mainly transfemoral aortic valve implantation technique is usually performed by interventional cardiologists who are experienced in catheter techniques, while the transapical aortic valve implantation through a left anterolateral thoracotomy is performed by cardiac surgeons. At our institution, a surgical team was trained in catheter skills and established a transcatheter aortic valve implantation program. Today, all treatment options for aortic valve stenosis, such as surgical aortic valve replacement with heart–lung machine through complete or partial upper sternotomy; transfemoral, transsubclavian, transaortic and transapical catheter-based aortic valve implantation, can be offered at our department choosing the most adequate option for the individual patient.

Patient selection for transcatheter valve implantation procedures is still subject to debate. In a position statement paper from the EACTS, ESC and EAPCI [12], the difficulties of surgical mortality risk prediction are discussed, while

catheter-based aortic valve implantation is explicitly recommended for high-risk patients, or for patients with contraindications for surgery. Clinical judgement is assessed as more valuable than risk scores (EuroSCORE, STS score, Ambler score) for the evaluation of surgical risk [12]. Our data confirm the assumption recently stated by Grossi et al. [13] that the EuroSCORE is not significantly correlated with the mortality in a highly selected cohort of aged patients with numerous cardiac and non-cardiac comorbidities, as demonstrated by the survival curves of our patients in Fig. 1b. There is the need for the development of new scores for this exceptional patient population. One of the main challenges in the future will be the determination of clear indications for surgical and interventional treatment of aortic stenosis.

Patients scheduled for transcatheter aortic valve implantation undergo careful assessment of the optimum access site and prosthesis type by computed tomography and echocardiography. We consider the transfemoral access as the technique of first choice, because it is least invasive. However, there is no conclusive evidence yet, that either approach may be preferable. Thirty-day mortality was 12% in both published series after percutaneous transfemoral implantation of the Edwards Sapien prosthesis (50 patients) [14] and of the CoreValve prosthesis (86 patients) [4]. Three series after transapical Edwards Sapien implantation report a 30-day mortality of 13.6% (59 patients) [7], 8% (50 patients) [3], and 17.5% (40 patients) [15]. In our combined cohort of 137 patients after transarterial and transapical implantation, the 30-day mortality of 12% is well in the range of the published series. Three- to six-month survival is reported to be 72–74% after transapical aortic valve implantation [3,15] and was 77% in our cohort. The results of the ongoing FDA approval study of the Edwards Sapien prosthesis will reveal potential differences in survival after surgical aortic valve replacement and transfemoral and transapical aortic valve implantation in a randomized trial (www.ClinicalTrials.gov). Further studies by our team will include the assessment of differences in survival rates between transapical and transarterial access routes. Comparisons to follow-up studies of octogenarians demonstrating an early mortality of 1.7–9% [16–18] (institutional data: 7.9%) after surgical aortic valve replacement are critical, because those patients are also a highly selected collective composed of lower risk candidates. At present, the recommendations of the European committee [12] and of the AHA [19] disapprove the inclusion of low risk surgical candidates for transcatheter aortic valve implantation until long-term results are available.

Within the six months follow-up period of our first 62 patients, we see remarkable clinical improvement in NYHA classification and in self-assessed health state (Fig. 2) in these multimorbid patients after transcatheter aortic valve implantation. The hemodynamic function of all implanted prosthesis types and sizes is satisfying with mean aortic gradients of 7–10 mmHg and prosthesis effective orifice areas of 1.5–1.7 cm^2 (Fig. 3). Prosthesis regurgitation is common due to stiff calcifications of the native aortic valve, which cannot be tightly attached to the aortic annulus by the prosthesis. Twelve percent of our patients were discharged with a clinically insignificant grade II regurgitation. No signs of prosthesis degeneration or other complications such as prosthesis migration were seen upon follow-up echocardiographic examination.

There is evidence that the incidence of neurological events is reduced with the transapical aortic valve implantation technique. The reported rates of neurological events after transapical valve implantation are 0–3% in the literature [3,7,15], and 0% in our cohort, while stroke rates are 4–10% in patients undergoing transfemoral aortic valve implantation [4,14] (6.1% in our cohort). This phenomenon might be explained by the avoidance of manipulation in a calcified aortic arch with the transapical technique. Stroke rates after conventional surgical aortic valve replacement are reported to be 2% in octogenarians [18], while again those cohorts are not comparable to our population. Previous stroke had occurred in 8% of our patients versus 4% in surgical patients [20]. If the difference in stroke rates between the transapical and transfemoral access becomes significant with larger implantation numbers, this should influence the decision which technique is chosen for a specific patient.

Postoperative AV block with the need of permanent pacemaker implantation was the most frequent complication in our series (19.7%), indicating the need for thorough ECG monitoring during the first postoperative days. Pacemaker implantation was performed according to the ESC Guidelines for cardiac pacing and cardiac resynchronization therapy [21]. Sinus node disease manifesting itself as symptomatic bradycardia or even sinus arrest ($n = 3$), symptomatic bradyarrhythmia ($n = 3$), type II second-degree AV or complete AV block ($n = 21$) was the most common indications for permanent pacing. When the AV block was diagnosed during the intraoperative or postoperative monitoring, pacemaker implantation was performed without further hesitation even in cases of intermittent AV block. This approach might be called a somewhat liberal indication, but in this population of elderly patients all with underlying organic heart disease we opted for patients' safety. Prostheses sizing might also be a critical issue here. As we opted for the larger valve size when the size of the aortic annulus was in between two valve sizes (21.5 mm for the Sapien valve, 23.5 mm for the CoreValve) to minimize the risk of valve migration and paravalvular leak we might have increased the risk of AV block. This is going to be the subject of further investigation from our side.

In 16 patients with vascular rupture, we benefited from the surgical environment and expertise in the surgical hybrid suite, as immediate surgical intervention could be performed ($n = 1$ hematoma revision, $n = 13$ vessel suture or vessel reconstruction with a patch, $n = 3$ implantation of a vascular prosthesis). In four patients with intraprocedural circulatory depression irresponsive to medical treatment, immediate establishment of extracorporeal bypass was performed. All patients were weaned from the heart–lung machine uneventfully after valve implantation. We assume that time delay to surgical intervention is minimized in a surgical hybrid suite compared to a catheterization laboratory.

5. Conclusions

After one year of experience, we demonstrate reasonable morbidity and mortality after transcatheter aortic valve

implantation performed by a surgical team. The included high-risk patients exhibited a remarkable improvement in symptoms and good hemodynamic function of the catheter prostheses six months postoperatively. Our data confirm that transcatheter aortic valve implantation is a promising technique for high-risk patients with severe aortic stenosis, although long-term safety and durability of the prostheses remain to be proven and compared to surgical results. A cross-trained surgeon is ideally positioned to make the most informed and unbiased treatment decision for patients with aortic stenosis and is, furthermore, equipped for the treatment of complications.

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Appendix A. Conference discussion

Dr J.R. Sádaba (*San Sebastián, Spain*): You have described your experience as surgeons using techniques which have traditionally belonged to the realm of the interventional cardiologists, and your results seem to be in line with those of other centers in which the interventional cardiologists play the main role in the transfemoral approach. In your manuscript you conclude, and I quote, 'a cross-trained surgeon is ideally positioned to make the most informed and unbiased treatment decision for patients with aortic stenosis and is, furthermore, equipped for the treatment of complications.' I have three questions for you.

The first one is that the perceived quality of life is, in my opinion, a very important parameter to take into account. In contrast with other studies relating to traditional aortic valve replacement, I was surprised to see no improvement in quality of life at six months. So I would like to know what type of quality of life test did you use and why do you think you failed to demonstrate an improvement?

My second question is that you had a 30-day mortality of 12.4% and a 90-day mortality overall of around 22%. I was wondering whether you could tell us what the cause of death was in these patients, and if there were any valve-related deaths.

And the last question is that, for instance our program as many others, is run by a group made up of cardiologists and surgeons, which form a very compact team. Both cardiologists and surgeons are involved in all procedures, with the cardiologists taking the main role in the transfemoral approach and the surgeons taking the lead in the transapical approach. I think this is the ideal scenario, and the one which has been suggested by the current guidelines and position statements. So I think here you are going against the flow, probably based on weak grounds. I would like to know the reasons for you to work independently from your cardiology colleagues. Was this decision taken in agreement with the cardiologists or was it because of some differences of opinions with them?

Dr Bleiziffer: According to your first question on life quality, we did show significant improvement from preoperatively to 6-month follow-up. This was assessed by one question to the patients, how their general health state was on a scale from 0% to 100%. We also do the SF-36 questionnaire, which has to be analyzed.

Your second question was on the causes of death?

Dr Sádaba: Whether there were any valve-related.

Dr Bleiziffer: Causes of death were 60% noncardiac and the rest were half valve-related and half cardiac deaths.

Dr Sádaba: And the decision about working independently from your cardiology colleagues?

Dr Bleiziffer: We finally think that the ideal environment for aortic valve implantation is actually a surgical hybrid suite, which also is in concordance with the actual guidelines and the statement papers. And we don't refuse the co-operation with the interventional cardiologists, but our opinion is that the team should be headed by cardiac surgeons.

Dr P. Kappetein (*Rotterdam, The Netherlands*): You said that the 30-day mortality is actually quite low, and one can see that most of the patients die during follow-up in the first two months, and then it seems that the curve is plateauing. The high hospital mortality is worrying. Is it patient selection? Is it the technique? What is your opinion about it? And do you have a special preference for using either the Sapien valve or the CoreValve?

Dr Bleiziffer: We evaluate each patient for the best access site. So in patients who can have implantation through the femoral artery, we will do that, and the CoreValve has a couple of advantages for the transfemoral approach, as the catheter size is much smaller.

And for the survival, I analyzed our learning curve. I compared the first 50 to the second 50 patients, and we didn't have an improvement in mortality or a difference.

Dr Kappetein: If you look at your curve, you see that most patients die in the beginning. I think that if you would put these patients on medical therapy, it might be that they are still alive after six months. So it is important that we need to get some guidance from experienced centers which patients we should select for percutaneous valve implantation.

Dr Bleiziffer: Yes, this will be the main challenge in the future. What we plan to do is to collect all patients who were refused for the transcatheter aortic valve replacement due to technical problems or due to anatomical reasons. As we even refused them for the transcatheter approach, we will follow-up them and then we make a comparison of patients who were even refused for the catheter valve implantation with our transcatheter series.

Dr Lange: Does the panel allow me a short comment? I just wanted to make a comment on the collaboration with the cardiologists. We have been discussing this issue with our friends from Leipzig now for a long time, and I think it is very nice if you have cardiologists with you and have a good team, and there is nothing to say against this. However, on the other hand, I want one person in this room to stand up and tell me for what kind of procedure you need a cardiologist here? I don't know. This is a very well-defined procedure which is always the same. So I don't know what any interventional cardiologist could do better than I can, because they are trained the same way by proctors. They don't go there and use their skills and implant those valves. They are trained the same way as we are trained. And I have a lot of friends who are cardiologists. I don't know anything they could do better in this specific kind of procedure. So if I can implant surgical valves by my own, why should I have a cardiologist to do this kind of procedure?

Dr B. Zipfel (*Berlin, Germany*): I congratulate you that you chose the transfemoral approach as surgeons. You reported 12% of vascular complications in the access route, which is a good argument to perform the procedure in the OR. As far as I know, these access route complications were not reported by the cardiologists. Is this because you are more encouraged to use this transfemoral procedure also in patients with more difficult vascular access? Is this 12% only for the transfemoral procedures or for the whole group?

Dr Bleiziffer: They were transfemoral complications. I cannot comment on that. That is what cardiologists also tell me, they don't have any complications in the groin, but perhaps they don't document it so thoroughly. I don't know.