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Immediate and 6-month outcomes of transapical and transfemoral Edwards-Sapien prosthesis implantation in patients with aortic stenosis

Piotr Chodór[1], Krzysztof Wilczek[2], Romuald Przybylski[3], Marcin Krasoń[3], Jan Głowacki[4], Tomasz Niklewski[3], Tomasz Podolecki[1], Zbigniew Kalarus[1], Lech Poloński[2], Marian Zembala[3]

[1]Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Silesian Medical University, Silesian Centre for Heart Diseases, Zabrze, Poland

[2]3rd Chair and Department of Cardiology, Silesian Medical University, Silesian Centre for Heart Diseases, Zabrze, Poland

[3]Chair and Department of Cardiac Surgery and Transplantology, Silesian Medical University, Silesian Centre for Heart Diseases, Zabrze, Poland

[4]Computed Tomography Laboratory, Silesian Medical University, Silesian Centre for Heart Diseases, Zabrze, Poland

Abstract

Background: Severe symptomatic aortic valve stenosis is an unequivocal indication for surgical valve replacement, assuring symptoms relief and increasing survival. About one third of elderly patients is not being operated due to, among others, high peri-procedural risk and comorbidities. Transcatheter aortic valve implantation (TAVI) has recently become a valuable therapeutic option for these patients.

Aim: To present early results of first TAVI Edwards-Sapien procedures in our hospital, performed in symptomatic patients with high operational risk or other contraindications for conventional surgery, as well as the results of 6-month follow-up.

Method: Twelve patients referred for TAVI were included in the analysis. The valve was implanted in 11 patients and in 1 patient the procedure was finished with aortic valve valvuloplasty. Eight (72.7%) patients underwent transapical (TA) and 3 (27.3%) patients transfemoral (TF) TAVI. Seven (63.6%) 26 mm valves and 4 (34.4%) 23 mm valves were implanted.

Results: The efficacy of the procedure was 92%: 100% in the TA group, and 75% in the TF group. During the procedure 1 patient developed ventricular fibrillation. Atrial fibrillation and right ventricle perforation by the endocavitary electrode was observed in another patient. Prolonged wound healing occurred in 4 patients and contrast-induced renal failure occurred in 2 patients. There were no deaths at 30-days. Two patients had a pacemaker implanted during hospitalisation. A significant improvement of echocardiographic parameters was observed: maximum gradient across the aortic valve was 104.4 ± 23.9 mm Hg before *vs* 25.2 ± 6.1 mm Hg after the intervention, p = 0.000001, mean gradient — 63.8 ± 18.3 *vs* 12.7 ± 3.7 mm Hg, p = 0.000004, and valvular surface — 0.7 ± 0.2 *vs* 1.5 ± 0.2 cm^2, p = 0.000106, respectively. During the 6-month follow-up period 1 patient died of multiorgan failure and 6 patients required another hospitalisation. After 6 months an improvement in physical capacity was observed in all but one patients (NYHA II — 9 patients, NYHA III — 1 patient).

Conclusions: 1. The authors' initial experiences with TAVI Edwards-Sapien procedure confirm its efficacy and safety in patients with symptomatic aortic stenosis and high surgical risk. 2. Echocardiographic parameters of the implanted valves, assessed during hospitalisation and 6 month later, are satisfactory. 3. Due to the risk of complications, patients require careful observation in the postoperative period and during short-term follow-up.

Key words: aortic stenosis, transcatheter aortic valve implanation (TAVI), Edwards-Sapien valve

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Address for correspondence:
dr n. med. Piotr Chodór, Department of Cardiology, Congenital Heart Diseases and Electrotherapy, Silesian Medical University, Silesian Centre for Heart Diseases, ul. Szpitalna 2, 41–800 Zabrze, Poland, e-mail: chodor_piotr@go2.pl
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INTRODUCTION

Aortic stenosis (AS) is currently the most common form of acquired valvular heart disease. This results from increasing population of the elderly patients. In the majority of cases, stenosis of the valve in this age group is due to calcification [1]. Severe symptomatic AS represents an unequivocal indication for valve replacement, which provides symptom relief and improves survival [1, 2]. Pharmacotherapy does not improve prognosis [3]. Approximately one third of elderly AS patients are not operated on. This is due to high perioperative risk and co-morbid conditions [4]. In 2002, Cribier et al. [5] performed the first transcatheter aortic valve implantation (TAVI). The first procedure was done with retrograde approach, via femoral vein and transseptal puncture. Subsequently, transfemoral technique was developed, and recently, transapical (TA) implantation of the valve was introduced [5–7]. Currently, two types of transcatheter aortic valves are used: balloon expandable Edwards-Sapien valve (E-S) and self-expandable CoreValve prosthesis (C-V). The TAVI procedures are performed in patients with severe symtomatic AS and high risk of surgical treatment, as well as in patients with contraindications to conventional surgery [1].

The aim of the study is to present immediate and 6-month follow-up results of the first TAVI procedures performed in our centre.

METHODS

Eleven TAVI procedures were performed between November 2008 and June 2009. The study group was selected out of 33 severe symptomatic AS patients (Fig. 1). The E-S valves were implanted either by transfemoral (TF) or by TA approach. The study group consisted of patients with symptomatic AS, aortic valve area (AVA) < 1 cm^2 or AVA index < 0.6 cm^2, disqualified from surgical treatment due to high risk (Logistic Euroscore > 20% or STS > 10%) or other contraindications not included in risk scores. After completion of diagnostic tests including transthoracic (TTE) or transoesophageal echocardiography (TEE), coronary angiography with aortography and femoral arteriography, computed tomography of the heart, aorta, iliac and femoral arteries, a decision was made concerning TAVI feasibility and choice of the implantation approach (TF or TA). All the patients expressed their written informed consent concerning the TAVI procedure.

Transapical TAVI

The procedures were performed in the cathlab under general anesthesia by a team including 2 cardiac surgeons, 2 interventional cardiologists, an anesthesiologist, a cardiologist-echocardiographer and a radiologist. Initially these procedures were performed under a proctor's supervision. Femoral artery (FA) and femoral vein were surgically accessed or punctured to be readily available in case cardiopulmonary bypass became necessary. Cardiac apex was surgically exposed and 2 matress sutures were placed with teflon patches. Vascular haemostatic sheath was inserted into 1 of the FA along with the pigtail catheter. After puncturing the apex with 18 G anesthesiologic needle, a 150 cm 0.035" guidewire was placed (Balton, Poland) and 6 F sheath (Balton, Poland) and a right coronary Judkins catheter (Ashai Intec, Japan) were introduced. The 150 cm guidewire was replaced with an Extra-Stiff 160 cm 0.035" guidewire (Cordis, USA) and was introduced into descending aorta. Next, 6 F sheath was replaced with 14 F sheath (Cordis, USA) and 20 mm balloon catheter (Edwards, Lifescience, USA) was introduced over the guide-

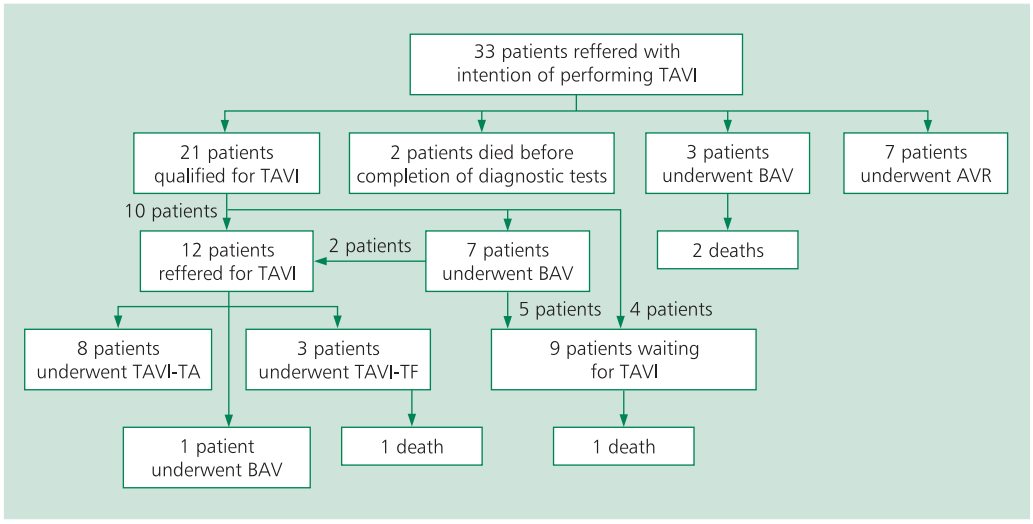

Figure 1. Qualification for TAVI procedure. Patient flowchart; TAVI — transcatheter aortic valve implantation; TAVI-TF — transcatheter aortic valve implantation-transfemoral; TAVI-TA — transcatheter aortic valve implantation-transapical; BAV — balloon aortic valvuloplasty; AVR — aortic valve replacement

wire and placed at the level of the aortic valve. During rapid ventricular pacing (180–200/min) 1–2 balloon inflations were performed (balloon filled with 15% solution of the contrast media in normal saline). Right ventricular lead (5 F or 6 F, B. Braun, Germany) or epicardial lead sutured in the apical region (5 patients) (Johnson & Johnson, USA) were used for pacing. After dilation of the valve, the 14 F sheath was replaced with 26 F sheath (Edwards Lfescience, USA). The prosthetic valve (E-S 23 or 26 mm) folded around the baloon catheter was introduced using the Ascendra set (Edwards Lifescience, USA) and advanced into the aortic valve position. After positioning, the aortic valve was implanted with one balloon inflation during fast ventricular pacing. Procedural success was assessed by aortography and by TEE study. The operation was finished with suturing the apex and thoracic wall as well as the previously prepared FA.

Transfemoral TAVI

All the procedures via FA were performed under general anesthesia. First, the FA was surgically accessed. Contralateral 6 F (Balton, Poland) sheaths were also introduced into FA and femoral vein. A 5 F (B. Braun, Germany) endocardial lead was advanced into right ventricular apex and pacing effectiveness was assessed. After placing a pig-tail catheter in the ascending aorta, aortography was done. A 7 F sheath (Balton, Poland) was introduced into the prepared FA, and a 150 cm 0.035" (Balton, Poland) straight guidewire was used to cross the aortic valve and to place Amplatz catheter in the left ventricle (Asahi Intec, Japan). Next, the guidewire was replaced with 260 cm 0.035" ExtraStiff guidewire (Cordis, USA), which, after replacing the 7 F sheath with a 14 F sheath, was used to introduce a 20 mm or 23 mm baloon catheter (Edwards, Lifescence, USA), across the aortic valve. During rapid ventricular pacing (180–200/min), 1 or 2 balloon inflations were performed. Then, with the Extra Stiff guidewire left in position, the balloon catheter and the 14 F sheath were removed. For FA dilation, 16, 18, 20, 22 and, provisionally, 24 F dilators were used (Edwards, Lifescence, USA). Under fluoroscopic control, a sheath suitable for 23 or 26 mm valve implantation was inserted (Edwards Lifescence, USA). Next, Retroflex system was introduced (Edwards Lifescence, USA), with the valve folded over the balloon. Retroflex system was then advanced to the aortic valve level to cross the native valve. Once the valve position was confirmed, the prosthesis was implanted by the balloon inflation during rapid ventricular pacing. Control aortography and TEE were performed to check the position of the valve. After Retroflex and sheath removal, control arteriography of the FA was performed. If no vascular complications were found, the FA was sutured. The patients were given 1 g of iv cephazolin before the procedure, and during the procedure they received heparin at the dosage adjusted so as to maintain activated clotting time of 250 ms. A more detailed description of the technique can be found in several international and Polish papers [5–11].

In-hospital follow-up

After the procedure, patients were admitted to a post-operative care unit. After 2–4 days they were transfered to cardiac surgery or cardiology departments. In the post-operative period echocardiography, chest X-ray, ECG, Holter monitoring and routine laboratory workup were performed.

Post-discharge follow-up

After succesful TAVI, the patients were followed at 1, 3 and 6 months. During each visit medical history, physical exam, echocardiography, 6-minute walk test and routine laboratory workup were performed.

Statistical analysis

Quantitative data are presented as means ± standard deviations. After checking for normality of data distribution by Kolmogorov-Smirnov test, the significance of between-group differences was assessed by two-tailed Student t-test. Homogeneity of variance was checked for by F-Fisher test. Differences between structural indices were assessed by structural index test. A p value < 0.05 was significant.

RESULTS

Out of 33 patients referred with intention of performing TAVI, 21 patients were selected for the procedure. Between November 26, 2008 and June 6, 2009, 12 patients were referred for the procedure (11 women, 1 man). Eventually, TAVI was performed in 11 patients. Patient characteristics are presented in Table 1. The mean age was 79 ± 5 years, mean BMI 32 ± 7, logistic Euroscore — 26 ± 8%, and the STS Score — 6 ± 4%.

In-hospital procedural results

In 11 out of the 12 patients TAVI was performed (91.7%). In 8 (72.7%) the valve was implanted by TA approach and in 3 (27.3%) — by TF approach. Seven (63.6%) 26 mm valves and 4 (34.4%) 23 mm valves were implanted. In 1 patient after balloon aortic valvuloplasty (BAV), replacement of the 14 F sheath for the sheath required for 26 mm E-S valve implantation was unsuccessful. This was due to failure of introduction of 22 mm dilator. In this patient, the prosthesis was not implanted and the procedure was terminated at the stage of BAV. During valve implantation ventricular fibrillation occurred in 1 patient, succesfully defibrillated by second discharge. In 1 patient after BAV and prior to valve implantation, atrial fibrillation occurred. In another patient, additional inflation of the balloon (increasing its volume by 1 cm^3) was performed, due to perivalvular leak after valve implantation. In 1 patient in whom aortic valve was implanted by TA approach, after accessing the apex, during endocardial lead placement, right ventricular wall was perforated, without any signs of bleeding. The perforation was sutured concomitantly with suturing the apex in the course of the procedure. In another patient, whose body mass index (BMI) was 37 kg/m^2, a part of a rib had to

Table 1. Patient characteristics

	1 (M.B.)	2 (S.N.)	3 (W.D.)	4 (J.S.)	5 (A.W.)	6 (T.S.)	7 (L.P.)	8 (U.W.)	9 (E.P.)	10 (H.K.)	11 (R.S.)	12 (W.J.)
Age [years]	80	77	81	80	71	79	73	70	86	78	88	79
Sex	F	F	F	F	F	M	F	F	F	F	F	F
BMI	26	33.3	33.2	30.8	38	29.7	37.0	21.6	46	35.2	19.6	32.0
Chest pain	No	No	Yes	Yes	Yes	Yes	Yes	Yes	No	Yes	No	Yes
Syncope	No	No	No	Yes	No	No	No	No	No	No	No	Yes
NYHA class	III	III	III	III	III	III	III	III	IV	III	III	III
Hypertension	Yes	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	Yes	Yes
Diabetes	No	No	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
CAD; stenosis > 50%	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No
Prior CABG	No	No	No	No	Yes	Yes	No	No	No	Yes	No	No
Prior PCI	No	No	Yes	Yes	Yes	Yes	No	Yes	No	Yes	No	No
Prior MI	No	No	No	Yes	Yes	Yes	No	No	No	No	No	No
History of stroke or TIA	No	No	No	No	No	No	No	Yes	No	No	No	No
Severe peripheral artery disease	No	Yes	Yes	No	Yes	No	No	Yes	Yes	Yes	Yes	No
Renal insufficiency	No	No	No	No	No	No	No	No	Yes	Yes	No	No
Severe COPD	No	Yes	No	No	No	No	No	No	No	No	No	No
Pulmonary hypertension (SPAP > 60 mm Hg)	No	Yes	Yes	No	No	No	Yes	No	Yes	No	Yes	Yes
Porcelain aorta	No	No	No	No	No	No	No	Yes	No	No	No	No
Other conditions	MS							Sternotomy		APE	Pancytopenia	Asthma
Logistic Euroscore	7.94	32.4	27.7	18.5	36.6	31.6	25.5	33.5	21.7	29.3	22.8	20.9
STS	2.9	4.3	4.8	10.1	5.0	5.0	3.0	4.0	15.7	6.5	8.7	4.0

F — female; M — male; BMI — body mass index; NYHA — New York Heart Association; CAD — coronary artery disease; CABG — coronary artery bypass grafting; PCI — percutaneous coronary intervention; MI — myocardial infarction; TIA — transient ischaemic attack; COPD — chronic obstructive pulmonary disease; SPAP — systolic pulmonary arterial pressure; MS — myelodysplastic syndrome; APE — acute pulmonary embolism

be removed during TA TAVI, in order to access the apex. Procedural data are presented in Table 2.

In-hospital complications

In a female patient aged 86, with diabetes, chronic kidney disease and BMI 45 kg/m^2, contrast-induced kidney disease progression was observed, and haemodiafiltration was necessary. At day 8, surgical wound infection in the right groin occurred and re-intubation was warranted. Echocardiography revealed normal function of the implanted aortic valve. After 2 months the patient died due to multiorgan failure. In another patient with a history of stroke transient consciousness alterations were observed; in another patient — contrast-induced nephropathy was found. In one patient at day 2 after

Table 2. Procedural data

Effective valvuloplasty	12/12 (100%)
Effective implantation	11/12 (91.7%)
Periprocedural death	0 (0%)
Stroke	0 (0%)
Need for urgent cardiac surgery	0 (0%)
Myocardial infarction	0 (0%)
Ventricular fibrillation	1 (8.3%)
Heart perforation*	1 (8.3%)
Fluoroscopy time [min]	17 ± 8
Time of procedure [min]	190 ± 31
Contrast media used [mL]	225 ± 114

*Perforation related to intracardiac lead insertion

Table 3. Six-month follow-up

	Baseline (n = 11)	1 month after procedure (n = 11)	3 months after procedure (n = 10)	6 months after procedure (n = 10)	P
NYHA class					
II (% patients)	0 (0%)	8 (72.7%)	8 (80%)	9 (90%)	
III (% patients)	10 (90.9%)	2 (18.2%)	2 (20%)	1 (90%)	
IV (% patients)	1 (9.1%)	1 (9.1%)	0 (0%)	0 (0%)	
6-min walk test [min]*		274.5 ± 73.7	303.10 ± 84.6	288.7 ± 65.9	NS
NT-proBNP [pg/mL]	6005.1 ± 6702.3	1546.4 ± 1001.6	1499.0 ± 1420.1	1172.9 ± 1245.9	NS

*Test performed in 8 patients; NT-proBNP — N-terminal prohormone brain natriuretic peptide

TA procedure intercostal artery bleeding was observed, warranting surgical wound revision. Later, left-sided diaphragm paresis was noticed in this patient. Two female patients with atrial fibrillation required pacemaker implantation due to tachycardia-bradycardia syndrome. In 4 patients, including the patient in whom BAV was the only procedure, prolonged wound healing was observed. Mean post-procedural hospitalisation time was 26.6 ± 12.5 days in the entire group. Among those discharged from hospital, this time amounted to 25.9 ± 4.8 days in TA group and 13.5 ± 3.5 days in TF group (p = 0.005).

Six-month follow-up

During 6-month follow-up, 6 patients required re-admission. One patient was re-admitted due to high risk of bleeding because of acenocumarol overdose (INR = 13), in another patient acute coronary syndrome was suspected and coronary angiography was performed in which no significant progression of atherosclerosis was noted. In another patient, suspicion of infective endocarditis was raised, and subsequently waived in the course of hospitalisation. However, prolonged wound healing at the apex was seen in this patient. In another patient after transapical implantation surgical revision of the wound in the left groin (i.e. in the region of preparation for cardiopulmoary bypass placement) was required. This patient also required a pacemaker implantation 4 months after the procedure, due to symptomatic bradycardia. Another patient was hospitalised twice for progression of heart failure and kidney disease, and the last patient was admitted for supraventricular arrhythmia. Despite the necessity of rehospitalisation, all patients are in stable, good condition, and all but one are in NYHA class II. The function of aortic prosthesis after 6 months is still normal. Selected clinical and echocardiographic data from the 6-month follow-up are presented in Tables 3 and 4.

DISCUSSION

Introduction of TAVI method to clinical practice by Cribier et al. in 2002 [5] offered a new chance for symptom relief in patients with severe aortic stenosis who were poor candidates for conventional surgery. In 2008, European Association of Cardio-Thoracic Surgeons (EACTS) and European Association of Percutaneous Cardiovascular Interventions (EAPCI) issued guidelines concerning patient selection for TAVI procedures [1]. These guidelines suggest that according to the current data concerning TAVI effectiveness, qualification should be restricted to patients who are not candidates for surgical treatment due to high perioperative risk according to commonly accepted risk scores (Logistic Euroscore > 20% and/or STS > 10%) or in whom other significant contraindications to conventional surgical treatment were found [1, 12, 13]. In our study, the majority of the patients were included due to high risk profile according to Logistic Euroscore whereas 2 patients were included based on other criteria, not included in the risk scores (porcelain aorta, high risk of infection due to haematological disturbances) and 1 patient was included based on high STS risk score. Only in 1 patient both risk scores were pointing to high risk.

In most patients (72.3%), TAVI was performed by apical approach. However, in larger groups the proportion of TA TAVI *vs* TF TAVI was reported to be as 1 to 3 [14]. In our group, higher proportion of patients undergoing TA procedure resulted from iliac and femoral arteries tortuosity and calcifications, the fact that initially the procedures were performed under proctor's supervision who performed TA; and the fact that delaying the procedure in a patient with symptomatic stenosis was hazardous. In 1 patient, despite qualification for TF concordant with manufacturer's guidance (FA diameter for 26 mm valve > 8 mm), 22 F dilator could not be introduced. The procedure ended with BAV. When qualifying for TF procedures it should be kept in mind that although the valve is inserted over the 24 F system, outer diameter of the vascular sheath is higher: 9 mm [7] and not every single artery, especially in elderly patients with diabetes can be dilated, even if its diameter is 8 mm, as the minimal requirement. This case was recorded as treatment failure in our group.

Thus, total success rate of the procedure was 91.6%; in patients operated with TF approach: 75%, and with TA approach: 100%. According to experts report, success rate in

Table 4. Echocardiographic data of patients in whom aortic valve was implanted

Parameter	Baseline (n = 11)	After procedure (n = 11)	1 month after procedure (n = 11)	3 months after procedure (n = 10)#	6 months after procedure (n = 10)#	P*
Peak gradient [mm Hg]	104.4 ± 23.9	25.2 ± 6.1	25.6 ± 5.1	21.6 ± 6.0	23.5 ± 6.0	0.000001*
Mean gradient [mm Hg]	63.8 ± 18.3	12.7 ± 3.7	12.9 ± 2.8	10.8 ± 3.3	12.1 ± 2.7	0.000004*
Aortic valve area [cm^2]	0.7 ± 0.2	1.5 ± 0.2	1.5 ± 0.2	1.5 ± 0.1	1.5 ± 0.2	0.000106*
Aortic valve area index [cm^2/m^2]	0.4 ± 0.1	0.8 ± 0.1	0.8 ± 0.2	0.8 ± 0.04	0.8 ± 0.11	0.000046*
Ejection fraction [%]	51.5 ± 7.1	51.1 ± 4.9	52.6 ± 3.7	52.0 ± 6.8	49.8 ± 5.4	NS*
AR						
None	6 (54.5%)	10 (90.9%)	10 (90.9%)	9 (90.0%)	8 (80%)	NS*
Mild (+)	3 (27.3%)	1 (9.1%)	1 (9.1%)	1 (10.0%)	1 (10%)	NS*
Moderate (++ or +++)	2 (18.2%)	0 (0%)	0 (0%)	0 (0%)	1 (10%)	NS*
Severe (> +++)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	NS*
PL						
None		9 (81.8%)	9 (81.8%)	7 (70.0%)	7 (70%)	NS*
Mild (+)		2 (18.2%)	2 (18.2%)	3 (30.0%)	3 (30%)	NS*
Moderate (++ or +++)		0 (9.1%)	0 (0%)	0 (0%)	0 (0%)	NS*
Severe (> +++)		0 (0%)	0 (0%)	0 (0%)	0 (0%)	NS*
MR						
None	1 (9.1%)	1 (9.1%)	1 (9.1%)	1 (10%)	1 (10%)	NS*
Mild (+)	3 (27.3%)	4 (36.4%)	4 (36.4%)	3 (30%)	3 (30%)	NS*
Moderate (++ or +++)	7 (63.6%)	6 (54.5%)	6 (54.5%)	6 (60%)	6 (60%)	NS*
Severe (> +++)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	NS*

*Differences between baseline and post-procedural values; #in 2 patients echocardiographic study was performed externally and some echocardiographic data were missing; AR — aortic regurgitation; PL — perivalvular leak after aortic valve replacement; MR — mitral regurgitation

experienced centres is around 90% with TA as well as with TF approach, but initially, these rates can be lower (57–84%) with TF approach [1, 6, 15, 16]. In our study, in all patients with adequate sheath in the FA, suitable for a given valve size, the valve was succesfully placed. No deaths were recorded periprocedurally and at 30 days. At 6 months there was 1 death — the patient had remained at intensive care unit since the operation, and she died there of multiorgan failure (in-hospital observation), despite good valve function, after 59 days. For high risk patients, the TAVI method offers a less invasive and safer (in terms of mortality and complication rates) alternative of conventional cardiac surgery. Mortality rates with TF approach are 5–18% and with TA approach: 9–18% [1]. In one of the recently published analyses, 30-day mortality was 11.2% in 153 patients who underwent TF procedure and 8.3% in 50 patients who were treated with TA approach [14]. The low mortality rates in our study can result from small number of patients, but also from meticulous training and the supervision of proctors during the first procedures. The last 4 TA procedures were performed without proctor supervision.

Vascular complications that are typical for TF approach, occur in 10–15% of cases and represent a frequent cause of in-hospital mortality [1]. In our group no vascular complications were observed, but in 1 patient infection and prolonged wound healing in the groin was noted. The patient died 59 days after the procedure. Another patient (TA approach) needed wound revision in the right groin due to chylorrhea that occurred several days after discharge. Revision was done in the region where FA and vein were surgically accessed and prepared for cardiopulmonary bypass placement. Such surgical preparation for cardiopulmonary bypass placement was done in the first 5 patients in whom the valve was implanted with TA approach. In the following patients, the preparation for cardiopulmonary bypass placement consisted of FA and vein puncture and guidewire insertion.

The need for cardiac pacemaker implantation is typical for self-expanding valve (ca 24%) and in case of balloon-expandable valve it can occur in 4–8% of patients. The most frequent indication for pacemaker implantation is atrio-ventricular conduction impairment [1]. In our group, pacemaker implantation was indicated in 3 patients due to symptoms of tachycardia-bradycardia syndrome. Previously published data indicate that TA technique is related to 9–12% risk of conversion to conventional operation, 30% of patients receiving cardiopulmonary bypass (10% in experienced centres) and low stroke rate (0–6%) [1]. We did not observe these complications, notwithstanding that our experience was limited at the

time. Increased risk for conventional operation, calculated by risk scores, refers to various factors describing the patient's cardiovascular status, age and comorbidities. The latter two factors increase the risk not only of death, but also of prolonged hospitalisation and in-hospital as well as post-discharge complications.

CONCLUSIONS

1. In our centre, initial experience with transcatheter implantation of E-S aortic valve confirms that the method is safe and effective in patients with high surgical risk and symptomatic aortic stenosis, who would not be qualified for surgical treatment.
2. Echocardiographic parameters of the implanted valves, assessed in-hospital and after 6 months are satisfactory, what can be related to significant clinical improvement in the majority of patients undergoing TAVI.
3. Immediately after the procedure and during short-term follow-up these patients require careful monitoring due to procedure-related complication risk and numerous comorbidities in this age group.

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References

1. Vahanian A, Baumgartner H, Bax J. Guidelines on the management of valvular heart disease: The Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology. Eur Heart J, 2007; 28: 230–268.
2. Schwarz F, Baumann P, Manthey J. The effect of aortic valve replacement on survival. Circulation, 1982; 66: 1105–1110.
3. Ross JJ, Braunwald E. Aortic stenosis. Circulation, 1968; 38 (suppl.): 61–67.
4. Iung B, Cachier A, Baron G et al. Decision-making in elderly patients with severe aortic stenosis: why are so many denied surgery? Eur Heart J, 2005; 26: 2714–2720.
5. Cribier A, Eltchaninoff H, Bash A et al. Percutaneus transcatheter implantation of an aortic valve prosthesis for calcific aortic stenosis; first human case description. Circulation, 2002; 106: 3006–3008.
6. Lichtenstein SV, Cheung A, Ye J et al. Transapical transcatheter aortic valve implantation in humans initial clinical experience. Circulation, 2006; 114: 591–596.
7. Webb JG, Chandavimol M, Thompson CR et al. Percutaneous aortic valve implantation retrograde from the femoral artery. Circulation, 2006; 113: 842–850.
8. Wilczek K, Chodór P, Przybylski P et al. Przezcewnikowe implantacje zastawek w objawowej stenozie aortalnej u chorych niebędących kandydatami do leczenia operacyjnego — wspólne zabiegi kardiologów i kardiochirurgów. Kardioch Torakoch Pol, 2008; 5: 386–396.
9. Wilczek K, Chodór P, Zembala M. Komu przezcewnikowo wszczepiać zastawkę aortalną? Czas na leczenie także w Polsce. Kardiol Pol, 2008; 66: 1148–1152.
10. Przybylski R, Wilczek K, Zembala M et al. Przezkoniuszkowe, małoinwazyjne wszczepienie zastawek aortalnych u dwóch kobiet z ciężką objawową stenozą aortalną i współistniejącymi obciążeniami szansą dla najtrudniejszych chorych. Pierwsze polskie pomyślne doświadczenia. Kardiol Pol, 2008; 66: 1350–1356.
11. Wilczek K, Chodór P, Przybylski R et al. Pierwsze w Polsce przezcewnikowe, z dostępu przez tętnicę udową wszczepienie zastawki aortalnej u starszej chorej z ciężką stenozą aortalną wysokiego ryzyka — nowe doświadczenie ośrodka zabrzańskiego. Kardiol Pol, 2009; 67: 219–223.
12. http://www.euroscore.org.
13. http://www.sts.org.
14. Bleiziffer S, Ruge H, Mazzitelli D et al. Survival after transapical and transfemoral aortic valve implantation: talking about two different patient populations. J Thorac Cardiovasc Surg, 2009; 138: 1073–1080.
15. Cribier A. Treatment of calcific aortic. J Am Coll Cardiol, 2006; 47: 1214–1223.
16. Grube E, Laborde JC, Gerckens U et al. Percutaneous implantation of the CoreValve self-expanding valve prosthesis in high-risk patients with aortic valve disease: the Siegburg first-in-man study. Circulation, 2006; 114: 1616–1624.

Wyniki bezpośrednie i obserwacji 6-miesięcznej leczenia chorych ze stenozą zastawki aortalnej za pomocą wszczepienia protezy Edwards-Sapien drogą przezkoniuszkową i przez tętnicę udową

Piotr Chodór[1], Krzysztof Wilczek[2], Romuald Przybylski[3], Marcin Krasoń[3], Jan Głowacki[4], Tomasz Niklewski[3], Tomasz Podolecki[1], Zbigniew Kalarus[1], Lech Poloński[2], Marian Zembala[3]

[1]Katedra Kardiologii, Wrodzonych Wad Serca i Elektroterapii, Oddział Kliniczny Kardiologii, Śląski Uniwersytet Medyczny w Katowicach, Śląskie Centrum Chorób Serca, Zabrze

[2]III Katedra i Oddział Kliniczny Kardiologii, Śląski Uniwersytet Medyczny w Katowicach, Śląskie Centrum Chorób Serca, Zabrze

[3]Katedra Kardiochirurgii i Transplantologii, Oddział Kliniczny Kardiochirurgii i Transplantologii, Śląski Uniwersytet Medyczny w Katowicach, Śląskie Centrum Chorób Serca, Zabrze

[4]Pracownia Tomografii Komputerowej, Śląski Uniwersytet Medyczny w Katowicach, Śląskie Centrum Chorób Serca, Zabrze

Streszczenie

Wstęp: Ciężkie objawowe zwężenie zastawki aortalnej jest jednoznacznym wskazaniem do operacyjnej jej wymiany zapewniającej ustąpienie dolegliwości i wydłużenie przeżycia. Około 1/3 chorych w wieku podeszłym nie jest operowanych z powodu m.in. wysokiego ryzyka operacyjnego i schorzeń współistniejących. Cribier zapoczątkował przezcewnikowe wszczepianie zastawek aortalnych (TAVI).

Cel: Celem pracy jest przedstawienie wyników bezpośrednich pierwszych zabiegów TAVI Edwards-Sapien u objawowych chorych z wysokim ryzykiem leczenia operacyjnego lub innymi przeciwwskazaniami do klasycznej operacji, a także wyników obserwacji 6-miesięcznej.

Metody: Analizie poddano 12 chorych zakwalifikowanych do TAVI. Zastawkę wszczepiono u 11 osób, u 1 chorej zabieg zakończono, wykonując walwuloplastykę zastawki aortalnej. U 8 (72,7%) pacjentów zastawkę wszczepiono drogą przezkoniuszkową (TA), a u 3 (27,3%) — przez tętnicę udową (TF). Wszczepiono 7 (63,6%) zastawek o rozmiarze 26 mm i 4 (34,4%) o rozmiarze 23 mm.

Wyniki: Skuteczność zabiegu wyniosła 92% (11/12), w grupie TA — 100%, a w grupie TF — 75%. W czasie zabiegu u 1 chorego zaobserwowano migotanie komór, u 1 — migotanie przedsionków i perforację prawej komory elektrodą endokawitarną. U 4 pacjentów po zabiegu stwierdzono przedłużone gojenie się rany, u 2 — pokontrastową niewydolność nerek. W obserwacji 30-dniowej nie zmarł żaden chory. U 2 osób wszczepiono układ stymulujący serca w okresie wewnątrzszpitalnym. Parametry echokardiograficzne przed zabiegiem i po nim istotnie się poprawiły: gradient maksymalny przez zastawkę aortalną: 104,4 ± 23,9 *v.* 25,2 ± 6,1 mm Hg; p = 0,000001; gradient średni: 63,8 ± 18,3 *v.* 12,7 ± 3,7 mm Hg; p = = 0,000004; pole powierzchni zastawki aortalnej: 0,7 ± 0,2 *v.* 1,5 ± 0,2 cm^2; p =0,000106. W ciągu 6-miesięcznej obserwacji zmarła 1 chora z powodu niewydolności wielonarządowej (zgon wewnątrzszpitalny), a 6 osób wymagało ponownej hospitalizacji. Po 6 miesiącach u wszystkich osób, poza jedną, stwierdzono poprawę wydolności (NYHA II — 9 chorych, NYHA III — 1 chora).

Wnioski: 1. Początkowe doświadczenia autorów z zabiegów TAVI Edwards-Sapien potwierdzają, że jest to metoda bezpieczna i skuteczna u chorych z wysokim ryzykiem operacyjnym i objawowym zwężeniem zastawki aortalnej. 2. Parametry echokardiograficzne wszczepionych zastawek oceniane w okresie wewnątrzszpitalnym i w obserwacji 6-miesięcznej są zadowalające. 3. Po zabiegu i w obserwacji krótkoterminowej pacjenci wymagają wnikliwej obserwacji ze względu na ryzyko powikłań.

Słowa kluczowe: zwężenie zastawki aortalnej, przezcewnikowa implantacja zastawki aortalnej, zastawka Edwards-Sapien

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Adres do korespondencji:
dr n. med. Piotr Chodór, Katedra Kardiologii, Wrodzonych Wad Serca i Elektroterapii, Oddział Kliniczny Kardiologii, Śląski Uniwersytet Medyczny w Katowicach, Śląskie Centrum Chorób Serca, ul. Szpitalna 2, 41–800 Zabrze, e-mail: chodor_piotr@go2.pl
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