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Transcatheter aortic valve implantation using transfemoral/transsubclavian or transapical approach: 30-day follow-up of the initial 30 patients

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Abstract

Background: Transcatheter aortic valve implantation (TAVI) is a new method for the treatment of aortic stenosis (AS).

Aim: To evaluate early results of TAVI using transfemoral/transsubclavian approach (TFA/TSA) or transapical approach (TAA) in patients with severe AS and high risk for surgical aortic valve replacement.

Methods: Between January 2009 and May 2010, 30 high-risk patients underwent TAVI. The primary treatment option was TFA, and TAA was used if contraindications to TFA were present; one patient underwent the procedure using TSA. Reasons for selecting TAA were as follows: small diameter (< 7 mm) and/or severe calcification of the iliofemoral arteries, peripheral atherosclerosis, "porcelain" aorta and a horizontal course of the ascending aorta. Edwards-Sapien or CoreValve devices were used in all cases, and procedures were performed without the use of cardiopulmonary bypass in a cardiac catheterisation laboratory.

Results: Mean patient age was 82.46 ± 5.79 years, mean NYHA class was 3.23 ± 0.41, and predicted mean surgical mortality using logistic Euroscore was 29.18 ± 16.9% (22.72 ± 12.07% in the TFA/TSA group *vs* 34.6 ± 15.4% in the TAA group; p = 0.031). Eleven patients were treated using TAA. The valve was implanted successfully in 96% of patients. In-hospital mortality was 3.3%. Mean 30-day mortality was 6.6% in the entire cohort, 0% in the TFA/TSA group and 18% in the TAA group. There were no cases of periprocedural myocardial infarction (MI), cardiogenic shock, stroke/transient ischaemic attack, or need for cardiopulmonary resuscitation. One patient died suddenly three weeks after the procedure; except for this case, there were no major adverse cardiovascular events (MACCE: MI, cerebrovascular accident, re-do procedure) at 30--day follow-up. The TAVI was associated with a significant reduction in the mean maximal aortic gradient in both groups (from 99.6 ± 22.07 mm Hg to 21.83 ± 9.38 mm Hg post-procedure and to 23.25 ± 9.22 mm Hg at 30-day follow up), with no cases of severe aortic valve regurgitation. The NYHA class at 30 days improved from 3.23 ± 0.41 to 1.72 ± 0.52 (p = 0.03).

Conclusions: Our results demonstrate lower 30-day complication rate and mortality in the TFA/TSA group. The availability of several techniques of valve implantation in the group of non-surgical patients with severe AS potentially broadens the patient population with indications for this treatment.

Key words: TAVI, transcatheter aortic valve implantation, transapical approach, transfemoral approach

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INTRODUCTION

Acquired aortic stenosis (AS) is the most prevalent valvular heart disease that becomes one of the major challenges in modern cardiology practice due to aging of the population [1–4]. The AS affects about 5% of patients above 75 years of age. Medical treatment does not improve prognosis in patients with severe AS, and the treatment of choice is surgical aortic valve replacement (AVR) using a mechanical or biological valve prosthesis [3, 5]. However, data from the Euro Heart Survey suggest that significant perioperative mortality in older patients with comorbidities results in nearly one third of patients (approximately 3000 patients in Poland) being not referred for surgery [4, 5].

In recent years, with introduction of a new treatment modality, transcatheter aortic valve implantation (TAVI), treatment options in patients with AS requiring invasive treatment have expanded significantly [4, 6–12]. The group that might benefit most from the introduction of TAVI are older patients with multiple comorbidities and a high risk of major complications, including death, during cardiac surgery that requires sternotomy and the use of cardiopulmonary bypass [1, 13, 14].

TAVI is usually performed using transvascular approach through the femoral artery (transfemoral approach — TFA) or, the left subclavian artery (transsubclavian approach — TSA), or via lateral minithoracotomy through the left ventricular (LV) apex (transapical approach — TAA). Occasionally, the procedure is performed through the ascending aorta via ministernotomy.

The purpose of this study was to compare periprocedural and 30-day outcomes of TAVI using transvascular (TFA/TSA) or TAA approach in patients with severe AS who were not candidates for surgical treatment.

METHODS

CoreValve and Edwards Sapien devices

The CoreValve prosthesis (Medtronic Inc.), made from porcine pericardium and mounted on a self-expanding nitinol stent, is implanted using an 18 F system designed for subclavian, femoral, and iliac arteries with the lumen diameter of at least 6.5 mm. The device is manufactured in two sizes, 26 and 29 mm, and dedicated for patients with the native aortic annulus diameter ranging from 19 to 27 mm. It has received the CE mark for transvalvular implantation only (through the common femoral artery or the left subclavian artery).

Edwards-Sapien and Edwards-Sapien XT prostheses (Edwards Lifesciences) are made for bovine pericardium and mounted on a balloon-expanded cobalt-chromium (previously stainless steel) stent. For transvalvular implantation of the device, a new 18 F system is currently used, designed for arteries with the lumen diameter of at least 7 mm (in our center, 6 out of 8, i.e. 75% of patients were treated using 22 F and 24 F systems). The device is manufactured in two sizes, 23 and 26 mm, and dedicated for patients with the native aortic annulus diameter ranging from 17 to 24.5 mm. The Edwards-Sapien device has received the CE mark for both transvalvular and transapical implantation.

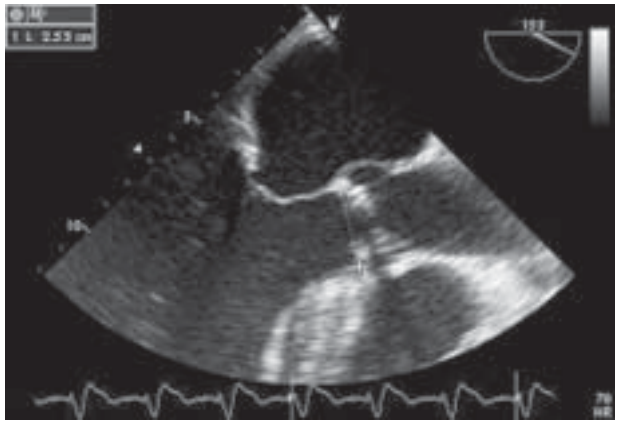

Figure 1. Transoesophageal echocardiography. Evaluation of the aortic annulus diameter

Patient selection

Patients with symptomatic AS selected for TAVI were not candidates for surgical treatment due to high operative risk (logistic Euroscore > 20% coronary artery disease, end-stage renal failure requiring dialysis treatment, chronic pulmonary disease, pulmonary hypertension defined as pulmonary artery systolic pressure > 60 mm Hg) or other contraindications to surgery that are not included in the risk scores ("porcelain" aorta, previous chest radiotherapy, previous pulmonary lobectomy, severe osteoporosis with chest deformities and/or leading to delayed sternal wound healing in patients with a history of compression spinal fractures, cirrhosis with portal hypertension, previous chest surgery, cognitive dysfunction due to neurological disease). During evaluation for TAVI, transthoracic (TTE) and transoesophageal (TEE) echocardiography was performed to assess aortic valve morphology, diameters of the aortic annulus, aortic root, and ascending aorta (Fig. 1), aortic valve area, and peak and mean transvalvular gradient. In addition, computed angiotomography (angio-CT) was performed to assess the anatomy of aortic valve, aortic root, and the ascending aorta, the distance between coronary ostia and the aortic valve, aortic anatomy including the presence of calcifications and thrombi, and the diameter and the course (tortuosity) of iliac and femoral arteries (Fig. 2A, B). Invasive angiographic evaluation was also performed to assess angle between left ventricle and ascending aorta, dimensions of coronary sinuses and aortic root, the diameter and the course of the ascending aorta, and the diameter and the course of iliac and femoral arteries.

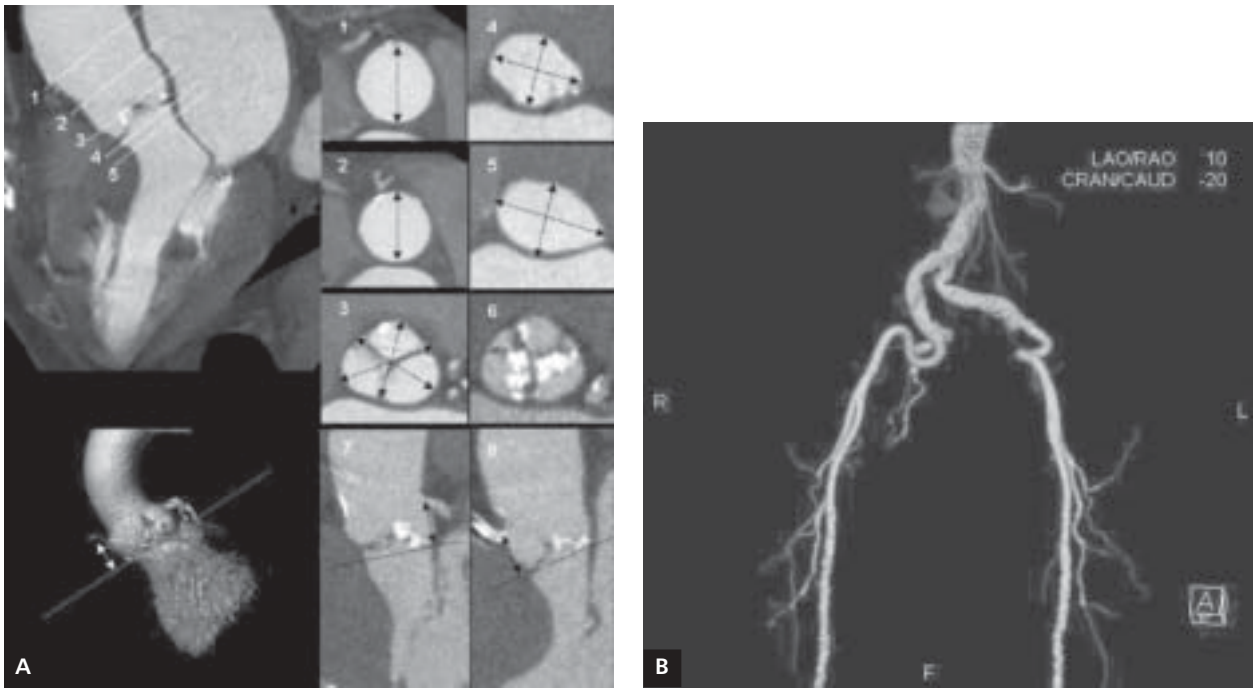

Figure 2. Computed angiotomography. Evaluation of the anatomy of the aortic valve, left ventricular outflow tract, aortic root and ascending aorta, and the distance between coronary ostia and the aortic valve (**A**). Evaluation of calcifications and thrombi, and the diameter and the course of iliac and femoral arteries (**B**). In this case, transapical approach was chosen due to tortuous course of the iliac arteries

In patients selected for TAVI, the primary approach we considered was TFA.

Contraindications for TFA included massive calcifications, tortuosity or small diameter of iliac or common femoral arteries (< 6.5 mm for the CoreValve device, < 7 mm for the Edwards-Sapien system), abdominal and/or thoracic aortic aneurysm, "porcelain" ascending aorta, and previous surgery involving these vessels.

Device type was selected based on measurements performed during invasive angiography, TTE, TEE and angio-CT (aortic annulus diameter, height of coronary sinuses, width of coronary sinuses, ascending aorta diameter) and the planned approach during TAVI, with TFA being the approach of choice. If TFA was contraindicated, patients were considered for TSA. If both TFA and TSA were not feasible, we selected TAA, possible only with the use of the Edwards-Sapien system.

Patients

The present analysis includes 30 consecutive patients who underwent TAVI. All patients were informed of the procedural details and risk and gave written informed consent for this treatment. All procedures were performed in our department between January 8, 2009, and May 13, 2010. All patients were referred for TAVI due to previous disqualification from surgery and high operative risk (mean logistic Euroscore 29.18 ± 16.9%). Baseline characteristics of the patients are shown in Table 1.

Valve implantation procedure

All procedures were performed in a cardiac catheterisation laboratory by the heart team that included invasive cardiologists, cardiac surgeons, vascular surgeon, anaesthesiologist, echocardiographer, invasive cardiac nurses and surgical nurses, and radiology technicians. Procedures were done under angiographic and TTE (CoreValve system) or TEE (Edwards-Sapien system) guidance, in general or local anaesthesia and sedation, without the use of cardiopulmonary bypass. Vascular access was obtained by cannulation of the right or left common femoral artery, with postprocedural vascular access closure using the ProStar XL system (n = 13), or by surgical exploration of the femoral or subclavian artery that was surgically sealed after the procedure (n = 6).

Transapical device implantation (n = 11) was performed by left anterolateral minithoracotomy, with postprocedural surgical closure of the apex and the chest wall with left pleural drainage.

Before the procedure, a temporary pacing lead was inserted into the right ventricle through a jugular or femoral vein. Device implantation was always preceded by balloon valvulo-

Table 1. Baseline patient characteristics

Variable	TFA/TSA (n = 19)	TAA (n = 11)	P
Age [years]	82.05 ± 5.4	83.18 ± 6.35	NS
Women	12/19 (66.6%)	9/11 (81.8%)	NS
Logistic Euroscore [%]	22.72 ± 12.07	34.60 ± 15.4	0.03
NYHA class	3.21 ± 0.4	3.27 ± 0.44	NS
Max. aortic gradient [mm Hg]	92.84 ± 20.56	111.27 ± 19.56	0.03
Aortic valve area [cm^2]	0.66 ± 0.11	0.7 ± 0.14	NS
Aortic annulus diameter	22.87 ± 1.16	22 ± 1.34	NS
Pulmonary artery pressure	53.6 ± 11.41	58.6 ± 11.38	NS
LVEF < 50%	7/19 (36.84%)	4/11 (36.36%)	NS
LVEF [%]	53.7 ± 12.6%	50.9 ± 13%	NS
Coronary artery disease:	14/19 (73.68%)	8/11 (72.72%)	NS
Previous MI	3/19 (15.79%)	4/11 (36.36%)	NS
Previous PTCA	6/19 (31.58%)	5/11 (45.45%)	NS
Previous CABG	1/19 (5.26%)	1/11 (9.09%)	NS
Peripheral arterial disease	6/19 (31.58%)	8/11 (72.72%)	0.03
Carotid artery disease	2/19 (10.5%)	3/11 (27.27%)	NS
COPD	7/19 (36.84%)	5/11 (45.45%)	NS
Pulmonary hypertension	11/19 (57.9%)	8/11 (72.72%)	NS
GFR	58.32 ± 16.76	49.5 ± 16.63	NS
Osteoporosis	3/19 (15.79%)	1/11 (9.09%)	NS
"Porcelain" aorta	0	1/11 (9.09%)	NS

Pulmonary hypertension was defined as peak pulmonary artery systolic pressure ≥ 60 mm Hg; NYHA — New York Heart Association; LVEF — left ventricular ejection fraction; MI — myocardial infarction; PTCA — percutaneous transluminal coronary angioplasty; CABG — coronary artery bypass grafting; COPD — chronic obstructive pulmonary disease; GFR — glomerular filtration rate

plasty of the stenosed aortic valve during rapid (160–200/min) cardiac pacing. The device was implanted into the aortic annulus under fluoroscopic guidance. Self-expandable CoreValve device was implanted during basic heart rhythm (Fig. 3), and balloon-expandable Edwards-Sapien valve was expanded using a balloon during rapid cardiac pacing (Fig. 4). Details of the implantation process were presented previously [8, 9, 12, 15–19]. The position and function of the implanted valve was evaluated angiographically and echocardiographically. If moderate/severe perivalvular regurgitation was found, the device was expanded using an appriopriately sized balloon during rapid cardiac pacing (in 6/30, or 20% of patients). After the procedure, patients were transported to an intensive care unit or a postoperative room.

In-hospital and 30-day follow-up

The effectiveness of TAVI was evaluated immediately after the procedure by direct (invasive) pressure gradient measurements and also using TTE or TEE. Before discharge, procedural results were verified clinically and echocardiographically (TTE). Follow-up visits were scheduled in our department at 30 days, 3, 6 and 12 months, and every 6 months thereafter. Follow-up evaluation included history, physical evaluation,

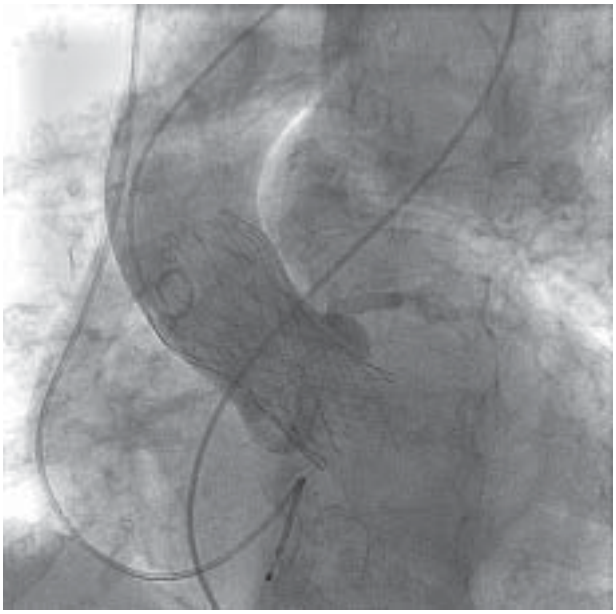

Figure 3. The CoreValve device in the aortic annulus, successfully implanted using the transfemoral approach. Control injection of the contrast agent to the ascending aorta is seen after the device was separated from the insertion catheter

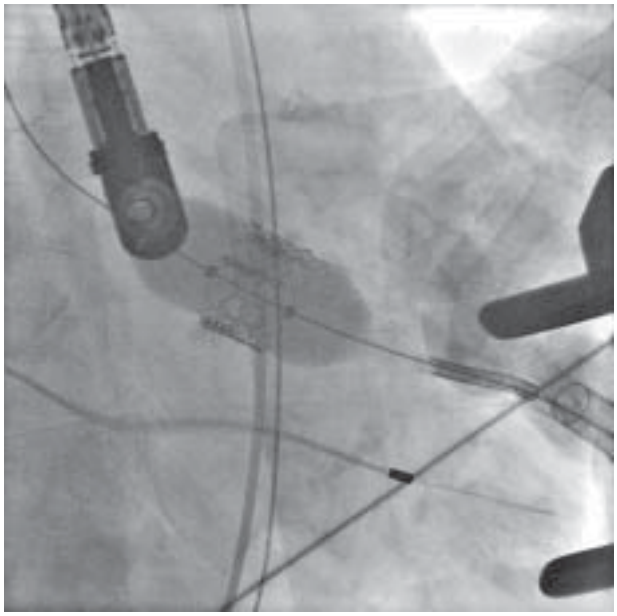

Figure 4. Implantation of the Edwards-Sapien device under transoesophageal echocardiography guidance using the transapical approach. This angiogram shows a 22 F sheath introduced to the left ventricle by myocardial puncture in the apical area (lower right) and transoesophageal echocardiography probe (upper left). Balloon inflation and valve implantation into the native aortic valve is seen

general clinical assessment, data regarding adverse events, TTE (or TEE in selected patients for better device visualisation), ECG, and routine biochemical testing.

Database and statistical analysis

Patient demographic data, procedural details, and data from periprocedural and 30-day follow-up were collected in a computerised database. Continuous variables are shown as mean values ± SD, and categorical variables as percentages. Two-sided Student t test for paired samples was used to compare selected clinical and echocardiographic data in both groups. A p value < 0.05 was considered statistically significant.

RESULTS

Among 38 patients initially selected for TAVI, the procedure was performed in 30 (79%) patients (TAA n = 11; TFA n = 18; TSA n = 1). Two (5.2%) patients did not give consent for the procedure. Two (5.2%) patients died following the initial qualification due to complications of severe AS. In two (5.2%) patients, anatomy was found to be not favourable for TAVI (annulus diameter > 27 mm). Two (5.2%) patients were ultimately treated medically due to comorbidities and relatively short life expectancy. Mean patient age in those treated with TAVI was 82.46 ± 5.79 years, and predicted mean surgical mortality using logistic Euroscore was 29.18 ± 16.9% (Table 1).

TAVI procedure

Successful device implantation was performed in 29 (96%) patients. In one patient in the TFA group, 24 F vascular sheath could not be passed through the common iliac artery and the device was not implanted; the only treatment performed was balloon aortic valvuloplasty that reduced the transvalvular gradient from 70 to 35 mm Hg in echocardiographic evaluation. One patient needed implantation of second Edwards-Sapien device during the same procedure due to a leak through one of the leaflets of valve prosthesis and severe aortic regurgitation ("valve-in-valve" implantation). In another patient, a CoreValve device was implanted too low, resulting in poorly tolerated perivalvular aortic regurgitation. During another session, the device was repositioned using a loop, resulting in reduction of the regurgitant jet and significant clinical improvement. None of the patients required cardiopulmonary resuscitation or cardiopulmonary bypass during the procedure. Two patients required small doses of catecholamines during and shortly after the procedure.

Transapical approach during TAVI was related with significantly lower amounts of the contrast agent used and shorter fluoroscopy duration, but the total procedure time was longer during transpical approach compared to the transvascular approach (Table 2).

Immediate results and in-hospital follow-up

Overall in-hospital mortality was 3.3% (TAA 9% *vs* TFA 0%, p = 0.19). One patient in the TAA group died several hours

Table 2. The procedure and hospitalisation

Variable	TFA/TSA (n = 19)	TAA (n = 11)	P
Amount of contrast agent [mL]	210 ± 63	159 ± 51	0.03
Fluoroscopy duration [min]	37.7 ± 22	18.7 ± 5.6	0.01
Procedure duration [min]	174 ± 32	221 ± 58	0.046
Successful implantation	18/19 (94.7%)	11/11 (100%)	NS
Max. aortic gradient after TAVI [mm Hg]	22.32 ± 10.39	19.7 ± 7.8	NS
Significant aortic regurgitation	0/19 (0%)	0/11 (0%)	
In-hospital mortality	0/19 (0%)	1/11 (9%)	NS
Duration of hospitalisation [days]	11.8 ± 8.52	18 ± 10.78	NS

after the procedure due to rupture of the native aortic annulus, despite urgent cardiac surgery. This complication most likely resulted from implantation of a too large Edwards-Sapien device. In all patients, substantial reduction of the transvalvular aortic gradient was seen both in direct measurements immediately after the procedure and in the follow-up TTE performed before discharge (mean maximal gradient 99.6 ± 22.07 mm Hg before TAVI *vs* 21.83 ± 9.38 mm Hg after TAVI). Although preprocedural maximal aortic gradient was significantly higher in the TAA group (p = 0.027), equally good results of the procedure were seen in both groups. Except for one (3.3%) patient requiring reposition of the CoreValve device using a loop due to significant regurgitation, we did not observed significant trans- or perivalvular regurgitation either immediately after the procedure or in the follow-up TTE performed before discharge (Table 2).

Except for one patient who required urgent cardiac surgery and died, as noted above, we did not see any other serious adverse events during hospitalisation such as myocardial infarction, cardiogenic shock, stroke/transient ischaemic attack, or need for cardiopulmonary resuscitation or cardiopulmonary bypass. Due to atrioventricular conduction disturbances, a cardiac pacemaker was implanted following TAVI in 9 (30%) patients, including two (18%) in the TAA group and seven (36.8%) in the TFA/TSA group. Pleural effusion was seen in two patients after TAA. One patient was treated with pleuracentesis and evacuation of approx. 1000 mL of fluid, and the other patient was treated medically. Peripheral embolism was seen in one patient in the TFA group, leading to worsening of pre-existing foot gangrene. Following vascular surgeon consultation, partial foot amputation was subsequently performed. One patient with a history of peptic ulcer disease in the TFA group experienced massive upper gastrointestinal bleeding following TAVI and was transferred to a department of gastrointestinal surgery for operative treatment. One patient in the TFA group required stent implantation due to iatrogenic stenosis of the femoral artery that was previously sealed using the ProStar system. Three patients, including two in the TFA group and one in the TAA group, experienced inguinal haematoma in the first few days following TAVI. One of these patients required surgical treatment. Transient disorientation was seen in the first days after the procedure in two patients in the TAA group, responding to hydration. In one patient in the TAA group, thrombocytopenia resulting in significantly prolonged hospital stay was seen, probably due to heparin administration during TAVI. Overall, the mean duration of hospitalisation after the procedure was 14.5 ± 9.47 days (18 ± 10.78 days in the TAA group *vs* 11.8 ± 8.52 days in the TFA/TSA group). In-hospital complications are summarised in Table 3.

30-day follow-up

During 30-day follow-up, one (3.3%) patient in the TAA group died suddenly at home, three weeks after TAVI. At 30 days, three (10%) patients were still hospitalised, including the patient with thrombocytopenia in the TAA group and two patients in the TFA/TSA group — one who underwent partial foot amputation and one who underwent surgical treatment of the upper gastrointestinal bleeding, respectively. The remaining patients did not require any additional hospitalisations. No patient experienced other serious cardiac adverse events or worsening of the renal failure requiring dialysis therapy. 28 patients showed up for the 30-day follow-up visit, with evaluation including history, physical examination, ECG, TTE and basic laboratory tests. Overall, mean exercise tolerance as measured using the New York Heart Association (NYHA) classification improved from 3.23 ± 0.41 before the procedure to 1.72 ± 0.52 at 30 days after the procedure (p = 0.03). Data on NYHA class in both groups at baseline and at 30 days are shown in Tables 1 and 4. Overall, mean maximal aortic gradient in TTE at 30 days after TAVI was 23.25 ± ± 9.22 mm Hg, and 30-day mortality was 6.6% (18% in the

Table 3. Complications of TAVI

Variable	TFA/TSA (n = 19)	TAA (n = 11)	P
Urgent cardiac surgery	0	1 (9%)	NS
Periprocedural death	0	1 (9%)	NS
Myocardial infarction/cardiogenic shock	0	0	
Stroke/transient ischaemic attack	0	0	
Pacemaker implantation	7 (36.9%)	2 (18%)	NS
Pleural effusion	0	2 (18%)	NS
Peripheral embolism	1 (5.26%)	0	NS
Gastrointestinal bleeding	1 (5.26%)	0	NS
Iatrogenic femoral artery stenosis	1 (5.26%)	0	NS
Inguinal haematoma	3 (15.79%)	2 (18%)	NS
Thrombocytopenia	0	1 (9%)	NS

Table 4. Results at 30-day follow-up

Variable	TFA/TSA (n = 19)	TAA (n = 9)	P
Age [years]	82.05 ± 5.4	83.18 ± 6.35	NS
Women	12/19 (66.6%)	9/11 (81.8%)	NS
NYHA class	1.78 ± 0.55	1.6 ± 0.48	NS
Max. aortic gradient [mm Hg]	24.7 ± 10.4	20.7 ± 6.1	NS
Significant aortic regurgitation	0/18 (0%)	0/10 (0%)	
Left ventricular ejection fraction < 50%	7/19 (36.84%)	4/11 (36.36%)	NS
Left ventricular ejection fraction [%]	59.8 ± 8.8%	59.4 ± 9.8%	NS
Death	0 (0%)	2 (18%)	0.05

TAA group *vs* 0% in the TFA/TSA group; p = 0.05). Selected clinical and echocardiographic data at 30-day follow-up are shown in Table 4.

DISCUSSION

The first TAVI procedure was performed through the femoral vein and interatrial septum by Cribier in 2002. Two years later, in July 2004, cardiologists Laborde, Lal and Grube performed the first transarterial aortic valve implantation, and in November 2005, invasive cardiologist Webb and cardiac surgeon Lichtenstein implanted the aortic valve into a beating heart using LV transapical approach. The first transcatheter TAVI implantation was performed by invasive cardiologists Serruys, DeJaegere and Laborde in October 2006 [4, 6, 17, 20].

The first TAVI procedure in Poland was performed in November 2008 in Cracow, and Zabrze, Katowice and Warsaw-Anin soon followed. By September 2010, approx. 160 implantations of Edwards Sapien and CoreValve devices were performed in 10 centres in Poland. First results of transcatheter treatment of patients with AS in Poland were presented in the POL-TAVI-First registry [21] and by Kapelak et al. [22].

Since the very first TAVI, it has been debated which of these approaches is the most effective and the safest. Minithoracotomy with opening of the pleura and the pericardium and LV apical puncture, required for transapical implantation, is more invasive and probably should be performed in the hybrid operation theatre. However, they allow avoidance of quite aggressive manipulation within peripheral arteries and aortic arch, and the duration of the implantation procedure is shorter. According to the 2008 European Association of Cardiac and Thoracic Surgeons (EACTS) guidelines, TAVI should be offered to patients with AS who were disqualified from surgery due to high operative risk or other contraindications to surgery, and the choice of implantation approach is left to the discretion of the operator [1, 23].

In our study, transcatheter treatment was offered to patients with a very high risk of surgical AVR, as determined by thorough evaluation of the clinical condition of the patient, comorbidities, and the predicted operative risk estimated using logistic Euroscore. In two female patients aged 83 and 77 years, we decided to perform TAVI following surgical disqualification despite relatively low values of logistic Euroscore (15.9% and 6.59%) due to advanced osteoporosis with compression fractures of thoracic and lumbar vertebrae.

In patients scheduled for TAVI, transfemoral approach was initially considered. If TFA was contraindicated (in 40% of patients in our group), we considered TSA and this approach was selected in one (3.3%) patient. The TAA was selected in 11 (36.6%) of our patients with contraindications to both TFA and TSA.

The algorithm of TAVI approach selection is primarily based on the presence of comorbidities. Advanced peripheral arterial disease is a contraindication to TFA and thus it was more prevalent in the TAA group (73% *vs* 31%; p = 0.02). In addition, a diffuse nature of atherosclerosis results in more prevalent coronary and carotid artery disease in these patients, with all clinical consequences such as history of myocardial infarction, percutaneous transluminal coronary angioplasty or coronary artery bypass grafting that was twice as common in the TAA group than in the TFA/TSA group, although the difference was not statistically significant due to low numbers of patients (Table 1). Other contraindications to TFA include small diameter (< 6.5–7 mm), tortuous course and extensive calcification in common femoral arteries, iliac arteries and/or aorta, "porcelain" aorta, and a horizontal course of the ascending aorta.

Despite these comorbidities and baseline differences between the two groups, as reflected by mean logistic Euroscore (34.6% in the TAA group *vs* 22.7% in the TFA/TSA group; p = 0.03), the choice of implantation approach had no significant effect on the effectiveness of treatment as evaluated both immediately after the procedure (Table 2) and at 30 days (Table 4). In published registries and observational studies, 30-day mortality following TAVI using TFA/TSA ranged from 0% to 25% [8, 9, 19, 24–27]. In our group of 19 patients who underwent TAVI using TFA/TSA, we did not

see any deaths both in the periprocedural period and at 30 days. In other reports regarding TAVI using TAA (performed in groups of 26–59 patients), 30-day mortality was 8–23% [16, 28–31]. In our study, 2/11 (18%) patients died among these treated with TAVI using TAA.

In addition to the previously noted problems and comorbidities, complications specific for the implantation approach have been reported in the literature regarding TAVI. Complications reported in patients treated using transvascular approach include rupture of a peripheral vessel, acute arterial occlusion or stenosis, and severe bleeding requiring vascular surgical intervention. These complications occurred in 9–20% patients treated with TFA/TSA [9, 19, 24–27].

In contrast, patients undergoing TAVI with TAA are most likely to experience chest wall bleeding, and occasionally bleeding from the site of the LV apex puncture. Surgical intervention for bleeding was necessary in 8–14% of patients treated using TAA [16, 30, 31]. Other rare but severe complication of TAA is the development of a LV pseudoaneurysm [32].

In our patients, we saw typical complications related to the route of the device implantation (Table 3). Evaluation with TTE at 30 days did not show other problems reported in the literature [30–32] such as LV wall motion abnormalities, thinning or weakening in the apical area. Published data show that valve implantation using TAA is associated with 9–12% risk of conversion to cardiac surgical procedure, while the use of cardiopulmonary bypass is required in 10–30% of patients [1]. In our group treated using TAA, only one (9%) patient required cardiac surgical intervention due to rupture of the aortic annulus.

In summary, acute complications related to the implantation approach for TAVI may occur with both TAA and TFA, may be potentially life-threatening and require urgent and careful invasive or surgical treatment [1]. Of note, according to the latest reports, mainly from the Source Registry, vascular complications of TFA/TSA do not lead to increased in-hospital mortality in contrast to TAA complications [33].

Apart from approach-specific complications, outcomes may also be affected by differences in the implantation procedure itself. The TAA is easier and more controllable for the operator, and it does not require angiography of the aortic bifurcation, iliac arteries, and femoral arteries. Thus, the amount of contrast used and fluoroscopy time are reduced, although the procedure is longer to complete and requires general anaesthesia.

Pacemaker implantation related to atrioventricular conduction disturbances has been more frequently reported following the CoreValve device implantation (25%) and is less frequent among patients treated with balloon-expandable valves (4–8%) [1]. This problem is related to differences in valve design, its anchoring, and radial forces generated by a large nitinol frame of the CoreValve device that act on the subvalvular region of the LV, and particularly the interventricular septum. In our study group, patients in the TFA/TSA group required pacemaker implantation more often than patients in the TAA group (2/11 patients, or 18%, in the TAA group *vs* 7/19 patients, or 37%, in the TFA/TSA group; $p = 0.29$). Overall, pacemaker insertion was necessary in 3/18 (16%) of patients treated with balloon-expandable Edwards-Sapien device, compared to 6/11 (54%) of patients treated with self-expandable CoreValve device with a nitinol frame ($p = 0.025$).

So far, it has not been proven that TAA leads to reduction of neurological complications. Review of the available literature indicates, however, that the risk of a neurological event in patients treated using TAA is 0–5% [16, 31, 34], compared to 0–20% among patients treated using TFA [9, 19, 24–26]. These differences may be related to the need of manipulating a relatively stiff transfemoral valve implantation system within the aortic arch. In our study, we noted no serious neurological complications in any of the patients in both groups.

As with all new treatment modalities, some complications may be related to the learning curve [19]. Our data from the immediate and 30-day follow-up are consistent with such a possibility. In-hospital mortality was 6.6% (1/15) among the first 15 patients and (0/15) among the remaining 15 patients.

CONCLUSION

In our opinion, good results of TAVI depend on proper patient selection including careful consideration of contraindications to TAA/TFA/TSA and AVR, and the experience of the heart team. Final decisions should be taken by a heart team including clinical cardiologists, invasive cardiologists and cardiac surgeons, taking into account the clinical condition of the patient and full spectrum of diagnostic data including imaging studies. Our experience with the first 30 patients indicates that transvascular TAVI approach (TFA/TSA) is associated with lower risk of complications, including mortality, during 30-day follow-up. It should be stressed, however, that the availability of several alternative implantation approaches resulting in a larger number of patients with AS referred for TAVI who may ultimately benefit from this treatment modality.

Conflict of interest: *none declared*

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Przezcewnikowa implantacja zastawki aortalnej z dostępu naczyniowego i przezkoniuszkowego: obserwacje 30-dniowe 30 pierwszych pacjentów

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Streszczenie

Wstęp i cel: Celem niniejszej pracy jest porównanie wyników przezcewnikowej implantacji zastawki aortalnej (TAVI), z dostępu przeznaczyniowego [od tętnicy udowej (TFA) lub podobojczykowej (TSA)] i przezkoniuszkowego (TAA) u pacjentów z ciężkim zwężeniem zastawki aortalnej zdyskwalifikowanych z leczenia chirurgicznego w okresie bezpośrednio po zabiegu i w obserwacji 30-dniowej.

Metody: Analizą objęto 30 kolejnych pacjentów poddanych zabiegowi TAVI z dostępu TFA (18 osób), TSA (1 chory) lub TAA (11 pacjentów). Wszystkie zabiegi wykonano w Samodzielnej Pracowni Hemodynamicznej IK w Warszawie między 8.01.2009 a 13.05.2010 r. Dostępem pierwszego wyboru był TFA, natomiast drugiego wyboru — TAA, przy przeciwwskazaniach do TFA. Przeciwwskazaniem do TFA były masywne zwapnienia, kręty przebieg lub mała średnica tętnic biodrowych lub udowych wspólnych (< 6,5 mm dla zastawek CoreValve i < 7 mm dla systemu Edwards-Sapien), tętniaki aorty brzusznej i/lub piersiowej, „porcelanowa" aorta wstępująca bądź wywiad wcześniejszych zabiegów chirurgicznych tych naczyń. We wszystkich przypadkach implantowano protezy Edwards-Sapien lub CoreValve. Zabiegi przeprowadzono bez krążenia pozaustrojowego.

Wyniki: Średni wiek pacjentów wynosił 82,46 ± 5,79 roku, klasa NYHA przed zabiegiem 3,23 ± 0,41, a przewidywane średnie ryzyko zgonu operacyjnego obliczone z zastosowaniem skali logistic Euroscore 29,18 ± 16,9% (TAA 34,6 ± 15,4% *v.* TFA/TSA 22,72 ± 12,07%; p = 0,031). Skuteczną implantację protezy przeprowadzono u 96% chorych. Całkowita śmiertelność szpitalna wyniosła 3,3% (TAA 9% *v.* TFA 0%; p = 0,19). W obserwacji 30-dniowej śmiertelność w całej grupie wyniosła 6,6% (TAA 18% i TFA/TSA 0%; p = 0,05). W trakcie hospitalizacji nie odnotowano poważnych zdarzeń, takich jak zawał serca, wstrząs, przemijający atak niedokrwienny/udar mózgu, konieczność zastosowania resuscytacji krążeniowo-oddechowej czy krążenia pozaustrojowego. Jeden pacjent zmarł nagle 3 tygodnie po TAVI. W obserwacji 30-dniowej nie zanotowano innych poważnych zdarzeń kardiologicznych. Po TAVI stwierdzono znamienną redukcję gradientu w obu grupach (z 99,6 ± 22,07 mm Hg do 21,83 ± 9,38 mm Hg po zabiegu i do 23,25 ± 9,22 mm Hg w obserwacji 30-dniowej), nie zaobserwowano ciężkiej niedomykalności aortalnej. Klasa wg NYHA w obserwacji 30-dniowej zmniejszyła się z 3,23 ± 0,41 do 1,72 ± 0,52 (p = 0,03).

Wnioski: Na podstawie doświadczeń autorów niniejszej pracy można sądzić, że zabiegi TAVI TFA/TSA wiążą się z mniejszym ryzykiem powikłań, w tym zgonu, w obserwacji 30-dniowej. Jednak możliwość zaproponowania chorym z ciężką AS, niekwalifikującym się do leczenia chirurgicznego, kilku alternatywnych sposobów implantacji zastawki, zwiększa grupę pacjentów mogących skorzystać z tej metody terapii.

Słowa kluczowe: przezcewnikowa implantacja zastawki aortalnej, stenoza aortalna

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