Kardiologia Polska 2014; 72, 2: 187–193; DOI: 10.5603/KP.2014.0029 ISSN 0022–9032

Symetis Acurate Transapical Aortic Valve: the initial experience with a second generation of transcatheter aortic valve replacement device

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Abstract

Background: Transcatheter aortic valve replacement (TAVR) has proven to be a valuable alternative to conventional surgical aortic valve replacement in high risk and surgically inoperable patients who suffer from severe symptomatic aortic stenosis. However, a significant number of complications, associated with both the learning curve and device specificity, have required attention and subsequent improvement. The Symetis transapical TAVR system is a self-positioning bioprosthesis composed of a non-coronary leaflet of surgical quality porcine tissue valve sewn into a self-expanding nitinol stent that is covered with a PET-skirt.

Methods: From June to September 2013 six patients have been operated on severe aortic stenosis using the new TAVR device. All patients have undergone critical assessment of a local Heart Team and have been disqualified from conventional AVR. Five were woman. Mean age was 82.3 ± 2.0 (mean LogEuroScore 23.9 ± 14.3). Four patients suffered from coronary artery disease — two had history of previous percutaneous coronary intervention with intracoronary stents, while the next two had history of coronary artery bypass grafting. Diabetes was frequent (n = 3) as well as chronic obstructive pulmonary disease (n = 4). Carotid artery disease was encountered in three patients similarly to atrial fibrillation. Mean left ventricular ejection fraction (LVEF) was 51.5 ± 11.8%, but one patient had suffered from low-flow-low-gradient aortic stenosis with LVEF of 29%.

Results: The procedure was carried out successfully in all six cases. Two patients have received the valve sized L, three — M and one — S. Mean procedure time was 180 ± 19 min, mean cine 7.2 ± 1.2 min. Mean X-ray dose 930 ± 439 mGy, while mean volume of contrast given was 135 ± 61 mL. In all patients but one perivalvular leak (PVL) was not present. One patient had trace of PVL. Also, good LVEF was noted in all patients. Similar findings were obtained 30 days post procedure. No strokes, transient ischaemic attack or other cerebrovascular incidents were observed.

Conclusions: This brief clinical communication reports the first Polish experience with the second generation of TAVR device — the Symetis Acurate Transapical Aortic Valve. While it lacks large patient population and longer follow-up, it reveals that TAVR procedure can be performed safely, with minimal X-ray exposure time and contrast given and successfully — with almost nonexistent PVL and no cerebrovascular incidents or heart rhythm disturbances. Heart Team approach is vital, and transapical access should not be treated inferiorly, but rather as an equally appealing TAVR option.

Key words: aortic stenosis, transcatheter aortic valve replacement, TAVI

Kardiol Pol 2014; 72, 2: 187–193

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Received: 25.12.2013 **Accepted:** 09.01.2014

Table 1. Patient baseline characteristics

	C.C.	K.E.	D.L.	G.J.	W.I.	B.B.
Sex	Female	Female	Male	Female	Female	Female
Age	84	81	85	85	81	81
Body mass index	32.9	32	22	28	27	32
Body surface area	1.79	1.96	1.69	1.82	1.73	1.89
LogE	10.11	7.96	29.32	18.8	32.61	45.14
STS	3.73	4.58	10.5	6.09	5.32	7.32
Hypertension	Yes	Yes	Yes	Yes	Yes	Yes
Diabetes mellitus (HbA1c)	5.8	8.7	–	7.4	–	–
Congestive heart failure (NT-proBNP)	3,322	161	4,802	2,146	505	3,592
Coronary artery disease (treated)	–	PCI+DES	PCI+DES	–	CABG	CABG
Atrial fibrillation	Permanent	–	Permanent	–	–	Paroxysmal
Cerebrovascular disease	–	–	RICA 100%	BILAT 50%	BILAT	–
Peripheral vascular disease	–	–	–	–	–	Tortuous
Chronic obstructive pulmonary disease	–	–	VC 45% FEV1 44%	VC 76% FEV1 66%	–	VC 75%, FEV1 58%
Chronic renal failure	55	–	–	–	51	GFR 44

CABG — coronary artery bypass grafting; DES — drug eluting stent; FEV1 — forced expiratory volume in 1 s; GFR — glomerular filtration rate; NT-proBNP — N-terminal-pro B type natriuretic peptide; PCI — percutaneous coronary intervention; STS — Society of Thoracic Surgeons; VC — vital capacity

INTRODUCTION

Transcatheter aortic valve replacement (TAVR) has proven to be a valuable alternative to conventional surgical aortic valve replacement in high risk and surgically inoperable patients who suffer from severe symptomatic aortic stenosis [1]. Since its introduction in 2002, more than 40,000 of these procedures have been performed worldwide, with less than one third reaching scientific databases and publications. Despite these shortcomings, the first generation of devices has demonstrated its safety and effectiveness in various clinical scenarios [2]. However, a significant number of complications associated with both the learning curve and device specificity have required attention and subsequent improvement. Paravalvular aortic regurgitation (or paravalvular leak — PVL), annular rupture, coronary ostia obstruction and conduction disturbances are still among the most common TAVR-specific issues associated with the first generation of TAVR devices [3]. The next generation (Sapien XT, Medtronic Engager, Symetis Acurate and Jena Valve) has been introduced to challenge these imperfections. This brief clinical communication reports the first Polish experience with the second generation of TAVR device — the Symetis Acurate Transapical Aortic Valve.

METHODS

Patients

All patients have been evaluated by the local Heart Team consisting of at least one cardiac surgeon, cardiologist and radiologist. All patients signed informed consent after careful discussion with team members (M.Z., J.W. and J.P.). Patients were informed about the procedure and its possible consequences and complications.

Six patients with severe symptomatic aortic stenosis had undergone TAVR procedure with the Symetis Acurate valve on 24.06.2013, 25.06.2013 and 05.08.2013. Patients were subject to 30 day evaluation. Patient metrics and risk assessment are depicted in Table 1, while baseline echocardiographic values are set out in Table 2.

Briefly: Patient 1 (C.C.) was an 84-year-old female with significant symptomatic aortic stenosis and systolic heart failure (NT-proBNP 3,322 pg/mL), permanent atrial fibrillation (CHADS-VASC 4, HAS-BLED 1), arterial hypertension, hyperlipidaemia and impaired renal function (GFR 55).

Patient 2 (K.E.) was an 81-year-old female with coronary artery disease (st/p PCI+DES [everolimus] in IM on 19.03.2013), diabetes (high HbA1c of 8.7% despite intensive insulin therapy) and hypertension.

Patient 3 (D.L.) was an 85-year-old male, in congestive heart failure (CHF) (NYHA IV, NT-proBNP 4,802 pg/mL) with coronary artery disease (zotarolimus eluting stent implanted into the LAD on 22.03.2013, chronic total occlusion of the RCA left intact) permanent atrial fibrillation (CHADS-VASC 5 HAS-BLED 3), cerebrovascular disease (total occlusion of the right internal carotid artery), and severe pulmonary disease (VC 54% and FEV1 40% of predicted values).

Table 2. Baseline echocardiographic and computed tomography findings

	C.C.	K.E.	D.L.	G.J.	W.I.	B.B.
Left ventricle	48/37	48/30	51/42	38/24	45/26	46/30
Intraventricular septum	15/18	12/15	10/13	15/22	13/19	14/19
Left ventricular outflow tract	19	18	19	18	19	21
Left ventricular ejection fraction	55	57	29	60	60	48
Peak/median gradient	84/54	71/42	39/20	123/77	111/58	66/46
AVA/Indexed AVA	0.47/0.26	0.8/0.4	0.5/0.29	0.4/0.22	0.7/0.4	0.8/0.42
Annulus TEE/CT [mm]	23/24	22/20	23/22	21/23	21/21	23/23
Root TEE/CT [mm]	30/34	30/32	29/32	28/28	29/29	36/30
Ascending TEE/CT [mm]	31/33	39/36	32/30	36/33	30/31	40/30
Perimeter	85	75	75	70	61.6	66.3

AVA — aortic valve area; CT — computed tomography; TEE — transoesophageal echocardiography

Patient 4 (G.J.) was an 85-year-old female with visible signs of heart failure (NT-proBNP 2,146 pg/mL), cardiovascular disease (LICA 50–60%) and chronic obstructive pulmonary disease (VC 76%, FEV1 66% of predicted values).

Patient 5 (W.I.) was an 81-year-old female with combined aortic valve disease with severe stenosis and moderate regurgitation, in NYHA class III. She had a history of coronary artery bypass grafting (2006) with left internal mammary to left anterior descending and two vein grafts to obtuse marginal and right coronary artery. Both vein grafts were found occluded in 2010 when she suffered from non-ST elevation myocardial infarction (NSTEMI) and had subsequent percutaneous coronary intervention with DES into the circumflex artery (Cx). Left and right internal carotid arteries were narrowed 90% and 50%, respectively.

The last patient, Patient 6 (B.B.), was an 81-year-old female in NYHA class III with symptoms of CHF (NT-proBNP 3592 pg/mL) and a history of surgical revascularisation (2006). All three grafts (LIMA-LAD, Ao-PDA, Ao-Cx) were patent at the time of evaluation for TAVR. She had also a history of NSTEMI in 2007 and percutaneous balloon angioplasty of the right postero-lateral in 2012. She underwent nephrectomy in 1979. Since 2009, her renal function worsened and now remains decreased with GFR 44 since then.

The valve

The Symetis transapical TAVR system is a self-positioning bioprosthesis composed of a non-coronary leaflet of surgical quality porcine tissue valve sewn into a self-expanding nitinol stent that is covered with a PET-skirt (Fig. 1) [4]. The transapical delivery system is designed for quick, two-step, single-operator deployment. The 'self-seating, self-sealing' concept coupled with a simple release mechanism was intended to facilitate accurate implantation of the valve. The valve is available in three sizes (S, M, L) to treat patients with aortic annulus diameters from 21 mm to 27 mm.

Implantation

The surgical procedure was performed as described previously [5]. Briefly: the patient was put in a supine position with left chest side raised 5% to facilitate surgical access. The patient was anaesthetised with sevoflurane and intubated with a single lumen intratracheal tube. External defibrillation pads (Covidien, USA) were secured on both sides of the thorax. Cerebral oximetry was initiated. A temporary pacing electrode (T.S. Hagmed, Poland) was inserted through the left jugular vein. A single 5 cm skin incision was made 1 cm below the

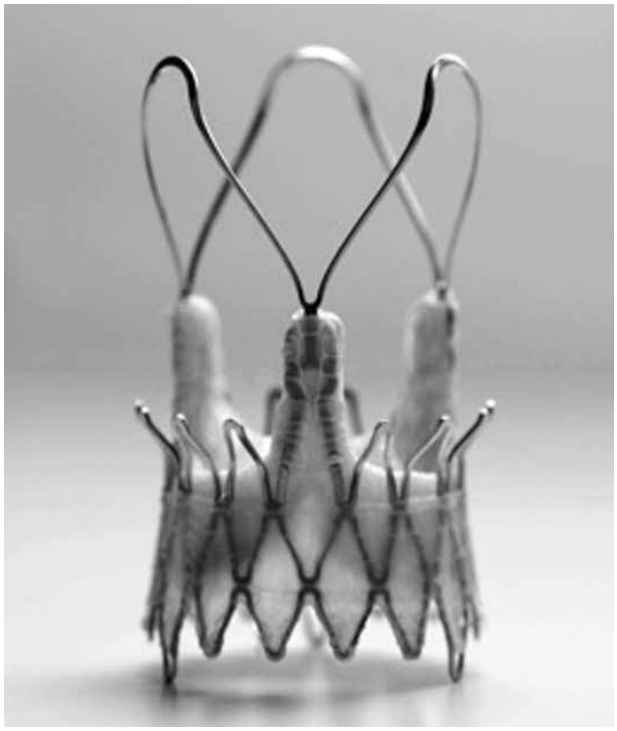

Figure 1. Symetis Acurate valve. Clearly visible upper crown and stabilisation struts (arches)

left mammary gland. Left pleural cavity was subsequently entered. Incision and intercostal space used to enter the left pleural cavity was chosen based on the location of the apex as seen on fluoroscopy. Usually 5th or 6th left intercostal space. Soft tissue retractor was placed to facilitate exposure. Two 2–0 polypropylene sutures with large pledgeds were placed on the anterior wall of the left ventricular (LV) in the vicinity of the LV apex. Meanwhile, the iliac vein and artery were punctured and a 5 F pig tail catheter (Boston Scientific) was introduced into the aortic bulb. At the same time, preselected valve was being cramped onto the delivery system. A soft tip catheter was introduced to the LV through a puncture in the LV apex, and advanced past the stenosed valve to the descending aorta. This was subsequently exchanged for super-stiff wire, upon which preselected balloon was introduced. Valvuloplasty was commenced once arterial blood pressure dropped below 40 mm Hg with ventricular rapid pacing (220/min). Aortic regurgitation was confirmed in transoesophageal echocardiography (TEE). Balloon catheter was exchanged for valve delivery system, which was positioned within the aortic annulus (Fig. 1). Step one was initiated as the stabilisation struts and upper crown were opened (Fig. 2). The valve was then realigned under fluoroscopy to ensure stabilising struts did not obstruct coronary ostia. Aortography confirmed proper valve placement, and step two (final deployment) was commenced. Once the valve had been deployed, TEE was used to evaluate valvular function with special attention to PVL. In all but one case (D.L.), TEE showed no PVL. In D.L., there was moderate PVL which required post deployment balloon dilatation. Performed immediately after evaluation, the valve showed only a trace of PVL afterwards. Table 3 contains intraoperative information.

RESULTS

TAVR was safely performed in all patients. There were no intraoperative complications. One patient had to be reoperated (through the same small incision) due to increased chest tube output within the first 2 h post procedure. Small muscular branch of the intercostal vein was found responsible and immediately coagulated. Although possible, patients were not extubated in the operating room, but shortly after in the cardiac surgical intensive care unit. All but one patient (D.L) had chest tubes removed on the 3rd post operative day (POD). D.L. had the chest tube removed on the 5th POD due to prolonged pleural effusion. No other major adverse events were noted. The first four patients were discharged home on the 8–9th postoperative day, and were asked to come to the out-patient clinic 30 days, three, six and 12 months after the procedure. During these follow-up visits, blood samples were drawn and functional tests performed. Transthoracic echocardiography was used to evaluate myocardial and valvular function. A mean pressure gradient of 12 ± 2 mm Hg was noted in all cases. A trace of PVL was noted in one patient (D.L.) and existed in the same insignificant degree one month post procedure. A slight decrease in the LV ejection fraction was noted in all but one patient (D.L.: improvement from 28% to 40%). Due to existing comorbidities, antithrombotic therapy was tailored to the specific patient, and included

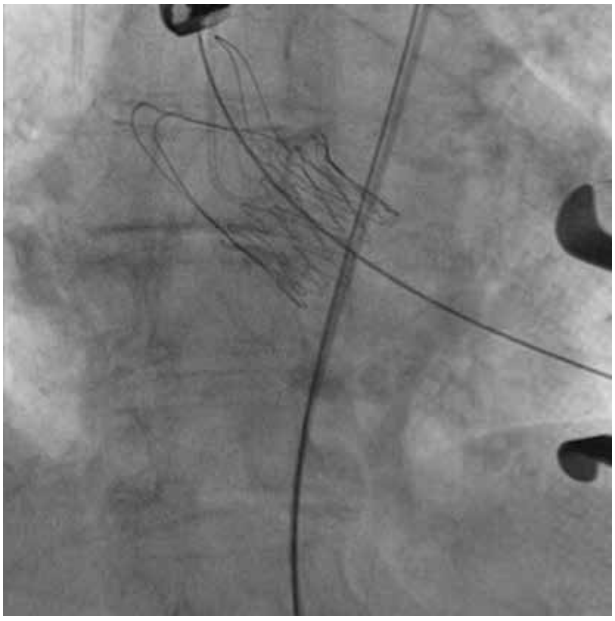

Figure 2. Intraoperative photograph revealing fully deployed valve. Super-stiff wire still in the left ventricle and aorta, as well as pig tail catheter

Table 3. Periprocedural data

	C.C.	K.E.	D.L.	G.J.	W.I.	B.B.
Balloon size	23	22	22 (25)*	20	20	22
Valve size	L	M	M	L	S	M
Total procedure time	195	165	180	190	200	150
Fluoro time [min]	7.4	9.3	7	9	6.2	6.5
Dose [uGy]	1,332	1,629	615	603	743	658
Contrast [mL]	230	150	150	140	100	45

*Postdilatation

Table 4. Follow-up data

	C.C.	K.E.	D.L.	G.J.	W.I.	B.B.
Left ventricle	49/32	50/30	56/40	47/28	48/25	52/26
Left ventricular ejection fraction	50%	53–55%	48%	56%	58%	55%
Peak/median gradient	26/11	24/12	14/7	24/15	30/15	20/10
Paravalvular leak	None	None	Mild	None	None	None
NT-proBNP	1,925	515	3,089	2,668	1,666	5,340

NT-proBNP — N-terminal-pro B type natriuretic peptide

75 mg of acetylsalicylic acid (ASA) once daily in two patients (G.J. and W.I), vitamin K antagonists (VKA) under international normalised ratio guidance in two patients (B.B. and C.C.), and ASA + 75 mg Plavix (PLX) once daily in one (K.E.) and ASA + PLX + VKA in one (D.L.). No bleeding complications possibly associated with either of these drugs were noted. A rapid improvement was noted in the six-minute walking test in all patients, considering the short interval post surgery. Table 4 summarizes echocardiographic and laboratory findings collected 30 days after the procedure.

DISCUSSION

This short paper documents the first use and early, 30-day, outcome of the Symetis Acurate Transapical Valve in six consecutive patients in Poland. Since September 2010 when this novel aortic prosthesis was first used, more than 1,000 implants have been performed worldwide, with encouraging results.

The Symetis Acurate Transapical Valve and delivery system represents a major improvement on the first generation of transapical devices in almost every field of contemporary TAVR research. The problem of perivalvular leakage often encountered with previous TAVR devices has been addressed by a newly designed cloth skirt. This polyester soft-shell covering the lower struts conforms itself to the diseased annulus, promoting faster thrombus formation on the pivot points. The lower part of the valve encompasses a distal part of the LV outflow tract high enough not to interfere with the anterior leaflet of the mitral valve. This, combined with extensive PET-Poliester (Dacron) cover, constitutes the concept of the self-sealing valve. Good safety profile and minimal PVL rate had already been observed in pre-market clinical trials. The SAVI Registry (n = 250) showed a 30-day all-cause mortality rate of 4.8% — one of the lowest rates reported in registries of other transcatheter aortic valves [6]. Haemodynamics and functional class improved solidly after implant procedure. The rates of serious adverse events, such as stroke (1.2%), myocardial infarction (0.8%), and new permanent pacemaker implantation (4.8%) were also very low. Furthermore, the ACURATE TA™ exhibits the lowest PVL reported in a TAVR registry with only 2.7% of patients with a PVL = grade 2 at follow-up and none with grade > 2 [6–8].

The second most striking improvement can be noticed during the valve delivery phase. The Symetis Acurate valve is a self-expanding device, and no rapid pacing (RP) is needed during final release. Although RP can be used to facilitate implantation, it is not mandatory. The tactile feedback introduced here eases correct valve placement, but may be difficult to sense at the beginning. Incidences of pulling the valve through the aortic annulus while trying to establish a 'feedback point' are therefore commonly experienced by new operators. Nevertheless, such a situation does not represent a major threat to the delivery process. While in the LV the valve, can then be re-sheathed and reintroduced to the ascending aorta, to repeat the implantation phase. It seems, however, that the more calcified the aortic annulus is, the better, stronger and more pronounced the feedback is. It is therefore advisable to choose the initial patients with care, so as to expedite the learning curve. Another simplification comes from the C-arm position. While it can be adjusted to match the plane of the aortic annulus, it may be also left at zero degree (PA), when slight elevation of the left side of the patient is applied. This helps visualise the incision site, while leaving the C-arm in one position throughout the entire procedure. This is especially important for professionals with limited C-arm experience. Last but not least is the improvement of the valve preparation process. The crimping phase was made simple by the introduction of a three-step procedure that can be mastered by a technician or a nurse within minutes. This makes all preparations user-friendly and very efficient, strongly augmenting the safety standards related to valve malposition on the delivery device.

Our Centre established the TAVR programme in 2008. The transapical TAVR was introduced two years later, on 26 November 2010.

Since then, 26 transapical, 61 transfemoral, 22 transsubclavian, and six transaortic TAVRs have been performed with 10.4% overall 30-day mortality and 97.4% device success, with transfemoral being the preferred route of valve delivery [9–11]. While such an approach promotes minimal invasiveness by eliminating chest incisions, it remains associated with a significant number of vascular complications [12]. In order to decrease access-related morbidity, a growing number of centres adopt what is known as a '50:50' strategy with a patient-tailored approach and nearly equal transapical–transfemoral distribu-

tion. Such a strategy has been proven not only to be reliable, safe and cost-effective, but also beneficial for cardiac professionals in bringing back the true meaning of the Heart Team, where both cardiac surgeon and cardiologist perform the procedure together, exchanging roles regardless of access site.

CONCLUSIONS

This brief clinical communication reports the first Polish experience with the second generation of TAVR device — the Symetis Acurate Transapical Aortic Valve. While it lacks large patient population and longer follow-up, it reveals that TAVR procedure can be performed safely, with minimal X-ray exposure time and contrast given and successfully — with almost nonexistent PVL and no cerebrovascular incidents or heart rhythm disturbances. Heart Team approach is vital, and transapical access should not be treated inferiorly, but rather as an equally appealing TAVR option.

Conflict of interest: *Prof. Michael Hilker is a consultant (proctor) for Symetis SA.*

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Symetis Acurate Transapical Aortic Valve: pierwsze polskie doświadczenia z nową generacją zastawek typu TAVR

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Streszczenie

Wstęp: Przezcewnikowa implantacja zastawki aortalnej (TAVR) jest uznaną metodą leczenia chorych, u których wykonanie klasycznego zabiegu chirurgicznej wymiany zastawki aortalnej wiąże się z bardzo wysokim ryzykiem powikłań. Intensywny rozwój kardiologii interwencyjnej i kardiochirurgii małoinwazyjnej, mocno wsparty przez postęp technologii i przemysłu medycznego, umożliwił bardzo szybki rozwój technologii TAVR. Pierwsza generacja protez aortalnych (Medtronic Corevalve, Edwards Sapien) udowodniła swoje bezpieczeństwo i efektywność, ukazując jednocześnie szereg niedostatków i wad, które w wielu przypadkach ograniczały istotnie ich zastosowanie. Biologiczna proteza aortalna Acurate-TA firmy Symetis reprezentuje nową, drugą generację zastawek typu TAVR, które w swym założeniu miały charakteryzować się prostotą implantacji i przygotowania, ale także dzięki udoskonalonej konstrukcji uszczelniać miejsce osadzenia zastawki, minimalizując tym samym nieszczelności okołozastawkowe. Ponadto system pozwala na wielokrotną repozycję protezy, ułatwiając tym samym jej pozycjonowanie w osi pierścienia aortalnego oraz pozwala na całkowite jej usunięcie, nawet po częściowym uwolnieniu (w dniu ukazania się niniejszego artykułu liczba implantowanych zastawek w Polsce wynosi 11, z czego u 10 chorych z bardzo dobrym efektem; 1 chory zmarł).

Metody: W okresie od czerwca do września 2013 r. operacji typu TAVR z zastosowaniem nowego typu protezy poddano 6 chorych (K:M = 5:1). Średni wiek wynosił 82,3 ± 2,0 lat (śr. LogEuroScore 23,9 ± 14,3 pkt.). U 4 osób rozpoznano stabilną chorobę wieńcową leczoną wcześniej przezskórnie (n = 2) i chirurgicznie (n = 2). Cukrzycę typu 2 stwierdzono u 3 pacjentów, przewlekłą obturacyjną chorobę płuc u 4 osób, migotanie przedsionków u 3 chorych, chorobę tętnic szyjnych u 3 pacjentów. Średnia wartość frakcji wyrzutowej lewej komory wynosiła 51,5 ± 11,8%, przy czym u 1 chorego — 29%.

Wyniki: Zabieg przeprowadzono pomyślnie u wszystkich 6 pacjentów. W 2 przypadkach implantowano zastawkę wielkości L, w 3 — M, a w 1 — S. Średni czas trwania zabiegu wynosił 180 ± 19 min, czas skopii — 7,2 ± 1,2 min. Średnia dawka promieniowania wyniosła 930 ± 439 mGy, a ilość podanego kontrastu — 135 ± 61 ml. U wszystkich chorych stwierdzono dobrą funkcję implantowanej zastawki, z niskimi gradientami ciśnień. W 5 przypadkach nie zaobserwowano przecieków okołozastawkowych, podczas gdy mały przeciek widoczny był u 1 chorego. W 30 dni po zabiegu parametry hemodynamiczne implantowanych protez nie uległy zmianie. Zanotowano nieznaczną poprawę kurczliwości u chorych z wcześniej upośledzoną wydolnością lewej komory. U wszystkich pacjentów stwierdzono poprawę w testach wysiłkowych.

Wnioski: W niniejszej pracy udokumentowano pierwsze zastosowanie zastawki Symetis Acurate-TA w Polsce u 6 chorych. Wczesne doświadczenie autorów pokazuje, że zabieg typu TAVR może być wykonany bezpiecznie, z krótkim czasem ekspozycji radiologicznej i małą ilością podanego kontrastu, by skutecznie pomóc najtrudniejszej grupie chorych cierpiących na zwężenie zastawki aortalnej.

Słowa kluczowe: stenoza aortalna, przezskórna implantacja zastawki aortalnej, TAVI

Kardiol Pol 2014; 72, 2: 187–193

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Praca wpłynęła: 25.12.2013 r. **Zaakceptowana do druku:** 09.01.2014 r.