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Symetis Acurate Neo transfemoral aortic bioprosthesis — initial Polish experience

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Abstract

Background and aim: Transcatheter aortic valve implantation (TAVI) 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. With the second generation of TAVI devices improvements in both handling and performance are highly demanded. This brief clinical communication reports the first Polish experience with the second generation of transfemoral TAVI device — Symetis Acurate Neo.

Methods: From November 19th 2014 until February 18th 2015 nine (n = 9) patients with severe symptomatic aortic stenosis have been operated on using the Symetis Acurate Neo. Patients were subject to seven-day evaluation and 30-day phone follow-up.

Results: The procedure was safely and successfully performed in all patients. A SMALL (S) valve (21–23 mm equivalent) was used in two patients, MEDIUM valve (M; 23–25 mm equivalent) in five patients, and a LARGE valve (L; 25–26 mm equivalent) in two patients. In three cases post-release balloon dilatation was required. There were no intraoperative complications and no major adverse events (as per VARC classification) during initial hospitalisation, including conduction or rhythm disturbances. In all cases, the mean gradient on the prosthetic valves was 7.8 mm Hg (10.2 mm Hg on the "S" valves). Rapid improvement in patients' functional class was noted. Perivalvular leak was evaluated as "mild" in three cases, "trace" in one, and "not existing" in five.

Conclusions: This initial experience with the Symetis Acurate Neo demonstrates its good safety profile and excellent haemodynamics. Low radial stress of the valve results in minimal incidence of atrioventricular rhythm disturbances, and a sealing crown for nearly non-existent paravalvular leak.

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

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INTRODUCTION

Transcatheter aortic valve implantation (TAVI) 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, the first generation of devices (CoreValve Medtronic, Sapien Edwards) has demonstrated its safety and effectiveness in various clinical scenarios. The high efficacy and acceptable safety profile of the pioneering devices opened an extremely dynamic field of research and development in cardiovascular medicine. Not only have the acknowledged imperfections of the first generation of TAVI devices been challenged, but also new solutions, concepts, and patents have been used, resulting in the creation of the next generation of catheter-based bioprostheses (Lotus, Direct Flow, Portico, Engager, Jena Valve, Acurate, Inovare, Trinity, Colibri, Centera) [2–5], and more are still in the pipeline. Simplification of design and handling should not be second-

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ary to improvements in annular sealing, stent anchoring, and the ability to remove or reposition the valve prior to final release. While only time and well-controlled clinical studies will solve issues of long-term durability, novel generations challenge two of the most important imperfections of the old version — perivalvular leaks and rhythm disturbances. This brief clinical communication reports the first Polish experience with the second generation of transfemoral TAVI device — Symetis Acurate Neo.

METHODS

Patients

The appropriate Institutional Review Board and Ethics Committee approvals were obtained for the study prior to initiating patient enrolment (Bioethics Committee of the Silesian Chamber of Physicians in Katowice no. 11/2015). Patients with severe symptomatic aortic stenosis, over 75 years of age, with either prohibitive risk or disqualification from conventional surgical treatment, with femoral arteries patent (diameter > 7 mm) were enrolled. The presented cohort is part of Symetis ACURATE Neo™ Valve Implantation Using TransFemoral Access: SAVI TF Registry, registered as NCT02306226. This post-market registry aims at further evaluation of the safety and performance of the ACURATE Neo™ Aortic Bioprosthesis and ACURATE TF™ Transfemoral Delivery System in consecutive patients with aortic stenosis. All patients have signed informed consent upon thoughtful conversation with the Team Members and were fully informed about the procedure and its possible consequences and complications. From November 19th 2014 until February 18th 2015 nine (n = 9) patients with severe symptomatic aortic stenosis have been operated on using Symetis Acurate Neo. Patients were subject to seven-day evaluation and 30-day phone follow-up. Patient baseline characteristics are depicted in Table 1.

Table 1. Patient baseline characteristics

Age [years]	81.22 ± 4.55
Female	7 (77%)
NYHA classification:	
Class II	3/9 (33%)
Class III	6/9 (66%)
STS score (%)	24.58 ± 3.4
Logistic EuroSCORE (%)	25.55 ± 12.4
Diabetes mellitus	4/9 (44%)
Glomerular filtration rate < 40 mL/min/1.73 m^2	3/9 (33%)
History of hypertension	8/9 (88%)
Peripheral vascular disease	3/9 (33%)
Cerebral vascular disease	4/9 (44%)
Prior stroke	2/9 (22%)
Prior TIA	1/9 (11%)
Cardiac history:	
Coronary artery disease	4/9 (44%)
Prior CABG	3/9 (33%)
Prior PCI	4/9 (44%)
Prior balloon valvuloplasty	0/9
Pre-existing pacemaker	0/9
Prior atrial fibrillation/flutter	3/9 (33%)
Chronic lung disease	1/9 (11%)
Echocardiographic parameters:	
Mean pressure gradient [mm Hg]	43.6 ± 7.7
Mean effective orifice area [cm^2]	0.47 ± 0.1
Left ventricular ejection fraction [%]	48.56 ± 8.2

CABG — coronary artery bypass grafting; NYHA — New York Heart Association; PCI — percutaneous coronary intervention; STS — Society of Thoracic Surgeons; TIA — transient ischaemic attack

The valve

The Symetis transfemoral TAVI system is based on the same self-seating, self-sealing design and stepped deployment concept as the ACURATE TA™ transapical system [6, 7]. The bioprosthesis ACURATE Neo™ is composed of a porcine pericardial tissue valve sutured within a self-expanding nitinol stent covered by a pericardial skirt on the outer and inner surface of the stent body (Fig. 1). ACURATE Neo™ is available in three sizes (SMALL, MEDIUM, LARGE) to treat patients with aortic annulus diameters from 21 mm to 27 mm, and its delivery system boasts an 18 F outer diameter.

Figure 1. The Symetis Acurate Neo transfemoral valve

The procedure

The procedure was performed as described previously [6]. Briefly, the patient was positioned in a supine position, anesthetised with Sevoflurane, and intubated with single lumen intratracheal tube. The last three patients were not intubated,

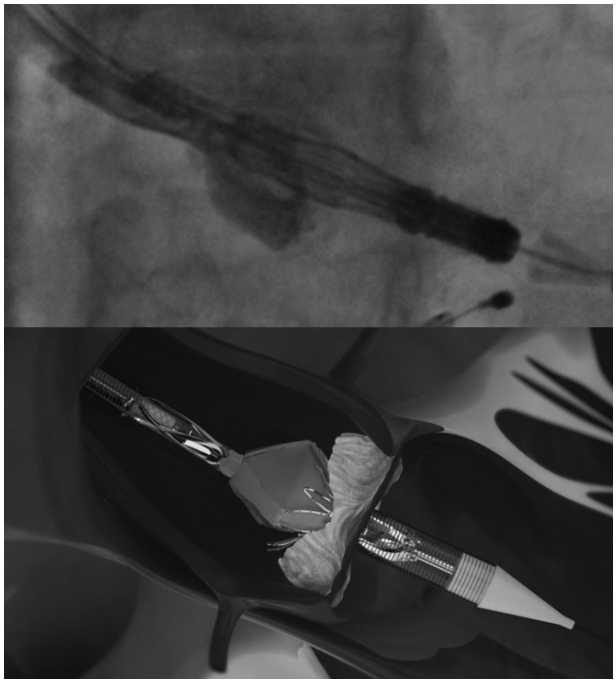

Figure 2. The valve is positioned at the level of the aortic annulus

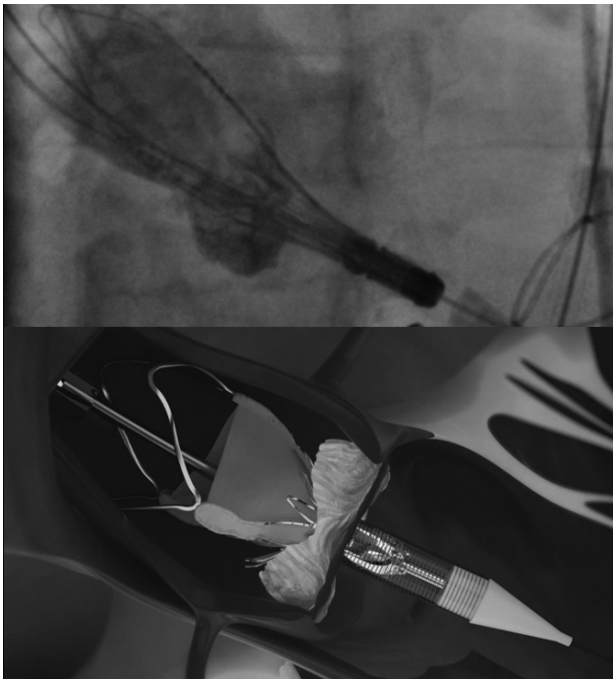

Figure 3. Step 1: Stabilisation arches are opened and the lower crown is gently pushed against the calcified aortic valve

as the procedure was performed under local anaesthesia and conscious sedation only. External defibrillation pads (Covidien, USA) were secured on both sides of the thorax. Cerebral oximetry (INVOS, Medtronic, USA) was initiated and a temporary pacing electrode (Balton, Poland) was inserted through the left jugular vein.

The right femoral artery was used for valve delivery in all patients, accessed via 3 cm surgical incision. The left femoral artery was cannulated percutaneously with a 5 F vascular sheath, and served as a diagnostic port for a 5 F pig-tail catheter (Balton, Poland). Once the aortic valve had been crossed with a soft-tip guidewire (Terumo, Japan), a guiding catheter was introduced into the left ventricle providing the route for a pre-shaped stiff wire (Confida). Then the 5 F vascular sheath was exchanged for an 18 F Cook vascular port. Rapid balloon valvuloplasty followed, with ventricular pacing (180/min). The functional status of the aortic valve was reassessed while a crimped valve was introduced into the ascending aorta. Once positioned within the aortic annulus (Fig. 2) the first step of the two-step deployment sequence was initiated. The stabilisation struts and upper crown were opened (Fig. 3) and the valve was gently pushed against native, calcified leaflets. When proper position had been achieved, final deployment (step two) was executed (Fig. 4) leading to full deployment. Transoesophageal electrocardiography was used to evaluate prosthetic function, seating, and possible paravalvular leaks. The delivery system was carefully withdrawn, and vascular access closed with a 5-0 purse string suture.

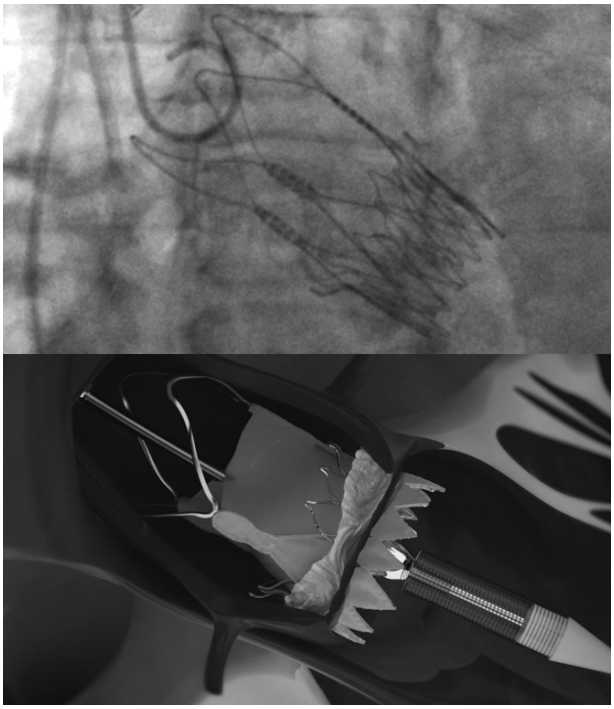

Figure 4. Step 2: Final release — lower crown encompasses aortic annulus

Statistical analysis

Continuous variables are presented as mean ± standard deviation. Categorical variables are given as frequencies

and percentages (%) and compared by Fisher's exact test. A two-sided p-value < 0.05 was considered statistically significant if applicable. All authors had full access to the complete data set and took responsibility for its integrity. All authors read and agreed to the manuscript as written.

RESULTS

The procedure was safely and successfully performed in all patients. A SMALL (S) valve (21–23 mm equivalent) was used in two patients, MEDIUM (M; 23–25 mm equivalent) in five, and LARGE (L; 25–26 mm equivalent) in the remaining two individuals. A slightly undersized balloon was used for valvuloplasty prior valve implantation: 20 mm in S, 23 mm in M, and 25 mm in L patients. The mean skin-to-skin time was 165 ± 36 min, with mean X-ray exposure of 20.7 ± 11.6 min (dose 1.3 ± 0.6 uGy). 220 mL of Visipaque contrast was used on average. A visible difference in procedural and X-ray exposure time and dose, as well as the amount of given contrast, could be observed in the last three cases (120 min; 15.4 min; 1.03 uGy and 170 mL, respectively). In three cases post-release balloon dilatation was required, with the same balloon as used previously and hand controlled filling with slight oversize in the L sized valves during rapid ventricular pacing. In all cases postdilatation reduced mild perivalvular leak to none or trace and was free from adverse events. There were no intraoperative complications and no major adverse events (as per VARC classification) during initial hospitalisation, including conduction or rhythm disturbances. All patients were subject to fast-track rehabilitation, mobilised on the second postoperative day (POD) and ambulating fully on the fourth POD. Pacing electrode was removed on the fourth POD together with central intravenous catheters and lines. All patients but one were discharged home on the fifth POD. In two cases pseudoaneurysm of the left femoral artery (diagnostic access, not delivery site) was diagnosed five and 15 days post procedure, respectively. In the first case the patient was successfully treated surgically and discharged home four days later, while thrombin injection was efficaciously used in the second case, who was evaluated in the out-patient clinic. Periprocedural and early outcomes are depicted in Table 2.

In all cases, as expected, a significant improvement in cardiac haemodynamics was noted (Fig. 5). Mean gradient on the prosthetic valves was 7.8 mm Hg (10.2 mm Hg on the "S" valves), and rapid improvement in patients' functional class was noted (Fig. 6). Perivalvular leak was evaluated as "mild" in three cases, "trace" in one, and "not existing" in five (Fig. 7).

DISCUSSION

This short paper documents the first use and early, 30-day outcome, of the Symetis Acurate Neo valve in nine consecutive patients in Poland.

The Symetis Acurate Neo represents the second generation of TAVI devices. The prosthesis, although resembling its transapical predecessor, has been redesigned to facilitate a vascular route of delivery. Its nitinol cage is slightly taller, with leaflets placed higher than in its transapical (TA) forerunner (Fig. 4). Stabilisation arches extend upwards, helping the prosthesis to self-align. The polyester, soft-shell, circular aortic ring sealant, was designed to minimise paravalvular leaks, first used in the TA version remained nearly unchanged. All

Table 2. Procedural, discharge and 30-day outcomes

Operating time [min]	165 ± 34.6
Amount of contrast agents [mL]	220 ± 90
Implanted valve size:	
SMALL — 23 mm	2/9 (22%)
MEDIUM — 25 mm	5/9 (55%)
LARGE — 27 mm	2/9 (22%)
Device success	9/9 (100%)
Requiring post-dilatation	3/9 (33%)
Requiring cardiopulmonary bypass	0 (0%)
Conversion to full sternotomy	0 (0%)
Valve-in-valve	0 (0%)
Coronary obstruction	0 (0%)
Atrio-ventricular rhythm disturbances	0 (0%)
Awake surgery	3/9 (33%)
30-day outcomes	
All-cause mortality	0 (0%)
Stroke (disabling)	0 (0%)
Life-threatening bleeding	0 (0%)
Atrio-ventricular rhythm disturbances	0 (0%)
Acute kidney injury	0 (0%)
Myocardial infarction	0 (0%)
Vascular complications:	
Valve-access/delivery site	0 (0%)
Pig-tail/diagnostic site	2 (22%)
Valve dysfunction	0 (0%)

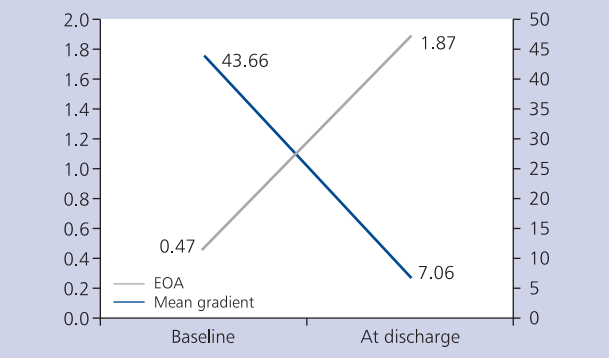

Figure 5. Mean transaortic pressure gradient and effective orifice area (EOA) at baseline and at discharge

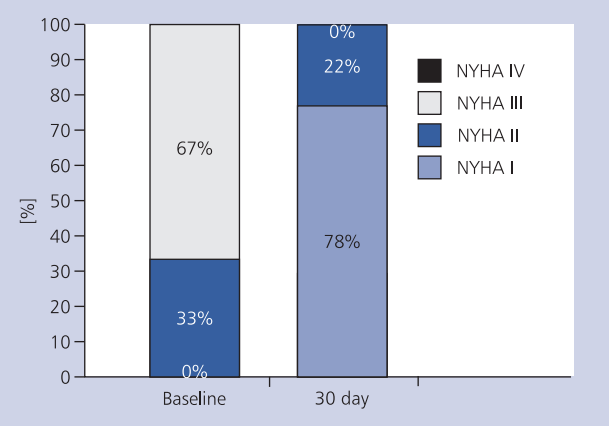

Figure 6. New York Heart Association class change overtime

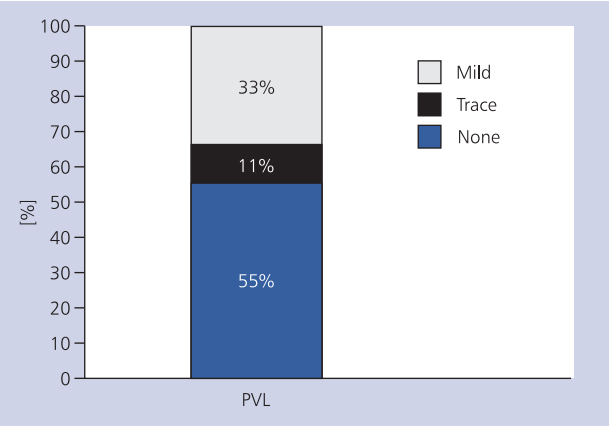

Figure 7. Paravalvular leak (PVL) at discharge

these features allow the valve to be crimped to a delivery system, which combines ease of operation with a low profile (15–18 F), where two knobs, clearly marked, facilitate valve deployment, guarded by a "safety button" familiar to Acurate-TA users. The implantation itself has been simplified and follows the same design of the Symetis transapical system: a two-step, hassle-free deployment with a possibility to reposition the valve within the aortic annulus (Fig. 2).

This well-thought design proved to be reliable and effective — published data indicate a low rate of both perivalvular leaks as well as pacemaker implantation [8, 9].

However, unlike TA, the Neo system lacks the ability to resheath the valve once the first step was executed (Fig. 3). With upper crown and stabilisation arches expanded, care must be taken not to pass the aortic annulus as withdraw from the ventriclular cavity will be impossible. When in position, second step is performed swiftly, with or without rapid ventricular pacing. This half-circle knob turn releases lower struts anchoring it to a calcified aortic apparatus and sealing the annulus. The delivery catheter is then realigned and gently removed. Caution is advised, not to remove stiff wire from the left ventricle, as its replacement can be extremely difficult and dangerous if postdilatation becomes necessary. In such circumstances, highly mounted valve commissures must be avoided — it is paramount to keep the balloon strictly at the level of the aortic annulus to prevent damage to the prosthetic leaflets.

The manufacturer recommends 18 F Cook Vascular Sheath or 15 F Terumo Solopath vascular introducer. While our experience with 15 F Solopath was negative, and abandoned after the first two cases (too soft, difficult to pass the delivery system through), we found the 18 F sheath to be user-friendly, simple, and reliable. Considering proper patient selection (no calcified, torqued femoral arteries) and with a small 3 cm skin incision, introduction, handling, and removal of the entire system remained straightforward. We did not observe any access-related complications (either vessel or wound related). Discussion on the cosmetic result is to be abandoned here, as a 3 cm incision is barely noticed by a patient with a usually rich history of previous abdominal surgeries, cardiac surgery, or both. In our experience, the system is far better than Medtronic CoreValve in terms of ease of operation and valve deployment. However, it lacks the tip steerability present in the Edwards' Sapien 3 Command system. Still, it represents a robust, minimalistic approach, which in many cases outperforms complex delivery solutions.

While a large post-marketing registry is ongoing, only brief reports on Acurate Neo have been published [10]. The results presented herein confirm the good haemodynamic profile of the valve regardless its size; however, slightly elevated mean transvalvular gradients of the smaller prostheses were noted. Similar (also in terms of periprocedural safety and efficacy) results were obtained by Maeda et al. [10], with the difference that there was no need for sternotomy or cardiopulmonary bypass in our study. Of note is that a Japanese group has experienced valve dislocation caused by the locking mechanism of the delivery catheter. Our fourth case seemed similar, as the valve did not expand fully due to heavy calcifications of both aortic valve, root, and left ventricular outflow tract. Simple retraction of the delivery catheter was considered hazardous as it could result in valve dislodgment. In order to achieve safe retrieval, the device was gently pushed forward into the left ventricular cavity and closed inside it, prior withdrawal. Post-dilatation was then successfully commenced. The elevated rate of balloon post-dilatation (43%) reported by Maeda et al. [10] was again, slightly lower, but still considerable, in our population (33%). Interestingly, a comparable rate (35–40%) was noted in studies involving the transapical version of the Acurate valve, indicating that prosthesis construction may limit radial force of the self-expanding stent. This imperfection of the Neo, easily treated with a balloon plasty, prevents atrioventricular conduction disturbances and results in a very low peacemaker implantation rate. However, post dilatation may substantially increase the periprocedural complication rate [11]. While little is known about the dura-

bility of the neo, Symetis' other product — the Acurate TA — which shares the same leaflet tissue and fixation process, introduced in 2008, has been used in over 5000 patients to date with excellent outcomes [6, 7, 12, 13].

Last but not least, it is noteworthy that a team previously inexperienced with transfemoral TAVIs has performed all procedures. A cardiac surgeon (MOZ) followed by a cardiologist (MH) performed the first three implants. Subsequently the two operators rotated, flawlessly exchanging roles. While of tertiary importance, our approach reveals not only the ease of adopting new technologies by a young dynamic Heart Team, but also an important understanding of equality of cardiovascular interventional medicine, where experienced professionals are able to handle the most complex intraoperative complications and perform "easy-looking" procedures in extremely demanding patients.

CONCLUSIONS

The Symetis Acurate Neo remains an interesting and valuable alternative to the two mainstream prostheses dominating the TAVI market. It is a robust and user-friendly device, allowing for predictable, effective and safe implantation with exceptionally low rate of perivalvular leak and rhythm disturbances. More importantly, its design minimises perivalvular leak and rate of pacemaker implantations due to atrio-ventricular rhythm disturbances. Nevertheless, the elevated rate of post-dilatation is the offset here.

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Conflict of interest: *none declared*

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Symetis Acurate Neo — pierwsze polskie doświadczenia z zastawką TAVI drugiej generacji wprowadzaną przezskórnie

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Streszczenie

Wstęp i cel: Przezcewnikowa implantacja zastawki aortalnej (TAVI) jest uznaną metodą leczenia chorych, u których wykonanie klasycznego zabiegu chirurgicznej wymiany zastawki aortalnej wiąże się z bardzo wysokim ryzykiem powikłań około- i pooperacyjnych. Po udanym debiucie zastawki TAVI drugiej generacji implantowanej przezkoniuszkowo (Acurate-TA) firma Symetis wprowadziła do użytku przezcewnikową wersję tej protezy, która podobnie jak wersja transapikalna charakteryzuje się specyficznym kołnierzem uszczelniającym i konstrukcją samocentrującą się w ujściu aortalnym. W niniejszej pracy przedstawiono pierwsze Polskie doświadczenia z zastawką aortalną Symetis Acurate Neo.

Metody i wyniki: W okresie od listopada 2014 do lutego 2015 r. implantacje zastawki Acurate Neo wykonano u 9 chorych. Zastawkę w rozmiarze „S" implantowano u 2 osób, rozmiar „M" u 5 pacjentów, a rozmiar największy — „L" u 2 chorych. W 3 przypadkach konieczne było doprężenie zastawki po jej uwolnieniu. Średni czas trwania zabiegu wynosił 165 ± 34 min. U wszystkich chorych stwierdzono dobrą funkcję implantowanej zastawki, z niskimi gradientami ciśnień. W 6 przypadkach nie zaobserwowano przecieków okołozastawkowych, podczas gdy mały przeciek był widoczny u 3 chorych. 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. W żadnym przypadku nie zaobserwowano zaburzeń przewodzenia czy rytmu serca.

Wnioski: Proteza zastawki aortalnej implantowana przezskórnie — Symetis Acurate Neo, reprezentuje drugą generację zastawek typu TAVI. Jej implantacja jest łatwa i bezpieczna, a uzyskane parametry hemodynamiczne bardzo dobre.

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

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