Komlev A. E., Imaev T. E., Kolegaev A. S.,
Lepilin P. M., Makeev M. I., Akchurin R. S.
Chazov National Medical Research Centre of Cardiology, Moscow, Russia

Results of new-generation self-expanding transcatheter Portico™ valve implantation in patients with degenerative aortic stenosis

Aim	To evaluate 30-day results of the transcatheter correction of degenerative aortic stenosis using a novel self-expandable valve, Portico™.
Material and Methods	Transcatheter aortic valve implantation (TAVI) was performed in 42 patients with an intermediate surgical risk (mean age, 74.3±6.5 years, 8 men, 34 women, EuroSCORE II risk, 2.5 (1.5;4.1)) with severe degenerative aortic stenosis (AS). 20 (48%) patients had ischemic heart disease; 8 (19%) of patients had atrial fibrillation, and 16 (38%) of patients had type 2 diabetes mellitus. Most of the patients (88%) had preserved systolic function, and 5 patients had a pronounced decrease in left ventricular ejection fraction. Early efficacy and safety of the intervention were evaluated with VARC-2 criteria.
Results	In-hospital and 30-day mortality following TAVI was absent. Also, there were no adverse events, including cerebrovascular disorders, perioperative myocardial infarction, and conversion to open surgery. One patient had prosthesis migration to the aorta, which required implantation of the second self-expandable valve. Mean duration of the procedure was 90 min (80;110), fluoroscopy time was 21 min (19;24), and contrast volume 154 ml (200;240). Following TAVI, the mean aortic valve (AV) pressure gradient significantly decreased from 56.1±21.2 to 11.2±4.0 mm Hg, the maximal gradient decreased from 88.9±27.8 to 20.0±7.0 mm Hg, and the AV effective orifice area increased from 0.67±0.2 to 1.9±0.3 cm2 ($p<0.001$). By the time of discharge from the hospital, all patients showed regression of AS clinical manifestations. The percentage of patients with NYHA functional class III chronic heart failure reduced from 62% to 7% ($p<0.001$) after TAVI. In one case after the implantation, grade 3 aortic regurgitation was observed, which required endovascular occlusion to close the paraprosthetic fistula. Moderate paraprosthetic regurgitation (grade <2) was observed in 3 (7%) patients. Only 2 (4.8%) patients required permanent pacemaker implantation.
Conclusion	Results of the single-center prospective TAVI study using a novel self-expandable valve Portico™ showed satisfactory hemodynamic parameters, efficacy and safety of the procedure for the 30-day follow-up period. A relatively low radial force of the carcass can be beneficial for reducing the incidence of permanent pacemaker implantation after TAVI.

Keywords	Aortic stenosis; transcatheter aortic valve implantation; Portico™ self-expandable bioprosthesis
For citations	Komlev A.E., Imaev T.E., Kolegaev A.S., Lepilin P.M., Makeev M.I., Akchurin R.S. Results of new-generation self-expanding transcatheter Portico™ valve implantation in patients with degenerative aortic stenosis. Kardiologiia. 2022;62(8):45–51. [Russian: Комлев А.Е., Имаев Т.Э., Колегаев А.С., Лепилин П.М., Макеев М.И., Акчурин Р.С. Результаты имплантации нового самораскрывающегося транскатетерного клапана Portico™ у пациентов с дегенеративным аортальным стенозом. Кардиология. 2022;62(8):45–51].

Corresponding Author	Komlev A.E. E-mail: pentatonika@bk.ru

Many transcatheter aortic valve (AV) prosthesis of different types, balloon-expandable and self-expandable, have appeared as a result of the rapid development of the transcatheter aortic valve replacement (TAVR) method. [1]. It is undoubtedly important to assess the outcomes of the clinical application of new TAVR devices, to identify the features of patient selection and insertion techniques, to study safety and efficacy of interventions.

Objective

Evaluate the 30 day outcomes of transcatheter treatment of degenerative aortic valve stenosis using the new Portico™ self-expandable valve.

Material and methods

In 2021, 42 patients with severe calcific aortic valve stenosis of intermediate surgical risk were operated in succession in the Department of Cardiovascular Surgery

of the Academician Chazov National Medical Research Center (Russian Federation). Median Euroscore II was 2.5 (1.5; 4.1). Mean age was 74.3±6.5 years (min-max 60–85); 8 patients were male, and 34 (81%) patients were female. All patients underwent transthoracic echocardiography (TTE), electrocardiogram (ECG), coronary artery angiography, ECG- gated multislice computed tomography angiography of the aorta, for preoperative examination. Transesophageal echocardiography (TEE) was used during surgery to control the position of the prosthesis and the degree of residual aortic regurgitation (AR). Control echocardiography was performed before the discharge from hospital.

Indications for the TAVR surgery were determined following the current clinical guidelines [2]. All patients signed the informed consent for the surgery and follow-up. The study was conducted following the Declaration of Helsinki. Special approval of the study protocol by the local ethics committee was not required because the study was observational using the transcatheter bioprosthesis approved in the Russian Federation.

The Porticotm self-expandable transcatheter bioprosthesis was placed via the transfemoral approach in a hybrid surgical room. The bioprosthesis had four sizes (23, 25, 27, and 29 mm) and was placed in the 19–27 mm annulus. Portico™ is the first-generation bioprosthesis based on the platform developed by Abbott (USA). It is a self-expandable nitinol frame with sewn-in bovine pericardial leaflets processed with Linx anticalcification technology (Figure 1). The prosthetic leaflets are positioned in the intra- annular manner. The valve is repositionable and can be trapped and extracted from the vessel before final disconnection from the delivery system, if necessary. The large size of the frame cells provides easy access to the coronary arteries. The large size of the cell also ensures a high radial force of the frame, allows most tightly press and fit dense calcium minimizing the incidence of paraprosthetic fistulas. The new low-profile (14-15F) delivery system FlexNav™ approved by the FDA in 2021 allows performing interventions in patients with small femoral arteries (from 5 mm) [3].

Figure 1. Portico self-expandable prosthetic valve and FlexNav delivery system

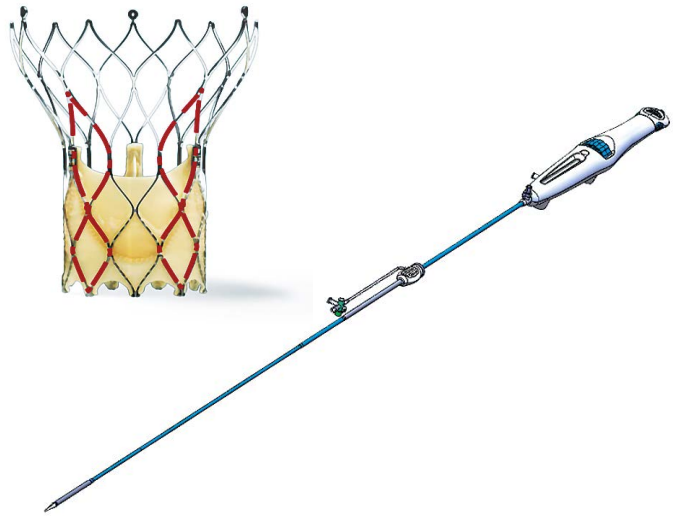
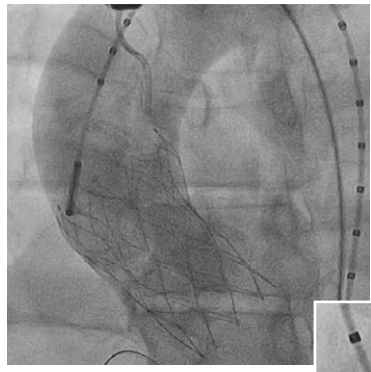
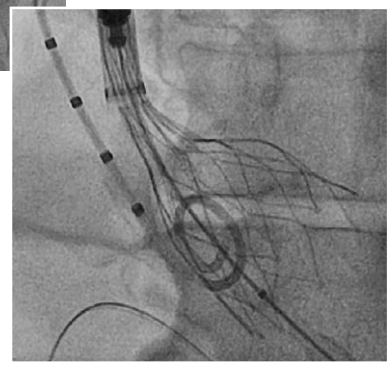


Figure 2. Placement of the prosthesis and final replacement result



A – placement of the prosthesis using a pigtail measuring catheter.



B – final aortography, no residual aortic regurgitation.

Surgery Protocol

The common femoral artery (CFA) was surgically accessed under endotracheal anesthesia and a 6F sheath introducer was inserted. Then, a percutaneous puncture of the contralateral CFA and femoral vein was performed and 6F sheaths were placed using the Seldinger technique, through which a pigtail diagnostic catheter was inserted into the non-coronary sinus and a high-frequency stimulation lead was placed in the right ventricle. The view of the aortic root was derived, in which all three sinuses of Valsalva were aline. Next, the pigtail catheter was inserted via CFA into the aortic root, aortography was performed, and a super rigid guidewire was inserted, on which a balloon catheter was placed at the AV site (balloon size was 20, 23 or 25 mm depending on the native valve diameter), and AV was incised during high-frequency stimulation. After removal of the balloon catheter via the super-rigid guidewire, the Portico™ bioprosthesis was placed and implanted using the FlexNav™ delivery system. Final aortography was conducted after removal of the delivery system to assess the patency of the coronary arteries and the degree of aortic regurgitation (Figure 2). After removal of guidewires, catheters, and sheath introducers, surgical hemostasis was performed, the wound was closed layer-by-layer, and aseptic bandages were applied.

ISSN 0022-9040. Kardiologiia. 2022;62(8). DOI: 10.18087/cardio.2022.8.n1923

The early efficacy and safety of TAVR (postoperative period and 30 days after the surgery) was assessed using the VARC-2 criteria [4]. The technical success of the procedure was studied, which implied the absence of perioperative lethality, hemodynamically significant AR and residual stenosis defined as the mean systolic pressure gradient (SPGm) > 19 mm Hg, prosthesis dislocation and the need for the second valve replacement; mortality (all-cause and surgery-related); serious vascular complications and bleeding; perioperative myocardial infarction; cerebrovascular accident; acute renal failure; permanent pacemaker implantation.

The data were processed using STATISTICA 8.0 (StatSoft). The normality of sample data distribution was evaluated using the Shapiro–Wilk test. Depending on the type of distribution, quantitative data are presented as the arithmetic means ± standard deviations (M±SD) or the medians and interquartile ranges [Me (25th percentile; 75th percentile)], categorical data are expressed as percentages. A two-tailed paired Student's t-test was applied to the dependent populations to assess the statistical significance of the differences of quantitative indicators before and after the surgery. Univariate analysis of variance with a Bonferroni correction for multiplicity was used to determine intergroup differences. When the prognostic role of some indicators was assessed, the odds ratio and confidence interval were calculated. A four-fold conjugation table was analyzed using Fisher's exact test for independent observations or the McNemar test to compare the frequency of a variable before and after the surgery. Differences were considered statistically significant with p less than 0.05.

Results

Coronary artery disease was present in 20 (48%) operated patients, 12 (29%) patients underwent coronary artery stenting, 8 (19%) patients had a history of atrial fibrillation, and in 16 (38%) patients had type 2 diabetes mellitus. One patient who had previously undergone a surgical AV replacement with a biological prosthesis was subjected to a valve-to-valve surgery. At baseline, 26 (62%), 13 (31%), and 3 (7%) patients had CHF FC III, FC II, and FC I, respectively. Most of the patients (88%) had preserved systolic function, and only 5 patients showed markedly decreased left ventricular ejection fraction (LVEF). Postcapillary pulmonary hypertension, defined as pulmonary artery systolic pressure (PASP) at rest > 35 mm Hg, was present in 26 (62%) patients. Advanced AV calcification grade 3–4 was shown by high-resolution multislice computed tomography in 17 (40%) patients. The baseline clinical and demographic characteristics of patients are shown in Table 1.

In hospital and 30-day postoperative mortality was nil. There were no cases of surgery-related or all-cause death, coronary obstruction, myocardial infarction, or acute renal injury in the study group within 30-day follow-up period. On day 2 after surgery, one patient developed cerebrovascular accident, such as minor splenial stroke with resolution of neurological deficit before discharge from the hospital. In one case, left CFA impairment was diagnosed after TAVR, which was sutured to completely restore adequate blood flow. One female patient had a pulsating hematoma at the CFA puncture site, which was treated by applying a pressure dressing. Mean intraoperative blood loss was 116.3±50.7 (min-max 20–300) mL, no one needed blood transfusion. Intervention characteristics are summarized in Table 2.

Table 1. Baseline clinical and demographic characteristics of patients (n = 42)

Parameter	Value
Sex Male, n (%) Female, n (%)	 8 (19) 34 (81)
Euroscore II, %	2.5 (1.5;4.1)
Euroscore log, %	7.6 (4.6;9.8)
Arterial hypertension, n (%)	38 (90)
Coronary artery disease, n (%)	20 (48)
History of myocardial infarction, n (%)	3 (7)
History of coronary artery stenting, n (%)	12 (29)
Coronary stenosis > 50 % (uncorrected before TAVI), n (%)	9 (21)
Atrial fibrillation, n (%)	8 (19)
Implanted pacemaker, n (%)	3 (7)
Diabetes mellitus type 2, n (%)	16 (38)
Carotid stenosis > 50 %, n (%)	9 (21)
Chronic obstructive pulmonary disease, n (%)	9 (21)
History of COVID-19, n (%)	10 (24)
Chronic kidney disease stage 2–3, n (%)	15 (36)

The data are expressed as n (%) or Me (25th percentile; 75th percentile). TAVR, transcatheter aortic valve replacement; COVID-19, novel coronavirus disease caused by SARS-COV-2.

New-onset paroxysm of atrial fibrillation occurred in 3 (7%) patients after TAVR, which was managed with drugs. Complete left bundle branch block was observed in the postoperative period in 12 (29%) patients, and the conduction disorder was transient in one case. The new onset of left bundle branch block was not associated with initial grade 34 AV calcification (p > 0.05). At the time of discharge, 5 (12%) patients still had asymptomatic grade 1 atrioventricular block on ECG. During hospital stay, 2 (4.8%) patients with grade 3 atrioventricular block persisting for more than 5 days after TAVR required permanent pacing. Patients stayed in the intensive care unit for not more than 24 hours. Mean duration of postoperative hospital stay after transfer from the intensive care unit was 6 (min-max 5–12) days.

According to angiography and intraoperative TEE, incomplete opening of the bioprosthesis was observed in 13 (31%) cases, accompanied by paraprosthetic AR, which was managed by the prosthesis postdilation with a positive effect.

One 77-year-old female patient with grade 4 calcification (Figure 3) was subjected to several balloon inflation procedures after TAVR, however, control echocardiography on day 2nd after surgery showed grade 3 AR due to paraprosthetic fistula. Given initial REDUCED LVEF (37%) and high pulmonary artery pressure (PASP 85 mm Hg), increasing mitral insufficiency and pulmonary congestion, it was decided to close the fistula by endovascular approach.

Surgery protocol. The left CFA was accessed and a 12F introducer was inserted under endotracheal anesthesia. Right superficial femoral artery was punctured, and a 6F diagnostic catheter was placed. Systemic heparinization was performed. A rigid guidewire with the diagnostic catheter was inserted through the introducer, placed in the left CFA, through the paraprosthetic fistula of the AV prosthesis into the left ventricle, then a 9F delivery system was inserted. Two Occlutech tm occluders were inserted into the paraprosthetic fistula (Figure 4). Echocardiography showed the occluder in the fistula position, residual AR was minimal (Figure 5). When the guidewires, catheters, introducers were removed, hemostasis was performed, and the wound was closed layer by layer.

Neither patient had residual paraprosthetic AR higher than grade 2 at the time of discharge. The percentage of patients with grade 2 AR significantly decreased after surgery: 24% and 9.5% before and after TAVR, respectively (p=0.025). There was statistically significant association between initial grade 3–4 AV calcification and residual AR above the trace levels (p=0.75).

There were no significant differences in LVEF and PASP before and after surgery. The presence of initially reduced LVEF (< 50%) turned out to be a risk factor for the persistence of pulmonary hypertension 30 days after TAVR (odds ratio (OR) 12.4, 95% confidence interval (CI) 1.2–126.2; p=0.026). There was no relationship between paraprosthetic AR grade >1 and persistence of increased PASP.

The maximum and mean AV pressure gradients decreased significantly in all patients after TAVR, and the area of the aortic orifice, on the contrary, significantly increased compared to the preoperative values (Table 3). When comparing prostheses of different diameters between the groups, using univariate analysis of variance, both maximum (p=0.043) and mean systolic pressure gradients (p=0.038) differed statistically significantly. The posterior analysis showed significant differences in SPGmax between prosthesis sizes 23 mm and 29 mm (p=0.001), in SPGm for the 23-mm and 27-mm prostheses (p=0.004) and 23-mm and 29-mm prostheses (p=0.0007) (Table 4).

One patient (2%) with a 25-mm prosthesis implanted had a moderate patient-prosthesis discrepancy (mean gradient on the prosthesis was 24 mm Hg) without clinical manifestation.

One patient experiences a migration of the prosthesis into the aorta immediately after the procedure, which required the implantation of a second self-expandable valve prosthesis (Figure 6).

Figure 3. Multislice computed tomography of the heart, frontal view

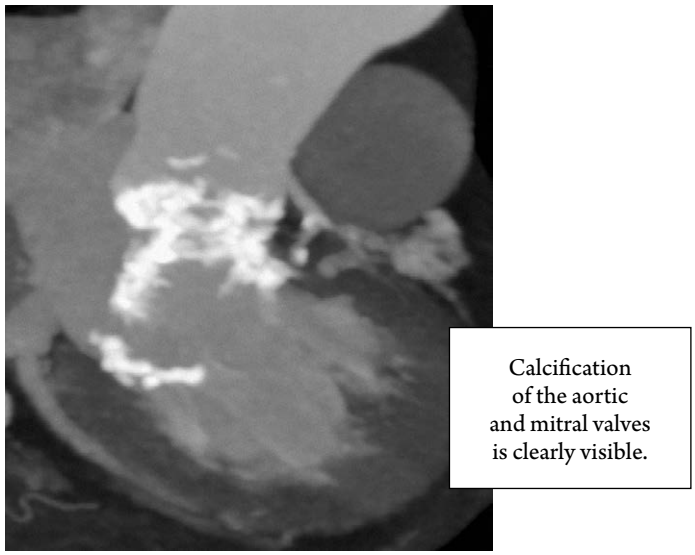


Table 2. Characteristics of the surgeries performed (n = 42)

Parameter		Value
Prosthesis dimension, mm	23, n (%)	9 (21)
	25, n (%)	11 (26)
	27, n (%)	10 (24)
	29, n (%)	12 (29)
Duration of surgery, min		90 (80;110)
Time of fluoroscopy, min		21 (19;24)
Volume of contrast agent administered, mL		154 (200;240)
Radiation exposure, mGy		1250 (1100;1844)
TEE, n (%)		41 (98)
Balloon predilation, n (%)		42 (100)
Balloon postdilation, n (%)		13 (31)
Duration of mechanical ventilation, min.		193 (160;226)
Second valve replacement needed, n (%)		1 (2)
Endovascular closure of paraprosthetic fistula, n (%)		1 (2)

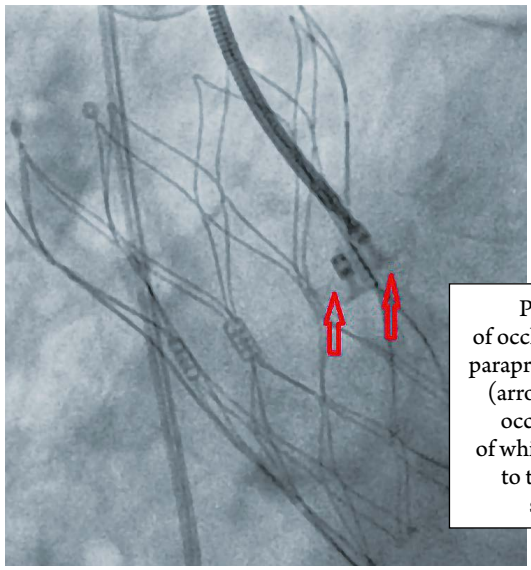
The data are expressed as n (%) or Me (25th percentile; 75th percentile). TEE, transesophageal echocardiography

At the end of hospital stay, all patients showed significant regression of clinical manifestations of AS and a decrease in CHF to FC≤2 in most patients (median FC 3 (2; 3) and 2 (1; 2) after TAVR, respectively, p < 0.001). The percentage of patients with CHF FC 3 after TAVR decreased from 62% to 7% (p < 0.001).

Analysis of changes in renal nitrogen excretion before and after TAVR showed a small, but statistically significant, decrease in the levels of serum creatinine from 83.3±22.9 μmol/L to 79.4±18.4 μmol/L (p=0.028) and an increase in the glomerular filtration rate (CKD-EPI) from 67.4±17.1 mL/min/1.73 m^2

ISSN 0022-9040. Kardiologiia. 2022;62(8). DOI: 10.18087/cardio.2022.8.n1923

Figure 4. Intraoperative fluoroscopy



Placement of occluders to close paraprosthetic fistula (arrows show the occluders, one of which is attached to the delivery system).

Table 3. Comparison of echocardiographic indicators before and after surgery

Parameter	Before surgery (n = 42)	After surgery (n = 42)	p value
LVEF, %	61.5±9.2	62.6±8.0	0.26
SPGmax, mm Hg	88.9±27.8	20.0±7.0	<0.001
SPGm, mm Hg	56.14±21.2	11.2±4.0	<0.001
Effective AV area, cm^2	0.67±0.2	1.9±0.3	<0.001
PASP, mm Hg	39.7±13.3	38.9±10.9	0.31
AR grade 2, n (%)	10 (24)	4 (9.5)	0.025

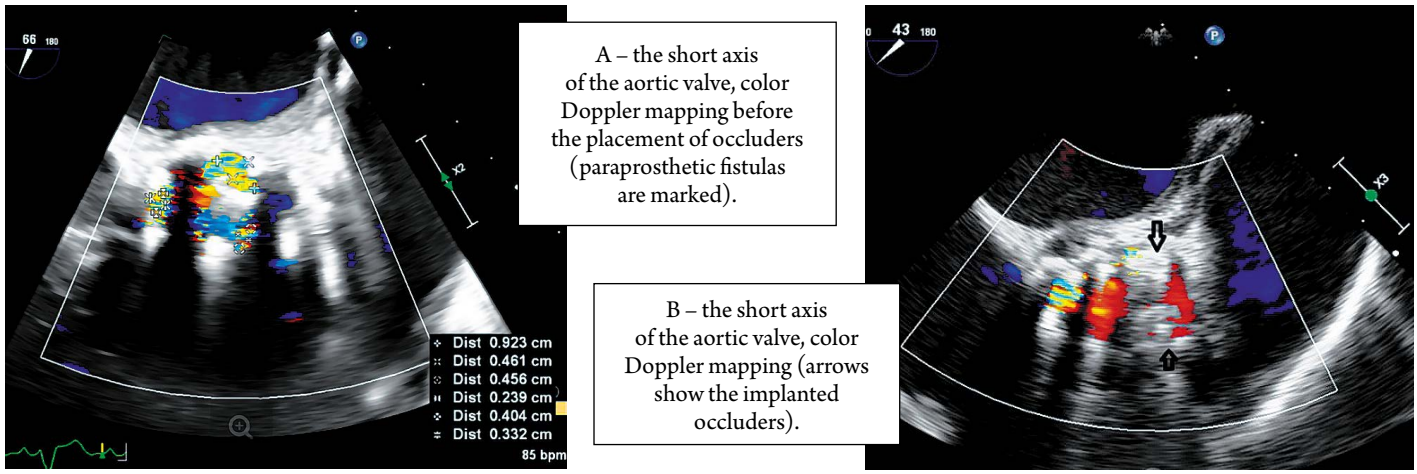
The data are expressed as % (n) or M ± SD; LVEF, left ventricular ejection fraction; SPGmax, maximum systolic pressure gradient, SPGm, mean systolic pressure gradient, AV, aortic valve; PASP, pulmonary artery systolic pressure, AR, aortic regurgitation.

to 71.2±16.8 mL/min/1.73 m^2 (p=0.018). The percentage of patients with stage 3b chronic kidney disease decreased from 14% to 7%, but the difference was not statistically significant (p=0.564).

Discussion

The immediate results of the first Russian series of transcatheter implantation of the Porticotm bioprosthesis support a good clinical efficacy and safety profile in patients with calcific aortic valve stenosis. Equivalent results were obtained in the PORTICO IDE study that included 750 patients (mean age 83 years, 53% of female patients), randomized to two groups: Portico™ (n=381) and other transcatheter valves (n=369). The study was designed to evaluate the non-inferiority of TAVR using Portico™ in safety and efficacy. 30-day all-cause mortality was 3.5% versus 1.9% (p=0.2), the incidence of postoperative stroke was 1.6% versus 1.1% (p=0.55), and major vascular complications were reported in 9.6% versus 6.3% of patients (p=0.1) in the Portico™ group and other (CoreValve and Sapien 3) groups, respectively. The groups did not differ significantly in the composite primary endpoint (12-month all-cause mortality or incidence of stroke) (14.9% in the Portico™ group versus 13.4% in other groups (p=0.006 for non-inferiority) [5]. A non-randomized

Figure 5. Intraoperative transesophageal echocardiography



A – the short axis of the aortic valve, color Doppler mapping before the placement of occluders (paraprosthetic fistulas are marked).

B – the short axis of the aortic valve, color Doppler mapping (arrows show the implanted occluders).

Table 4. Residual systolic pressure gradients on prostheses of different diameters

Parameter	23 mm (n = 9)	25 mm (n = 10)	27 mm (n = 10)	29 mm (n = 12)	p value
SPGmax, mm Hg	23.6±3.3	22.5±10.2	18.6±5.0	16.0±5.4	<0.001#
SPGmean, mm Hg	13.0±1.5	12.6±5.9	9.8±2.6	9.0±2.9	<0.001#. <0.05*

The data are expressed as M ± SD, # – for 23-mm and 29-mm prostheses,
* – for 23-mm and 27-mm prostheses; SPGmax, maximum systolic pressure gradient, SPGm, mean systolic pressure gradient.

prospective multicenter study by Möllmann H. et al. included 222 patients (mean age 83±4.6 years, 74.3% of female patients, mean STS risk 5.8%). 30-day all-cause mortality was 3.6%, the incidence of stroke was 3.2%, and major vascular complications occurred in 7.2% of patients. 13.5% of patients needed permanent pacing, moderate paraprosthetic regurgitation was observed in 5.7% of patients, none of the patients had severe regurgitation. An improvement in NYHA FC by at least one class was observed in 78.5% of patients [6].

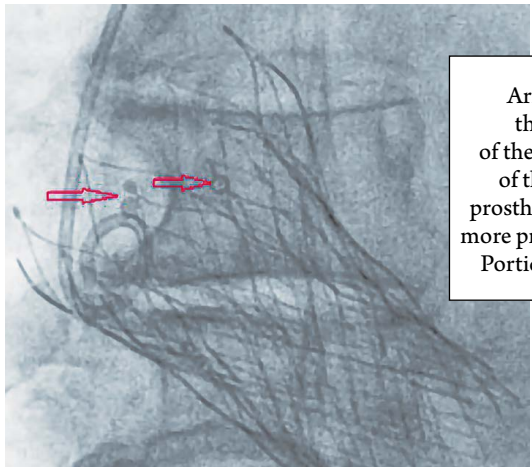
Our findings also show a significant improvement in heart FC after TAVR. Higher glomerular filtration rate may be indirectly indicative of generally improved organ perfusion [7, 8].

The presence of pronounced AV calcinosis in patients who underwent TAVR is a known risk factor of paraprosthetic insufficiency of various degree due to the incomplete opening of the metal frame and the formation of paravalvular fistulas [9, 10]. According to Kumar et al., the radial force of the Portico valve™ is 2-times lower than that of CoreValve™ [11], which increases the probability of incomplete frame apposition to the fibrous AV ring and the formation of a paraprosthetic fistula [12]. However, the incidence of significant paraprosthetic fistulas was not significant in our study.

The hemodynamic result of the intervention can be improved by postdilation of the prosthesis with a balloon of a subnominal diameter (20–25 mm). In our clinic, more than 600 self-expandable CoreValve™/Evolut R™ and Acurate Neo™ bioprostheses were implanted, therefore, we accumulated considerable experience in balloon postdilation to reduce paraprosthetic regurgitation. For example, we applied balloon postdilation for the Accurate Neo™ bioprosthesis in 55% of cases [13]. As for the Portico™ valve, the frequency of bioprosthesis postdilation was only 31% (Table 2). These differences may be due to the fact that, given the lower radial force of the Portico™ valve, there were fewer patients with massive grade 3–4 AV calcification among the patients selected for the implantation of a new prosthesis. This circumstance can probably also be an explanation for the extremely low need for an implantable pacemaker in our study (4.8%), since valvular and subvalvular calcification of AV is a significant risk factor for atrioventricular conduction abnormalities [14]. On the other hand, the possible contribution of decreased frame rigidity to reducing the frequency of transverse block cannot be disregarded.

Due to the high prevalence of coronary artery disease (CAD) in patients with severe AS (48% of patients in our study), it is relevant to keep free access to coronary arteries after TAVR. The design of this prosthesis (wide frame cells) facilitates performing coronary artery angioplasty and allowing using of a 15F sheath introducer, if necessary. Although there was no need for emergency myocardial revascularization after or during TAVR in the study group, 9 (21%) patients had uncorrected stenosis of one or more coronary arteries before the replacement, which may further require percutaneous intervention.

Figure 6. Intraoperative fluoroscopy



The study was limited by the small number of patients and the lack of long-term outcomes, which we are going to evaluate and compare with other types of self-expandable bioprostheses in future.

Conclusion

The immediate results of a single-center prospective study of transcatheter replacement of the new Portico™ self-expandable prosthetic valve demonstrated its satisfactory hemodynamic performance, and the good efficacy and safety profile of the procedure. Relatively low radial force of the frame can contribute to reducing the frequency of permanent pacemaker implantation after TAVR. The prosthesis allows achieving the best possible hemodynamic performance even in patients with severe calcification due to good apposition of the frame to the native AV structures and the possibility of carrying out balloon postdilation.

No conflict of interest is reported.

The article was received on 03/11/21

REFERENCES

1. Kolegaev A.S., Komlev A.E., Lepilin P.M. Novel devices for transcatheter aortic valve implantation. Russian Journal of Cardiology and Cardiovascular Surgery. 2021;14(1):32–9. [Russian: Колегаев А.С., Комлев А.Е., Лепилин П.М. Новые устройства для транскатетерной имплантации аортального клапана. Кардиология и сердечно-сосудистая хирургия. 2021;14(1):32-9]. DOI: 10.17116/kardio20211401132
2. Otto CM, Nishimura RA, Bonow RO, Carabello BA, Erwin JP, Gentile F et al. 2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease. Journal of the American College of Cardiology. 2021;77(4):e25–197. DOI: 10.1016/j.jacc.2020.11.018
3. Fontana GP, Bedogni F, Groh M, Smith D, Chehab BM, Garrett HE et al. Safety Profile of an Intra-Annular Self-Expanding Transcatheter

ISSN 0022-9040. Kardiologiia. 2022;62(8). DOI: 10.18087/cardio.2022.8.n1923

Aortic Valve and Next-Generation Low-Profile Delivery System. JACC: Cardiovascular Interventions. 2020;13(21):2467–78. DOI: 10.1016/j.jcin.2020.06.041
4. Kappetein AP, Head SJ, Généreux P, Piazza N, van Mieghem NM, Blackstone EH et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: The Valve Academic Research Consortium-2 consensus document. The Journal of Thoracic and Cardiovascular Surgery. 2013;145(1):6–23. DOI: 10.1016/j.jtcvs.2012.09.002
5. Makkar RR, Cheng W, Waksman R, Satler LF, Chakravarty T, Groh M et al. Self-expanding intra-annular versus commercially available transcatheter heart valves in high and extreme risk patients with severe aortic stenosis (PORTICO IDE): a randomised, controlled, non-inferiority trial. The Lancet. 2020;396(10252):669–83. DOI: 10.1016/S0140-6736(20)31358-1
6. Möllmann H, Linke A, Holzhey DM, Walther T, Manoharan G, Schäfer U et al. Implantation and 30-Day Follow-Up on All 4 Valve Sizes Within the Portico Transcatheter Aortic Bioprosthetic Family. JACC: Cardiovascular Interventions. 2017;10(15):1538–47. DOI: 10.1016/j.jcin.2017.05.021
7. Beohar N, Doshi D, Thourani V, Jensen H, Kodali S, Zhang F et al. Association of Transcatheter Aortic Valve Replacement With 30-Day Renal Function and 1-Year Outcomes Among Patients Presenting With Compromised Baseline Renal Function: Experience From the PARTNER 1 Trial and Registry. JAMA Cardiology. 2017;2(7):742–9. DOI: 10.1001/jamacardio.2017.1220
8. Lemes da Silva MV, Nunes Filho ACB, Rosa VEE, Caixeta A, Lemos Neto PA, Ribeiro HB et al. Improvement of renal function after transcatheter aortic valve replacement in patients with chronic kidney disease. PLOS ONE. 2021;16(5):e0251066. DOI: 10.1371/journal.pone.0251066
9. John D, Buellesfeld L, Yuecel S, Mueller R, Latsios G, Beucher H et al. Correlation of Device Landing Zone Calcification and Acute Procedural Success in Patients Undergoing Transcatheter Aortic Valve Implantations With the Self-Expanding CoreValve Prosthesis. JACC: Cardiovascular Interventions. 2010;3(2):233–43. DOI: 10.1016/j.jcin.2009.11.015
10. Di Martino LFM, Vletter WB, Ren B, Schultz C, Van Mieghem NM, Soliman OII et al. Prediction of paravalvular leakage after transcatheter aortic valve implantation. The International Journal of Cardiovascular Imaging. 2015;31(7):1461–8. DOI: 10.1007/s10554-015-0703-1
11. Kumar S, Moseman B, Vietmeier K. Abstract 16952: Stent Geometry and Radial Force Comparison of Portico vs CoreValve. Circulation. 2014;130(Suppl 2):A16952. DOI: 10.1161/circ.130.suppl_2.16952
12. Regazzoli D, Chiarito M, Cannata F, Pagnesi M, Miura M, Ziviello F et al. Transcatheter Self-Expandable Valve Implantation for Aortic Stenosis in Small Aortic Annuli. JACC: Cardiovascular Interventions. 2020;13(2):196–206. DOI: 10.1016/j.jcin.2019.08.041
13. Imaev T.E., Komlev A.E., Lepilin P.M., Kolegaev A.S., Salichkin D.V., Kuchin I.V. et al. First experience of transcatheter implantation of new-generation self-expanding bioprosthesis Acurate neo. Russian Journal of Cardiology. 2019;24(8):59–64. [Russian: Имаев Т.Э., Комлев А.Е., Лепилин П.М., Колегаев А.С., Саличкин Д.В., Кучин И.В. и др. Первый опыт транскатетерной имплантации самораскрывающегося биопротеза нового поколения Acurate Neo. Российский кардиологический журнал. 2019;24(8):59-64]. DOI: 10.15829/1560-4071-2019-8-59-64
14. Maeno Y, Abramowitz Y, Kawamori H, Kazuno Y, Kubo S, Takahashi N et al. A Highly Predictive Risk Model for Pacemaker Implantation After TAVR. JACC: Cardiovascular Imaging. 2017;10(10):1139–47. DOI: 10.1016/j.jcmg.2016.11.020