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VALVE-IN-VALVE TRANSCATHETER AORTIC VALVE REPLACEMENT ON A SELF-EXPANDABLE NITINOL FRAME DUE TO DEGENERATION OF PRIMARY BIOPROSTHETIC VALVE CUSPS. CLINICAL CASE OF A HIGH-RISK SURGICAL FEMALE PATIENT

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Introduction. We present the clinical observation of a 72-year-old female patient with high surgical risk and structural degeneration of a bioprosthetic aortic valve (AV) cusps in the form of stenosis, accompanied by severe dysfunction. Transcatheter implantation of bioprosthesis Medtronic CoreValve™ Evolut™ R-23 was performed using the valve-in-valve technique. The choice of minimally invasive treatment tactics is substantiated, a preoperative examination algorithm and a specific bioprosthesis model for such intervention are provided. **Materials and methods.** Imaging – echocardiography (Echo), electrocardiography, multispiral computed tomography, coronary angiography. Bioprosthetic valve calcification and stenosis with critical parameters of the bioprosthetic AV peak pressure gradient according to Echo data were the indications for minimally invasive surgery. **Results.** Dynamic observation revealed a progressive deterioration in the function of the previously implanted bioprosthetic heart valve in the aortic position, and a critical deterioration in the patient's condition. After additional examination of the patient and selection of a new prosthesis, valve-in-valve transcatheter aortic valve replacement was done. The positive dynamics of the general state of the patient was noted in the early postoperative period. Echo data showed that the bioprosthetic AV peak systolic pressure gradient decreased from 90 to 29 mmHg, average gradient – from 42 to 19 mmHg. **Conclusion.** The minimally invasive valve-in-valve transcatheter aortic valve replacement used to correct the dysfunction of a bioprosthetic AV that was previously implanted during an open surgery was shown to be safe and effective and can be considered as one of the options for repeat valve replacement.

Keywords: valve-in-valve transcatheter aortic valve replacement, aortic valve, aortic valve bioprosthesis, structural valve degeneration.

INTRODUCTION

Stenosis of the aortic valve (AV) is the most common acquired disease among all valvular heart diseases, requiring surgical treatment – open under artificial circulation (CP) or minimally invasive endovascular intervention. In view of the increasing tendency of population aging every year in the world, and in particular in Russia, the number of uses of biological prostheses for the correction of AV failure in case of its stenotic lesion is increasing [1].

The use of a biological prosthesis (BP) allows to abandon lifelong anticoagulant therapy [2, 3–7]. At the same time, among its significant drawback are the limited period of normal functioning associated with the degeneration of the biomaterial of the leaflets and dysfunction of the valve prosthesis as a whole, which necessitates a repeated intervention in the long term (after 5–10 years) [1, 3–7].

Today there are two possible ways to solve this problem. The first one is to perform re-implantation of the prosthesis in a standard way on an "open heart" in AC conditions. This path is associated with the risk of complications and mortality due to the elderly and senile age of patients, the presence of concomitant diseases in patients of this category and the trauma of the intervention itself. The second method – minimally invasive – is the transcatheter aortic valve implantation (TAVI). In the case of placing a new prosthesis in the frame of an old invalid one, this technique is called "valve-in-valve" [1, 3, 4].

Currently, in the world and especially in Russia, a small number of observations of reprosthetics using TAVI using the valve-to-valve technique have been published. Therefore, we consider it possible to offer our own experience of such an operation.

CLINICAL CASE

Patient K., 72, was routinely hospitalized in the emergency cardiac surgery department of the N.V. Sklifo-

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sovsky Research Institute for Emergency Medicine in November 2019. Upon admission, she complained of shortness of breath with minimal physical exertion (walking a distance of 50–100 m), episodes of tachycardia, and weakness.

The anamnesis showed that 11 years ago (in 2008), the patient underwent AV prosthetics with a Carpentier-Edwards 21 xenoaortic bioprosthesis, linear resection and exoprosthetics of the ascending aorta with a synthetic InterGard prosthesis, due to bicuspid AV stenosis and expansion of the ascending aorta up to 5 cm under AC conditions. 10 years after AV prosthetics, angina attacks began to recur, and therefore the patient was examined in June 2018. According to the results of coronary angiography, hemodynamically significant stenoses were not found. Echocardiography (EchoCG) revealed moderate dysfunction of the AV prosthesis (peak gradient 45–50 mm Hg), which did not require surgical treatment.

The patient has begun to notice a significant deterioration in her condition from February 2019 in the form of shortness of breath, weakness, and tachycardia attacks. Upon re-hospitalization six months later, the following data were obtained during the examination. ECG showed no pathological changes. According to echocardiography: ejection fraction (EF) of the left ventricle (LV) – 65%, local myocardial contractility is not impaired. AV: the contours of the previously implanted prosthesis are determined, the valves are compacted, thickened, their opening is sharply limited, the peak gradient is 90 mm Hg. Art., the average gradient is 42 mm Hg, regurgitation of the 0–1st degree. Mitral valve: grade 1 regurgitation, average diastolic gradient 2.6 mm Hg. Tricuspid valve: 2nd degree regurgitation. The systolic pressure in the pulmonary artery is 40 mm Hg.

Coronary angiography did not detect any hemodynamically significant stenoses.

From the anamnesis, it is known that the patient suffers from arterial hypertension for a long time (maximum BP values 160/80 mm Hg, adapted to BP values 110/60 mm Hg), type 2 diabetes mellitus, bronchial asthma, chronic obstructive pulmonary disease, obliterating atherosclerosis of the vessels of the lower extremities, chronic heart failure.

A consultation was held by a multidisciplinary team consisting of a cardiologist, cardiac surgeon, X-ray endovascular surgeon, anesthesiologist. When discussing the options for correcting the pathology, the following factors were considered, which determine the high risk of repeated open surgery in AC conditions: previous surgery – AV prosthetics and intervention on the ascending aorta, older age, the presence of concomitant pathology. Surgical risk stratification indices EuroSCORE II >10% and STS >10% were determined, exceeding the maximum allowable level for open surgery. In connection with all of the above, it was decided to carry out transcatheter endovascular AV reprosthetics using the valve-to-valve technique. An additional examination is scheduled.

Multispiral computed tomography (MSCT) of the heart with ECG synchronization and the introduction of a contrast agent (Iopromide 370 mg iodine / ml in a volume of 100 ml intravenous bolus). In the AV projection, an X-ray-positive frame of a previously installed bioprosthesis with signs of asymmetric calcification of its valves is visualized (it is not possible to objectively assess the volume and degree of calcification due to the presence of a metal frame of the prosthesis) (Fig. 1). In the projection of the ascending aorta – a vascular prosthesis. The sizes at the levels that are fundamental for the preoperative planning of TAVI were determined (Tables 1, 2). According to preliminary estimates, the diameter of the passage hole of the previously installed Carpentier Edwards 21 bioprosthesis was 19 mm.

High bifurcation of both common femoral arteries (CFA), left CFA aneurysm (up to 20 mm) were also revealed. The wall of the aorta and main branches throughout the entire length is unevenly thickened with the presence of multiple calcifications, the contrasting of the lumen is uniform. In the projection of the coronary arteries and the base of the posterior cusp of the mitral valve, calcifications of various sizes were also revealed. Below the renal arteries – a moderate deviation of the aorta to the right. There was a deficit in the diameter of the external iliac arteries (APA) on both sides.

After the examination, it was decided to implant a Medtronic CoreValve Evolut R23 transcatheter biopros-

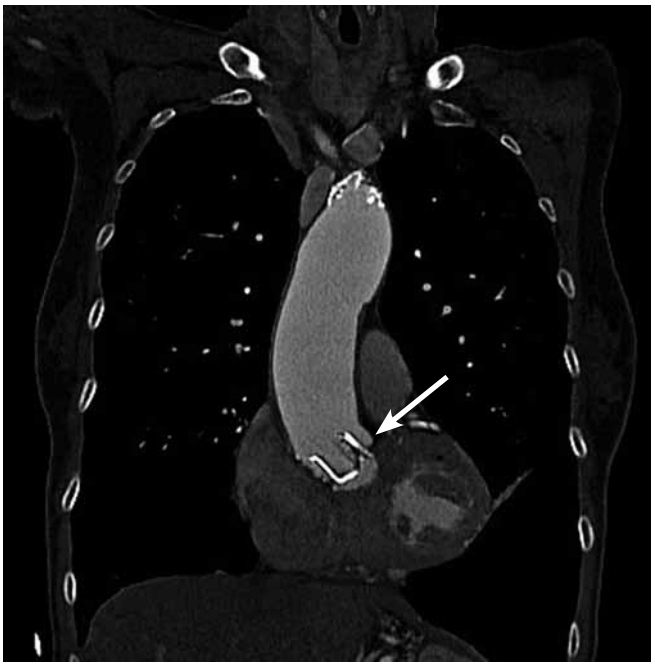

Fig. 1. MSCT of the heart before transcatheter AV bioprosthesis implantation; coronary projection; metal frame of the "prior" bioprosthesis Carpentier Edvards 21 (white arrow)

Table 1

MSCT data of the aortic valve elements and the left ventricle outflow tract

Analysis component	Diameter (mm)	Perimeter (mm)	Area (mm^2)	Height (mm)
Passage opening of the AV prosthesis	16.3	52.1	211.6	–
LV outlet	18.1	67.2	345.8	–
Sinuses of Valsalva	32.4	–	–	Right – 19 Left – 23
Sinotubular ridge	31–33	–	–	–
Distance from the annulus fibrosus to the orifices of the coronary arteries	–	–	–	To LCA – 15.7 To RCA – 13.2

thesis on a self-expanding nitinol framework through a transfemoral approach on the left.

Endovascular AV reprosthetics was performed in December 2019. Under endotracheal anesthesia, the left common femoral artery (CFA) was exposed and catheterized in the femoral triangle, and sheath 7F was installed. An electrode for temporary pacing was passed through the right jugular vein into the right ventricular cavity.

Through the puncture access of the right BOTH, a Pig tail 6F catheter was inserted into the aortic root. From the left-sided femoral approach, a diagnostic catheter was passed into the LV cavity, and a 0.035" Confida guidewire was inserted through it. The 7F introducer was replaced by the 12F introducer. Through its lumen, the previously implanted AV prosthesis was predilated with an Atlas Gold balloon catheter 18 × 40 mm with high-frequency pacemaker up to 180 per minute. Further, the 12F introducer was replaced with the 18F delivery system. The AV Medtronic CoreValve Evolut R23 prosthesis on a self-expanding nitinol framework was implanted in the aortic position.

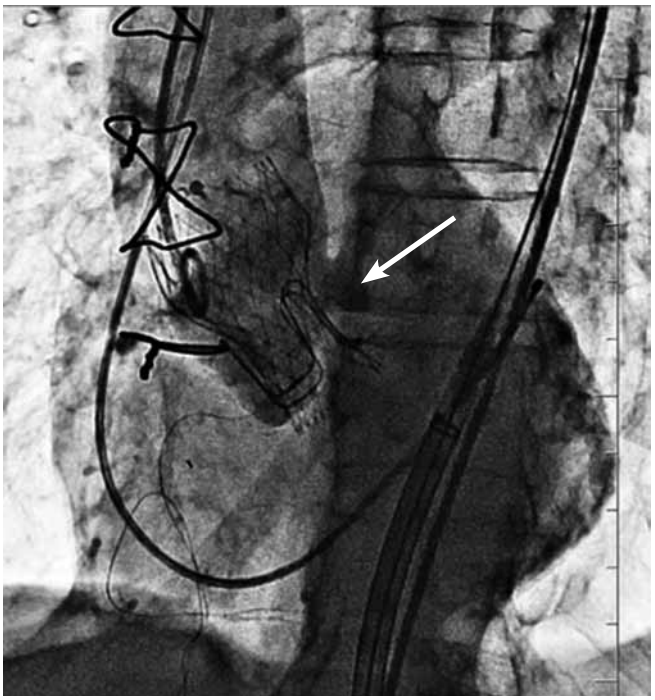

Fig. 2. Control aortogram after transcatheter aortic valve-in-valve bioprosthesis implantation; the position of the Medtronic CoreValve Evolut R23 prosthesis is optimal (white arrow); regurgitation is not determined

Table 2

MSCT data on the aorta diameter at different levels and its main branches

Analysis component	Diameter (mm)
Ascending aorta	33.9
Descending aorta	23
Abdominal aorta region in suprarenal area	20
At the level of renal arteries	13
Infrarenal area	12
Common iliac arteries	Right 4.6–6.3 Left 7.5–8.4
External iliac arteries	Right 4.4–4.7 Left 4.0–4.2
Common femoral arteries	Right 5.4–6.1 Left 5.4–5.7

Control aortography showed no regurgitation into the LV cavity (Fig. 2). Delivery system removed. Control transthoracic echocardiography was performed intraoperatively. The new prosthesis is located in the frame of the previously implanted one, paraprosthetic regurgitation of the 0–1st degree.

No events in the early postoperative period. There was a noticeable positive dynamics, both in the patient's objective condition and according to the data of instrumental examination.

ECG showed no signs of ischemic changes in the myocardium. The control echocardiography was performed (Table 3): LVEF – 65%, local contractility is not impaired. In the study in the color Doppler mapping mode, AV regurgitation of the 0–1st degree (Fig. 3, a), in the pulse-wave Doppler mode, the peak pressure gradient at the level of the AV prosthesis is 29 mm Hg. Art., the average gradient is 19 mm Hg. Art. (Fig. 3, b). Regurgitation on the mitral valve – grade 1–2, on the tricuspid valve – grade 2, systolic pressure in the pulmonary artery – 39 mm Hg. Art.

To assess the structures of the aortic root and the position of bioprostheses, MSCT of the heart with ECG

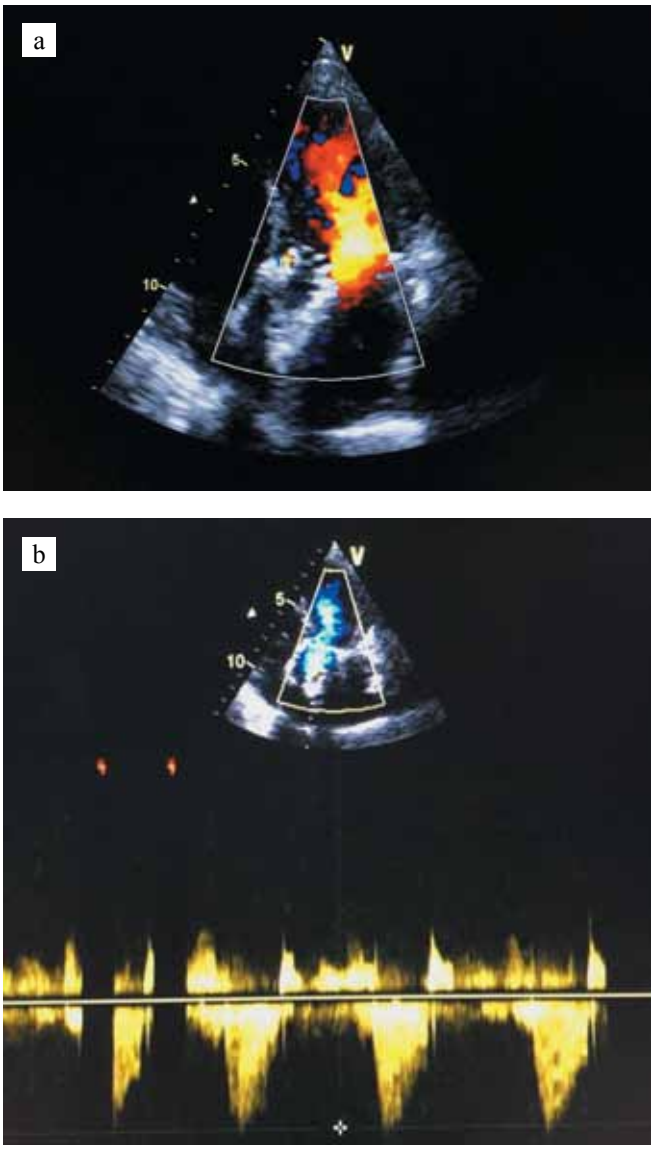

Fig. 3. Control Echo-CG after transcatheter aortic valve-in-valve bioprosthesis implantation: a – apical 5-chamber view, color Doppler mapping mode-regurgitation on the AV 0–1 degree; b – pulse-wave Doppler mode, peak pressure gradient at the prosthesis level AV – 29 mm Hg, mean pressure gradient – 19 mm Hg

Table 3

Echo-CG indicators before and after implantation of the AV bioprosthesis

Parameter	At admission	At discharge
LVEF	65%	65%
Peak gradient	90 mm Hg	29 mm Hg
Mean gradient	42 mm Hg	19 mm Hg
Regurgitation	0–1 grade	0–1 grade (interprosthetic)
Mitral valve	Regurgitation 1 grade	Regurgitation 1–2 grade
Tricuspid valve	Regurgitation 2 grade	Regurgitation 2 grade
mPAP	40 mm Hg	39 mm Hg

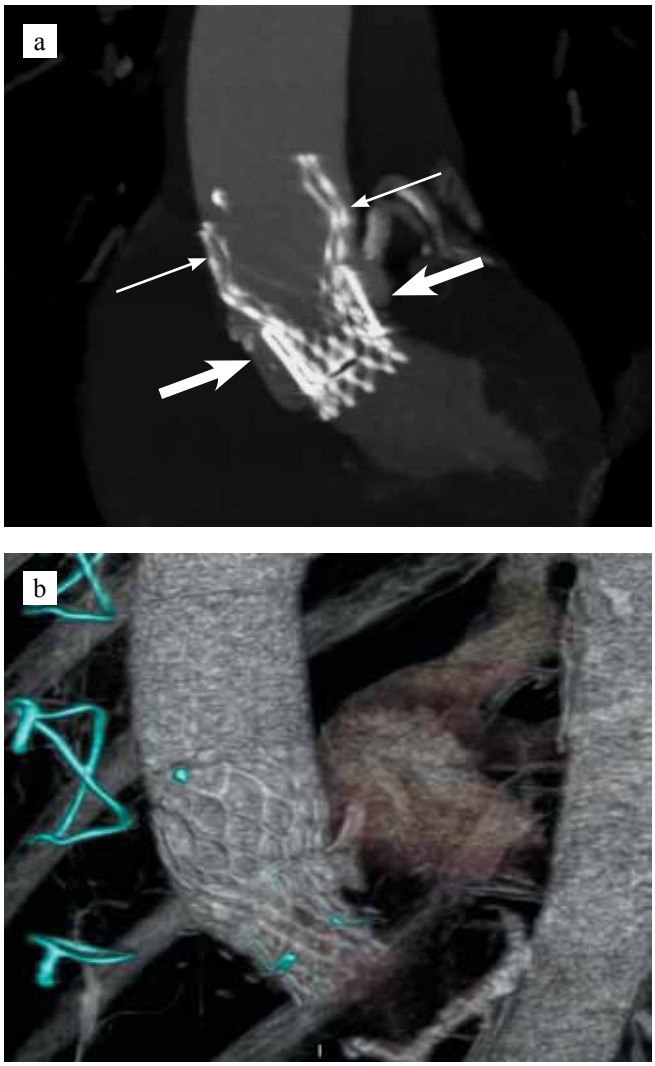

Fig. 4. MSCT of the heart after transcatheter aortic valve-in-valve bioprosthesis implantation: a – coronary plane, MIP view, bioprosthesis frame Medtronic CoreValve Evolut R23 (thin arrows) inside the bioprosthesis Carpentier Edvards 21 (thick arrows); b – 3D volume reconstruction of the aortic root with visualization of both prostheses

synchronization was performed on the 5th day (Fig. 4). In the AV projection, aortic root, sinotubular ridge, an implanted prosthesis is visualized, located in the frame of a previously installed biological prosthesis. There were no signs of valve dislocation. The position of the implanted valve complies with established standards. Contrasting of the trunks of the coronary arteries was preserved.

The patient was discharged on the 7th day after the operation with recommendations to control blood pressure, heart rate, control ECG, echocardiography, outpatient observation by a physician, cardiologist, pulmonologist.

DISCUSSION

When choosing the type of implantable prosthesis in the aortic position, bioprostheses are now more often

preferred, a significant advantage of which is the absence of the need for lifelong intake of anticoagulants and the associated risk of bleeding, constant laboratory monitoring of blood clotting. In addition, biological prostheses have a higher effective valve opening area, which leads to a low residual pressure gradient and a good hemodynamic effect. At the same time, a significant disadvantage of the bioprosthesis is the relatively short period of its normal functioning [1–7]. According to various studies, up to 60% of prostheses require replacement after 15–20 years. At the same time, according to the Global Valve-in-Valve Registry, the median life of bioprostheses is 9 years (interquartile range is 7–13 years) [1, 8, 9].

Dysfunction of the bioprosthesis is caused by degenerative changes in the structure of the valves (calcification and damage). This eventually leads to the need for reprosthetics [2, 5–9].

The standard method of bioprosthesis restenosis correction is repeated surgical implantation, as a rule, of a similar prosthesis, which is associated with a high risk of complications and mortality, which is primarily due to the high trauma of the intervention itself, as well as the advanced age of patients and the presence of concomitant diseases [1, 3–5].

In such difficult situations, a new alternative to open AV interventions is a minimally invasive operation – transcatheter implantation of AV bioprostheses with a sutureless fixation method [1, 3–7].

The presented clinical observation of a patient with dysfunction of a previously implanted AV bioprosthesis due to its calcification and stenosis and a high surgical risk showed the high efficiency of transcatheter implantation of the prosthesis by the "valve-in-valve" technique. The use of a bioprosthesis manufactured by Medtronic CoreValve Evolut R (Medtronic Inc., USA) with a self-opening function and the possibility of repositioning made it possible to implant it exactly into the frame of a previously implanted prosthesis. According to postoperative echocardiography, interprosthetic regurgitation was grade 0–1. Dislocation of prostheses in the early postoperative period was not revealed.

A distinctive feature of this clinical observation is the need for careful selection of a "new" bioprosthesis and delivery device of appropriate parameters, taking into account the size of the "old" bioprosthesis and individual anatomical features (small lumen) of the patient's iliac arteries. The complexity of endovascular intervention consisted in pronounced calcification of the walls of the aorta and its branches, and a deficit in the diameter of both APA, which increased the risk of dangerous complications. A bioprosthesis was used, used, according to the literature, in addition to the standard TAVI by "valve-in-valve" technique. This device is a percutaneous delivery system and porcine pericardial valve housed on a self-expanding nitinol mesh structure. The delivery system provides controlled and portioned repositioning. Radiopaque design allows for optimal positioning. The framework is designed to maintain coronary perfusion. An intraannular position and a sealed valve skirt reduce paraprosthetic regurgitation. The diameter of the delivery catheter at 18F is the smallest among those known today, its use was the only acceptable option for passing instruments through the ABP in the patient under discussion, and in combination with other features of the device determined our choice.

Currently, various models of transcatheter bioprostheses are widely used for valve-in-valve implantation: the first generation – Sapien, Sapien XT, Sapien 3 (Edwards LifeScience, USA), CoreValve, CoreValve Evolut R, Melody (Medtronic Inc., USA); second generation – Portico (St. Jude Medical, USA), Lotus (Boston Scientific, USA), Accurate TA (Symetis SA, Switzerland), Engager (Medtronic Inc., USA) [1]. In our observation, a Medtronic CoreValve Evolut R bioprosthesis with a diameter of 23 mm was successfully used.

Today, transcatheter heart valve reprosthesis is the only method that can significantly reduce the likelihood of complications of surgical treatment in high-risk patients with severe stenosis of the previously installed AV bioprosthesis [2, 3–7].

Based on the analysis of literature sources, various types of intra- and postoperative complications are possible limitation of the application of the valve-in-valve technique: the formation of a high transprosthetic pressure gradient, para- and transprosthetic regurgitation, device dislocation, obstruction of the coronary arteries with exfoliated calcifications, heart rhythm disturbances, as well as complications associated with the operational features of the procedure itself [1, 6, 7]. To prevent the occurrence of such complications, a thorough preoperative examination of the patient using echocardiography, coronary angiography, MSCT of the heart, the entire aorta and arteries of the lower extremities up to the level of the ilio-femoral segment is necessary. This allows making an accurate selection of the model of the AV transcatheter prosthesis, considering the anatomical features of the access arteries, the parameters of the aortic root, the design and size of the "old" bioprosthesis.

The X-ray endovascular technique of re-implantation of a bioprosthesis in the aortic position using the valve-in-valve technique is a rational treatment option, especially in elderly patients with a high surgical risk due to existing concomitant pathology [10]. The use of surgical risk scales known in cardiac surgery (EuroSCORE, STS-score) [11, 12] made it possible not only to predict the likelihood of complications, but also to prevent them in the postoperative period in the high-risk patient we described and, refraining from surgical AV reprosthetics, to successfully carry out transcatheter intervention.

CONCLUSION

The presented clinical case of successful transcatheter aortic valve replacement using the valve-in-valve technique demonstrates the safety and effectiveness of this treatment method. It can be argued that this method is a real alternative to the classical open intervention. This type of surgical intervention, of course, can be considered as one of the options for reprosthetics in patients with high surgical risk, for whom reoperation is indicated due to dysfunction of previously implanted biological prostheses of heart valves.

The authors declare no conflict of interest.

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