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Comparative Evaluation of Aortic Valve Replacement Methods in Patients Over 70 with Aortic Stenosis

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BACKGROUND As life expectancy and quality of health improve, more and more people reach old age, and so does the number of heart diseases. One of the most urgent problems among elderly patients is degenerative stenosis of the aortic valve (AV). The conservative treatment of symptoms of chronic heart failure with AV stenosis improves the patient's condition only for a while, whereas surgical treatment such as replacement of AV is recognized as the main effective method of treating a defect. Recently, alternative technologies for prosthetic AV have been developed, aimed at reducing adverse effects of artificial circulation (AC) in high-risk patients and minimizing the scope of surgical intervention.

AIM OF STUDY The aim of the study was to evaluate the immediate results of surgical treatment of aortic stenosis using different methods in patients over 70.

MATERIAL AND METHODS The article presents the results of treatment of 64 patients over 70 with isolated AV stenosis, operated with different surgical techniques from July, 2016 to January, 2018. All patients were divided into three groups, differing in the severity of the initial condition and the method treatment. Group 1 (transcatheter implantation of the prosthetic AV, EuroSCORE II — 21.81%) consisted of 19 patients, Group 2 (non-suture implantation of a Perceval prosthetic valve under the AC, EuroSCORE II — 13.81%) consisted of 13 patients and Group 3 ("standard" prosthetics, EuroSCORE II — 9.89%) consisted of 32 patients.

RESULTS In Group 1, two patients died, the hospital mortality was 10.5%. In Group 2 and Group 3, one patient died, the hospital mortality was 7.6 and 3.1%, respectively. Implantation of a permanent pacemaker was required in three patients (15.7%) from the TAVI group after installation of Medtronic Core Valve and two patients (15.3%) from the Perceval group.

CONCLUSION The obtained results of AV replacement by various methods allowed to expand indications for the management of AV stenosis in patients of the older age group with a high surgical risk of operation under AC conditions who had not previously been considered candidates for surgical treatment of aortic malformation due to the age and severity of the concomitant pathology.

Keywords: aortic stenosis, surgical treatment, transcatheter implantation of the aortic valve, artificial circulation

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AC — artificial circulation
AV— aortic valve
CABS — coronary artery bypass surgery
RCA — right coronary artery
SRAV — standard aortic valve replacement
TAVI — transcatheter aortic valve implantation

Aortic valve replacement (AV) remains the second most common operation in cardiac surgery. Thus, in 2016, out of 52,377 heart operations in adults, the proportion of coronary artery bypass surgery (CABS) was 70.5% and the proportion of AV replacement was 11.6% (more than 6,000 surgeries) [1]. A "standard" operation involves sternotomy, using artificial circulation (AC), excision of the diseased AV and fixation of the prosthesis with sutures to the fibrous ring of AV. The mortality rate in such surgeries is 4–8% [2, 3] and depends on the age and initial condition of patients, in the group of older patients it exceeds 7% and may reach 13% [4-6].

The justified desire to reduce mortality in patients of the older age group and expand the indications for elimination of an aortic defect in patients with significant comorbidities led to the development of less aggressive methods for replacing AV. In 2002, the transcatheter AV implantation (TAVI) [7] was proposed, not involving the

use of AC, and in 2007, the method of non-suture implantation of the AV prosthesis under the conditions of open intervention and AC was presented [8, 9].

The aim of this study is to evaluate immediate results of the surgical treatment in patients over 70 with AV stenosis using various methods for its management.

MATERIAL AND METHODS

The study included the results of treatment in 64 patients over 70 (mean age 76.6±3.0 years) with isolated aortic stenosis, operated in the emergency room for cardiac surgery, artificial circulation and heart transplantation at the N.V. Sklifosovsky Research Institute for Emergency Medicine from July 2016 to January 2018.

Three groups of patients were distinguished, differing in the severity of comorbidities and the chosen method of AV replacement.

In the Group 1 (TAVI group), 19 patients with high surgical risk (EuroSCORE II 21.81%) received transcatheter implantation of the AV prosthesis. The average age of patients in this group was 78.7±7.7 years, the maximum age was 87 years.

The Group 2 (Perceval group) included 13 patients with a less significant degree of surgical risk (EuroSCORE II 13.81%), who underwent non-suture implantation of the AV prosthesis under AC conditions. In this group, the average age of patients was 77.3±2.2 years, the maximum was 81 years.

The Group 3 was the "standard" AV replacement (SRAV). It consisted of 32 patients with moderate surgical risk (EuroSCORE II 9.89%), who underwent open-heart surgery in the conditions of artificial circulation according to standard methods. The average age of patients was 75.3±3.0 years, the maximum was 83 years.

There were no statistically significant differences in age and severity of failure between groups. However, the groups differed significantly in the type of comorbidities (Table 1).

Table 1

Comparative characteristics of groups

Concomitant pathology	Group 1 TAVI	Group 2 Perceval	Group 3 SRAV
Vascular atherosclerosis	12	10	7
Postinfarction cardiosclerosis	11	10	7
Pulmonary hypertension	11	7	5
Atrial fibrillation	11	5	10
Diabetes mellitus	9	2	6
Mobility impairment	9	2	-
Acute cerebrvascular event in history	7	3	4
Cancer	6	4	1
Chronic obstructive pulmonary disease	6	-	5
Obesity	6	1	7
Reduced ejection fraction of the left ventricle	5	1	1
Critical states	2	1	-
Permanent pacemaking	2	-	-
Chronic renal failure	1	1	2
Repeated interventions	1	1	-

Notes: SRAV – standart replacement of the aortic valve

All patients from three groups with stenotic lesions of the coronary arteries underwent angioplasty prior to the surgery in order to reduce the time and amount of intervention.

In the TAVI group, 15 patients got CoreValve transcatheter prostheses (Medtronic, USA) and 4 patients had Edwards Sapien prostheses (Edwards Lifesciences, USA) of various sizes: 23 mm — 2 prostheses, 26 mm — 7 prostheses, 29 mm — 8 prostheses and 31 mm — 2 prostheses. Perceval S (Sorin Group, Italy) non-suture prostheses of the following sizes were implanted to all patients of the second group: S (19–21 mm) — 5, M (21–23 mm) — 4, L (23–25 mm) — 4 prostheses. In the third group (SRAV), Carpentier-Edwards Perimount (5), Aspire (2), Braile Biomedica (20) and SJM BioCor (5) were also used in various sizes: 19 mm — 1 prosthesis, 20 mm — 2 prostheses, 21 mm — 14 prostheses, 23 mm — 13 prostheses and 25 mm — 2 prostheses. AC operations were performed under

spontaneous hypothermia (34–35° C) and crystalloid high-volume cardioplegia (58%) or blood cardioplegia (42%) was used to protect the myocardium.

RESULTS

In the Group 1 (TAVI), two patients died, the mortality rate was 10.5%. In one observation, a 78-year-old female patient (EuroSCORE II 23.6%), needed reposition of the prosthesis during transcatheter implantation, which was accompanied by embolism of cerebral vessels by calcium masses and extensive brain infarction. In another observation, (EuroSCORE II 18.2%) after implantation of the prosthesis, heart rhythm disturbances and progressive hemodynamic deterioration developed in a 76-year-old female patient. The control aortography revealed ostial occlusion of the right coronary artery (RCA), which was absent immediately after implantation of the prosthesis. The stent was installed into the RCA with complete restoration of blood flow, which contributed to the regression of myocardial and arrhythmogenic heart failure. However, serious rhythm disturbances reappeared soon, which required resuscitation measures which were ineffective. At autopsy, it was established that one of the prosthetic paddles was pressing the RCA, which could result in impaired blood flow in the artery. The coronary stent, which clearly went out into the aortic lumen immediately after implantation, was displaced approximately 4–5 mm distal to the artery, which led to a repeated impairment of blood flow in RCA and acute myocardial ischemia. The position of the prosthesis was correct, and the proximity of the mouth of the RCA, most likely, was associated with the individual anatomy of a patient.

In the Group 2 (Perceval) and 3 (SRAV), one patient died, the mortality rate was 7.6 and 3.1%, respectively. Both patients were at the age of 77 years (EuroSCORE II 12.9% and 5.4%, respectively) and had an initial mild multiple organ failure, which progressed after the operation under AC conditions.

Three patients (15.7%) from the TAVI group and two patients (15.3%) from the Perceval group had the complete atrioventricular block after installing Medtronic CoreValve prostheses, which required implantation of a permanent pacemaker.

DISCUSSION

With increasing life expectancy and improving the quality of health care, an increasing number of people reach old age, and therefore the number of heart diseases is growing [10]. Today, degenerative AV stenosis remains an extremely urgent problem among older patients [11]. The conservative treatment of the symptoms of chronic heart failure in AV stenosis improves the patient's condition only for a while. Among patients with clinical manifestations of AV stenosis, receiving conservative treatment, the mortality during the first year is 25% and during the second year it may reach 50% [12]. The surgical treatment such as AV replacement is the main effective treatment for heart disease [13–15].

Today, there are three main most commonly used surgical methods of AV replacement for aortic stenosis.

The “gold standard” is the replacement of AV under AC by fixed sutures with a biological or mechanical prosthesis (much less frequently in older patients). The world's first successful AV replacement surgery was performed by D. Harken in 1960 [16]. In our country, the first operations were performed by S.A. Kolesnikov, G.M. Solovyov and G.I. Zuckerman in 1964 [17–19]. The mortality rate in such an operation varies from 4 to 8% and depends on the initial state and the age of patients [2, 3].

Older patients are more likely to have significant comorbidities than younger patients (Table 2). In this regard, the risk of “standard” surgery in patients under AC is higher in patients of the older age group, which is accompanied by the growth of hospital mortality up to 7–13% [4–6] and increases the frequency of justified refusals to perform such an operation.

Table 2

The incidence of concomitant disease in patients of the older age group (>80) [11]

Disease	Incidence, %
And shectic heart disease	40–60
Arterial hypertension	20–50
Chronic obstructive pulmonary disease	15–25
Cerebrovascular disease	5–25
Diabetes	10–20
Chronic renal failure	5–10
Multifocal atherosclerosis	2–10

This fact resulted in the development of alternative, less aggressive methods of AV replacement. In 2002, A. Cribier performed the world's first transcatheter AV implantation in France [20]. The first TAVI procedure in the Russian Federation was carried out in 2009 [2]. Today, the world has accumulated a great experience of such operations, data from the PARTNER-2 (Placement of AoRTic TraNscathetER Valve) study indicate a low hospital

mortality rate and a low incidence of intra- and postoperative complications in patients with high surgical risk [21]. At present, TAVI is indicated in patients with increased risk of AV stenosis as an alternative to the standard method of AV replacement under AC conditions [22]. Two systems for TAVI are widely used in Russia: the balloon-expandable stent prosthesis Edwards Sapien (Edwards Lifesciences, Irvine, CA, USA) and the self-expanding stent prosthesis CoreValve (Medtronic Inc, Minneapolis, MN, USA). Various modifications of these types of prostheses from other manufacturers are used rarely.

Like most methods, this procedure has its drawbacks, including:

- moderate and severe paraprosthetic regurgitation;
- violation of cerebral circulation;
- heart rhythm disturbances;
- occlusion of the mouth of the coronary arteries;
- acute aortic dissection or aortic root rupture;
- vascular complications.

Paraprosthetic regurgitation, according to a PARTNER study, is found in 11.7% of cases (most commonly in CoreValve prostheses) and is an alarming diagnostic predictor of a decrease in one-year survival [23, 24]. In our work, according to aortography and transesophageal echocardiography, aortic regurgitation was assessed as not exceeding grade I. The frequency of cerebral circulation disorders varies from 1.7 to 8.4% [23], in the presented material it was 1.9%.

Cardiac rhythm disturbances requiring implantation of a permanent pacemaker, according to the literature, occur in 20–43% of cases after implantation of the CoreValve [25, 26] and in 4–6% of patients after implantation of the Edwards Sapien prosthesis [23]. In our study, permanent pacemaker implantation was needed in 3 (15.7%) patients with CoreValve prostheses. The more frequent development of complete atrioventricular block after implantation of the CoreValve prosthesis is due to the peculiarities of its design: the "skirt" of the CoreValve drops into the left ventricular cavity a few millimeters, while Edwards Sapien fits directly into the aortic ring. This position of the CoreValve may lead to increased pressure on the conductive path area.

The occlusion of the coronary arteries mouth is a rare (0.3–1.5%) but very dangerous complication [27–29]. We experienced such a fatal complication in one patient (1.9%). Acute aortic dissection and aortic root rupture are even rarer (0.4–0.6% of observations [29]) and no less dangerous. Finally, vascular complications associated with the need for a delivery of the device through the main branches of the aorta, in particular through the femoral artery, occur in 15.9% of patients [28]. In our group, such complications were observed in 2 patients (10.5%); in both cases, due to calcification of the femoral artery, its plastic surgery was required after the removal of an introducer.

The economic aspect is important, the high cost of the high-tech TAVI procedure does not allow routine use of this technique in all patients with degenerative AV stenosis.

In 2007, the Perceval S (Sorin Group, Italy) xenopericardial bioprosthesis was introduced into clinical practice in a self-expanding anchor device for non-suture implantation under AC conditions [8, 9]. The technique was adopted in Russia in 2013 [30]. The non-suture biological stent valve consists of two rings interconnected by nine connecting paddles, a double sheet of bovine pericardium is fixed to the commissural paddles. After excision of the native valve with the help of three guiding sutures, a stent bioprosthesis, which does not require suturing of the fibrous ring and tying knots, is implanted into the fibrous ring (guiding situres are later removed). The valve is then further expanded with a balloon. In 2012, Edwards Lifesciences introduced the so-called Edwards Intuity Elite valve of quick opening, which is an alternative to Perceval S [31]. When using this system with the help of three guiding sutures, a stent bioprosthesis is implanted into the fibrous ring of AV on a balloon-openable anchor system under visual control, which is then fixed to the fibrous ring with the same sutures. Thus, both Perceval S and Edwards Intuity Elite provide fast implantation.

Despite the short period of use of the method of sutureless implantation of an AV prosthesis under AC conditions, its advantages are obvious:

- reduction in the duration of myocardial ischemia (in hospitals with a high experience in using Perceval S, myocardial ischemia decreased to 20 minutes [32]);
- reduction of the duration of surgery as a whole and the frequency of complications associated with AC;
- usability with a narrow fibrous ring and calcified aorta;
- good hemodynamic parameters;
- simplified implantation during repeated operations.

In our practice, an aortic right ventricular fistula was detected in one patient in the immediate postoperative period after the supposed "standard" replacement (SRAV), and therefore a successful second operation was performed 2 weeks after the initial surgical procedure — suturing of the aortic ventricular fistula, repeated replacement with Perceval S and ACB of RCA due to the impossibility of plastic surgery of the defect not involving the mouth of the RCA into suturing.

According to P. Kevin et al. [33], 30-day mortality after implantation of a Perceval S prosthesis is 2.1%. In the presented material, one patient died, which in a small group was 7.6%.

The complications of the sutureless method of AV replacement include the following:

- impaired conduction of the heart, which, according to the literature, occurs in 13.3% of observations [34];

- violation of cerebral circulation — 1.5%;
- paraprosthetic regurgitation — 3.0%;
- degeneration of bioprosthetic valves — 0.4% [33].

In our experience, the implantation of a permanent pacemaker was needed in two patients (15.3%), other complications were absent.

FINDINGS

1. The introduction of new "smooth" methods of aortic valve replacement (transcatheter implantation without artificial circulation and sutureless implantation of the aortic valve bioprosthesis during an "open" operation) ensured a differentiated approach to the choice of treatment depending on the severity of the patient's initial state and allowed achieving good immediate results in patients of the older age group with a high risk of surgical treatment.

2. At the same time, the results of a "standard" aortic valve replacement in patients with low initial risk of surgical intervention do not exclude the possibility of such an approach in patients of the older age group, including patients over 80.

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