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RESULTS OF AORTIC VALVE PROSTHESIS WITH "BIOLAB KA/PT" SKELETAL BIOLOGICAL IMPLANTS IN PATIENTS ABOVE 60

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Abstract

Introduction of valve replacement methods into clinical practice has ensured new prospects for treatment of patients with severe valval heart disease. In surgery of acquired heart defects the isolated aortic defects account for 10-23% of all valvular lesions, half of those patients are over 60 years of age. The low thrombogenicity of biological prostheses, the abolition of anti-coagulant drugs, and the formation of blood flow close to the physiological one make those prostheses means of choice for the elderly and senile age patients.

From January 2009 to May 2010, "Biolab KA/ PT" biologic prostheses were implanted in the aortic position into 92 patients. The immediate results of testing in the clinic of our institution demonstrated adequate recovery of intracardiac hemodynamics leading to normalization of parametric and functional characteristics of the heart. Implantation of "Biolab KA/ PT" bioprostheses was accompanied by a minimum level of prosthesis-related hospital mortality and complications.

Keywords: aortic defect, prosthetic aortic valve, bioprosthesis, frame, patients older than 60 years.

INTRODUCTION

Development and application of biological substitutes for heart valve have a half-century history. Their continuous improvement and use in the clinic is largely due to the shortcomings of mechanical prostheses: the need to receive lifelong anticoagulation, risk of thromboembolic complications, prosthetic endocarditis, and acoustic discomfort. In contrast, biological substitutes form the structure of blood flow close to the physiological one, have low thrombogenicity, in most cases allow to avoid anticoagulant therapy, and the gradual development of their dysfunction makes it possible to perform a second operation in a planned manner. Biological prosthetic heart valves were widely used in the late 1960s and 1970s.

The founders of the clinical application of biological substitutes for heart valves and the creators of the first models are B. Barratt-Boyes, D. Ross, A. Carpentier, W. Hancock, W. Angell [*Ross D., 1962; Hancock W., Sattler F., 1977; Angell W. et al., 1979; Carpantier A. et al., 1984; Barrat-Boyes B. et al., 1998*]. Since then, the development of bioprostheses was carried out mainly in two directions: the first aimed to develop design of bioprostheses, the second - to improve the technology of biological tissue structural stabilization. In 1967, A. Geha was the first who suggested to fix bio valve to the support frame (stent) covered with synthetic fabric [*Angell W. et al., 1979;* Geha A., 1987; *Malinovsky N. et al., 1988; Barrat-Boyes B. et al., 1998*]. Many subsequent studies were aimed at improving the structure and properties of the supporting frames for fixing the biological part of the prosthesis. Modern support frame of "Biolab KA/PT" xenoprosthesis has a variable stiffness, consists of a frame and a base made of high quality, durable and biocompatible cobalt-chromium-nickel alloy. The frame is made of wire and has three flexible racks. Mechanism for regulating the process of valves opening due to the elastic radial displacement of flexible

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wire racks of the frame significantly improved hydrodynamic characteristics of the valve. The elasticity of the valve has reduced the stress on the valve during valve closure, thereby increasing resistance to deformation and, consequently, the durability of the prosthesis [*Kamolov S., 2009*].

According to F.J. Schoen, during the recent years ratio of implanted biovalves and mechanical prostheses in the world clinical practice makes 45% and 55%, and by L.H. Edmunds: 40% and 60%, respectively [*Carpantier A. et al., 1984; Barbarash L. et al., 1995; Orlovsky P. et al., 2007; Kamolov S., 2009*].

The aim of our study was to evaluate the hemodynamic properties of "Biolab KA/PT" prosthesis and clinical effects of its implantation in the aortic position in the early postoperative period.

MATERIAL AND METHODS

From January 2009 to May 2010, "Biolab KA/PT" low-profile xenopericardial bioprosthesis was implanted into 92 patients (in the aortic position). The mean age was 69.1± 4.5 (61-82 years), of which there were 48 men (52%), 44 women (48%). Mean index (NYHA) was III. Stage I circulatory failure was diagnosed in four patients (4.3%); stage IIA in 65 patients (70.6%), stage IIB in 23 (25%). The reason for aortic valve disease formation in 59 patients (64%) were degenerative aortic valves, 23 (25%) patients were diagnosed with aortic stenosis on the background of rheumatic disease, 5 (5.5%) patients had bicuspid congenital aortic valve, and 5 (5.5%): the primary infective endocarditis. The average body surface area (by Du Bois) was 1.7± 0.2 m^2 (1.4-2.1 m^2). Access was performed by the usual method: the isolated aortic vice with a standard heart-lung machine to connect using a double-barreled vein cannula, which is inserted into the right atrium, with multivalve prosthesis - with a separate hollow vein cannulation. Visualization of the aortic valve was achieved through cross aortotomy. Dimensions of implantable prostheses were determined from data of preoperation ultrasound, and (if necessary) from CT data. The bioprosthesis selected in accordance with the size of the fibrous ring of the aortic valve was washed for 90 *min* in isotonic sodium chloride solution three times with the change every 30 minutes. At the next step, bioprosthesis was implanted in the aortal position with 2-0 polyester threads or in supra annular position (Figure).

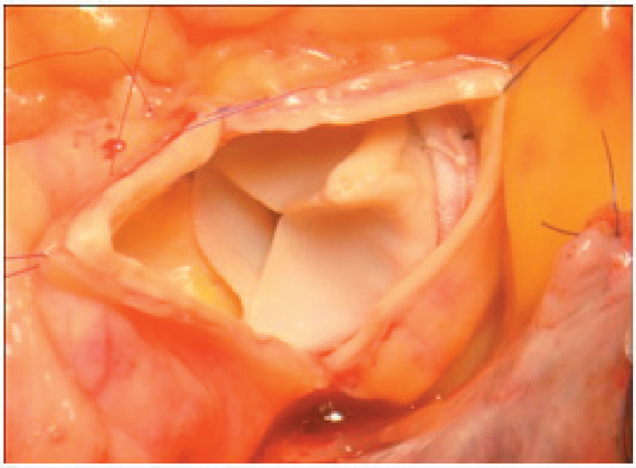

Figure. *"Biolab KA/PT" bioprosthesis in the aortic position.*

Twenty-four patients (26.1%) implanted prostheses No. 20; 42 (45.7%); No. 22; 24 (26.1%); No. 24 and 2 (2.1%); No. 26. In 57 (61.9%) cases, correction of the aortic defect was performed in the framework of a combined intervention on the heart (Table 1).

Table 1.

Associated surgical procedures

Ongoing intervention	Number of patients
Coronary artery bypass surgery	33 (35.8%)
Mitral valve replacement	9 (9.7%)
Plastic tricuspid valve	5 (5.4%)
Mitral valve plasty	4 (4.3%)
Supracoronar prosthetic ascending aorta	3 (3.2%)
Cava tricuspid istmotomiy	2 (2.1%)
Aortic annuloplasty (Method of Manouguian-Seibold-Epting)	2 (2.1%)
Mioectomy USLV	1 (1.08%)
Other interventions	3 (3.2%)

Table 2.

Dynamics of the echocardiographic parameters in patients with "Biolab SC/PT" prosthesis implanted in aortic position

Index	Before surgery	Postoperatively	The level of significance, *p*
EDVI LV (mL/m^2)	65.4 ± 27.9	53.6 ± 16.3	0.002
IEDS (cm/m^2)	2.7 ± 0.6	2.5 ± 0.3	0.03
IMMLV (g/m^2)	222.7 ± 66.7	179,7 ± 47,6	0.00008
LVEF (%)	63.0 ± 10.6	61.4 ± 9.6	0.2
Peak trans prosthetic gradient (*mm* Hg)		19.7 ± 6.7	
The effective area of the prosthesis (cm^2)		2.7 ± 0.2	

RESULTS

The results showed that by the time of hospital discharge, most patients significantly reduced heart failure events in large and small circle of blood circulation, increased exercise tolerance.

No cases of death were recorded in the hospital. One patient showed a type II De Bakey aortic dissection in 30 days after surgery. The cause of delamination was the intima expressed atherosclerotic changes in the vascular wall in aortic access. Supra coronary prosthesis of ascending aorta was successfully completed in this patient

In 2 (2.1) patients in the first postoperative day bleeding was noted that required surgical haemostasis performance. In 40 (43.4%) patients in the early postoperative period heart failure developed requiring cardiac support for more than 3 hours. Full form of atrioventricular block was observed in 4 patients (4.3%) requiring permanent pacemaker implantation. In connection with the development of rhythm disturbances by type of atrial fibrillation 4 patients (4.3%) carried the EMF with the restoration of sinus rhythm in 14 (15.2%) recovered with medical rhythm method.

At the hospital stage not a single case of venous thromboembolism was registered. In the absence of indications to the permanent acceptance of oral anticoagulants (atrial fibrillation, thrombosis of the heart cavities in the history of decreased myocardial contractility, atriomegaly), anticoagulant therapy was administered during the period required for endothelialization of braided prosthesis (three months).

All patients underwent control echocardiographic study, according to which a statistically significant reduction in size of the left ventricle was observed (Table 2).

Dynamics of the echocardiographic parameters depending on type of prosthesis is presented in Table 3.

To identify the factors that have the greatest influence on the pressure gradient of "Biolab KA/PT" bioprosthesis a nonlinear multivariate statistical analysis was performed. The analysis includes indicators of peak performance transprosthesis pressure gradient (PTPG *mm* Hg), prosthesis size (*mm*), body surface area (BSA, m^2), body mass index (BMI, kg/m^2), indexed to BSA figures LV EDV (mL/m^2), the RIC LV (cm/m^2) and left ventricular mass (LVMI (g/m^2), left ventricular ejection fraction (LVEF, %), aortic valve opening area (cm^2). The analysis revealed that there is a strong *($p < 0.05$)* relationship between the values of PTPG and BMI, number of prosthesis and prosthesis area openings. PTPG dependence on other variables was not identified. Since the area of prosthesis opening is directly proportional to its size ($p < 0.05$), in further analysis we included only the BMI number and the prosthesis. At further nonlinear multi-dimensional modeling of relationships we came to the conclusion that the function depends on mentioned parameters as follows: PTPG = 27.7 + 3.09 BMI^2 – 0.036 (No. of $prosthesis)^2$. Thus, the body mass index has a direct and number prosthesis the reverse effect on the peak of transprosthesis gradient in the early postoperative period. At the same time, we do not have reliable relationship between the parametric and functional parameters of left ventricular PTPG that may be related to an insufficient number of observations.

Table 3.

Dynamics of the echocardiographic parameters depending on type of prosthesis

Number of the aortic graft		20	22	24	26
Number of patients		24	42	24	2
BMI		26.0±5.6	28.0±5.1	28.1±5.4	32.0±3.9
Sex	Men.	6	23	18	1
	Women.	18	19	6	1
Age		70.6±4.9	68.9±4.1	68.3±4.6	65±5.6
Body surface area, m^2		1.6±0.1	1.7±0.2	1.8±0.1	1.9±0.2
Data prior to surgery					
Transaortic gradient (*mm* Hg)	Peak	91.9±21.7	93.3±32.1	88.9±35.6	103±2.8
	Average	56.2±15.3	55.9±18.6	50.7±23.9	68±2.8
LVEF (%)		64.1±9.5	63.8±10.9	61±11.8	59.5±0.7
LVMIM (g/m^2)		199.4±43.7	230.5±84.5	234.1±42.8	183.9±52.5
ILVEDV (mL/m^2)		65±43.7	60.3±24.5	73.5±35.6	75.7±35
Data post-surgery					
Transprosthetic gradient (*mm* Hg)	Peak	22.4±6.7	19.3±4.9	18±8.7	13.8±1.6
	Average	12.1±4.3	9.8±3	8.6±3.7	7.9±0.3
Effective S implant prosthesis (cm^2)		2.5±0.2	2.7±0.1	2.8±0.1	2.9±0.1
LVEF (%)		61.2±6.1	63.3±9.3	59.1±12.2	52±9.8
LVMIM (g/m^2)		158.9±28.9	180.3±43.1	198.4±60.4	–
ILVEDV (mL/m^2)		50.1±10	48.6±12.8	63.3±21.1	–
Ratio S:graft to BSA (cm^2/m^2)		1.7±0.2	1.5±0.1	1.4±0.1	1.5±0.3

DISCUSSION

The current stage of acquired heart diseases surgery is characterized by increased levels of safety and effectiveness of surgical treatment of heart diseases, development of new cost-effective and efficient technologies, reduction of contraindications to the operation. Improvement of surgical techniques, tools, techniques of artificial blood circulation and myocardial protection have led to significant improvement of immediate results of surgical treatment of aortic defects. The immediate results of surgical treatment for blemish is defined as its etiology, initial severity of the disease and the severity of changes in the valve and correct choice of method and adequacy of correction. Implantation of mechanical heart valve prostheses is still fraught with disadvantages such as the need for continuous use of anticoagulants, a high risk of thromboembolic complications, which significantly reduce the quality of life for patients. Alternatively, the use of biological prostheses provide a better quality of life, forms the structure of flow close to the physiological one, and the majority of patients do not require taking anticoagulants. According to foreign authors, the interest in aortic valve bioprosthesis is unabated. And the reason for that are new methods of processing and storage, which increased the lifetime of bioprostheses, as well as increasing the number of elderly and senile age patients. Prosthetic aortic valve xenopericardial prostheses are accompanied by low mortality, both in early and late periods, in low incidence of specific complications. Optimal hemodynamic characteristics, resistance to infection, low risk of thrombotic events and "major" anticoagulant-rated complications, according to many authors, make frame bioprosthesis a real alternative to modern mechanical prostheses. Relatively low thrombogenicity of frame bioprostheses allowed the majority of patients to refuse life-prolonged or anticoagulant therapy, which is especially important in patients of older age group, being undesirable. At the same time, we adhere to generally accepted method, according to which the reception of anticoagulants was recommended, under the strict control of the state of the blood coagulation system, to all patients in whom the basic rhythm was atrial fibrillation type, patients with low left ventricular ejection fraction, and thrombosis of the heart cavities in history.

CONCLUSIONS

"Biolab KA/PT" series bioprostheses for implantation in the aortic position restore adequate hemodynamics, which creates favorable conditions for the normalization of left heart function, increase exercise tolerance. Formation of the peak gradient of "Biolab KA/PT" frame prosthesis significantly affects body mass index (direct relationship) and the size of implanted xenovalve (inverse relationship).

Thus, we recommend the implantation of "Biolab KA/PT" frame xenoprostheses as an alternative to mechanical prostheses in patients of older age groups. In some situations, the minimum age that limits the use of biological prostheses can be reduced to 50-55 years or above (social indications).

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