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IMMEDIATE AND LONG-TERM RESULTS OF APPLICATION OF THE UNILINE BIOPROSTHESES IN THE AORTIC POSITION

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This study presents a clinical analysis, as well as an assessment of surgical treatment results of 81 (41 male and 40 female) patients with aortic valve defects. From October 2011 to December 2013, they were implanted the UniLine bioprostheses at Research Institute for Cardiology, Tomsk, Russia. Pre-discharge echocardiography showed that the UniLine aortic bioprostheses have good hemodynamic properties, adequately correct cardiac hemodynamics and show great results compared to the best foreign analogs in such parameters as peak and mean transprosthetic gradient. Some echocardiographic parameters related to LV function had a tendency for improvement. For the entire follow-up period of 5 years, there was not a single case of reoperation because of the inconsistency of the aortic bioprosthesis.

Keywords:
aortic valve replacement, bioprostheses

Aortic valve replacement is the method of choice in patients suffering from severe stenosis [1]. Treatment options for aortic valve disease include AV replacement with a mechanical or biological prosthesis and transcatheter aortic valve implantation. To make a decision, it is extremely important to assess possible complications for each option and risks of structural destruction of the prosthetic heart valve. They may lead to heart failure and the need for reintervention.

The main advantage of a bioprosthesis over a mechanical heart valve is the relative freedom from anticoagulant therapy, which improves patient's quality of life [2]. Over the last decade, bioprostheses have increasingly been implanted in patients of all ages. According to a number of studies, the lifespan of biological prostheses has considerably grown [3, 4].

The UniLine xenopericardial AV bioprostheses (NeoCor CJSC, Kemerovo, Russia) were introduced in the clinical practice in late 2011. The key benefits of these bioprostheses are as follows: the unique leaflet apparatus and cover completely made of xenopericardium and the composite stent made of plastic and nitinol designed to damp the entire structure load.

Table 1. Characteristics of the UniLine aortic bioprostheses recipients

Parameter	No. patients, abs. (%)
Male/female	41/40
Mean age (min—max), years	70.159 ± 6.33
Valve disease origin:	
Degenerative disease	69 (85.1)
Congenital defect	4 (7)
Rheumatic disease	2 (3.33)
Infective endocarditis	1 (1.23)
Valve disease morphology:	
Stenosis	48 (59.2)
Insufficiency	9 (11.1)
Stenosis + insufficiency	23 (28.3)
Comorbidities:	
Hypertension	27 (33.3)
Diabetes mellitus (DM)	5 (8.3)
Coronary artery disease (CAD)	12 (14.8)
Arrhythmia	1 (1.23)
COPD	1 (1.23)
Hypertension + DM	4 (6.6)
Hypertension + CAD	15 (18.5)
Hypertension + DM + CAD	4 (4.9)
Other	10 (16.6)
Coronary artery stenosis:	
No	16 (19.7)
< 50%	17 (20.9)
> 50%	43 (53)
NYHA functional class	2.412 ± 0.49

In this study, we performed a clinical analysis, as well as an assessment of the surgical treatment results for 81 (41 male and 40 female) patients with AV defects, who underwent implantation of the UniLine biological valve in the aortic position from October 2011 to December 2013 at the Research Institute for Cardiology, Tomsk, Russia.

Materials and methods

The mean age of the patients was 70.159 ± 6.33 (Table 1). The majority of patients had a degenerative disease (85.1%), which resulted in the prevalence of stenosis (59.2%) over other anatomical variants: congenital defect (7%), rheumatic heart disease (3.33%), and infective endocarditis (1.23 %). The mean NYHA functional class was 2.412 ± 0.49. The peak pressure gradient was increased up to 73.988 ± 30.79 mm Hg on average, the mean gradient – up to 43.815 ± 20.82 mm Hg. Coronary angiography revealed atherosclerotic coronary artery disease in 60 patients, with > 50% stenosis in 43 patients. Thus, coronary artery bypass surgery was the most frequent combined intervention (29.6%). Four patients underwent ascending aorta replacement, two patients received additional interventions on other valves, and two more patients underwent aortic annuloplasty. The patients underwent echocardiography to check the function of AV (prosthesis) and left ventricle (LV) prior to surgery, pre-discharge, and in the long-term. The maximum and mean gradients of AV were studied to check the valve (prosthesis) function (post-surgery — at the bioprosthesis level).

The LV function was assessed by linear and volumetric dimensions during systole and diastole: left ventricular end-diastolic and end-systolic dimensions and volumes (LVEDD, LVEDV, LVESD, LVESV). In addition, end-diastolic values were indexed for the body surface area. The LV contractility was assessed using ejection fraction. The myocardial hypertrophy severity was determined using the LV myocardial mass and LV myocardial mass index. The statistical analysis was performed with the Statistica 10.0 software. Differences were regarded as statistically significant at $p \leq 0.05$.

Results

The mean time of cardiopulmonary bypass was 120 ± 17 min, with 95 ± 15 min during isolated AV replacement, while the mean

time of aortic cross-clamping was 87 ± 10 min, with 87 ± 10 min during isolated aortic valve replacement (Table 2). Pre-discharge echocardiography showed good hemodynamic properties of the UniLine aortic valve bioprostheses. Some echocardiographic parameters of LV function showed only a tendency towards improvement (Table 3). Prior to surgery the interventricular septal (IVS) thickness was 13.16129 ± 2.7 on average, 12.56452 ± 2.1 on average after surgery, and 12.05484 ± 1.7 on average in the long-term (six months to one year). The posterior LV wall thickness was 12.04839 ± 2.05 mm prior to surgery, 11.56774 ± 1.54 after surgery, and 10.81935 ±1.50 in the long-term. The myocardial mass was 236.3226 ± 71.6 g prior to surgery, 198.3871 ± 48 g after surgery, and 196.1290 ± 39.1 g in the long-term. The myocardial mass index was 236.3226 ± 71.6 g on average prior to surgery, 198.3871 ± 48 g on average after surgery, and 196.1290 ± 39.1 g on average in the long-term. Besides, significant EDV and ESV changes were observed in the short- and long-term postoperative periods. EDV varied from 66.0000 ± 48.95 to 430.00 ± 48.95 mL prior to surgery. The mean EDV was 120.580 mL. The mean post-surgery EDV was 104.427 ± 41.13 mL, with 102.025 ± 19.82 mL in the long-term. Prior to surgery, the mean gradient of the aortic valve was 43.815 ± 20.82 mm Hg, while the peak gradient was 73.988 ± 30.79 mm Hg. On average, the AV mean gradient in 20 days after surgery was 12.689 ± 5.89 mm Hg, with the peak gradient of 25.783 ± 12.14 mm Hg. In the long-term, the AV mean gradient was 13.342 ± 9.44 mm Hg, with the peak gradient of 23.361 ± 7.5 mm Hg.

Discussion

The share of implanted biological prostheses has dramatically increased in the USA over time (84% in 2010 vs 36% in 1995) [5, 6]. Over the past years, the number of aortic valve surgeries has been going up in Russia. Interestingly, the share of biological prostheses in the structure of valve prostheses has grown: it was 4% in 2007 and 21.8% in 2015. Thus, the number of annually implanted biological prostheses has increased in 14 times over the past 10 years: from 173 to 2,398 [7].

It is mainly associated with the rise of domestic cardiac surgery, which allowed to set less strict limits in terms of patient age and increase the number of

Table 2. Characteristics of interventions performed

Parameter	No. patients, abs. (%)
Prosthesis diameter:	
21 **mm**	36 (44.4)
23 **mm**	32 (39.5)
25 **mm**	14 (17.2)
Combined interventions:	
Coronary artery bypass surgery	24 (29.6)
Mitral valve replacement	1 (1.23)
Tricuspid valve plasty	1 (1.23)
Aortic annuloplasty	2 (2.46)
Ascending aorta replacement	4 (4.93)
Radiofrequency ablation	1 (1.23)
Time of cardiopulmonary bypass, min	120 ± 17
Time of cardiopulmonary bypass during isolated AVR, min	95 ± 15
Time of aortic cross-clamping, min	87 ± 10
Time of aortic cross-clamping during isolated AVR, min	75 ± 7

Table 3. Dynamics of echocardiography functional parameters in patients before and after the UniLine aortic bioprosthesis implantation

Parameter	Medical ultrasound pre-surgery	Medical ultrasound post-surgery	Medical ultrasound long-term	*p**	*p***
EDV	114.7692 ± 35.6	97.8205 ± 25.8	102.1538 ± 20.06	0.001	0.001
ESV	45.14211 ± 27.8	38.69211 ± 20.2	39.63947 ± 17.5	0.17	0.26
EF	63.50000 ± 11.4	62.55263 ± 10.1	64.05263 ± 7.8	0.46	0.449
MM	236.3226 ± 71.6	198.3871 ± 48	196.1290 ± 39.1	< 0.001	0.715
MMI	132.1290 ± 34.9	111.3871 ± 23.4	111.1613 ± 18.9	< 0.001	0.717
IVS	13.16129 ± 2.7	12.56452 ± 2.1	12.05484 ± 1.7	< 0.001	0.022
PLVW	12.04839 ± 2.05	11.56774 ± 1.54	10.81935 ± 1.50	< 0.001	< 0.001
Aortic valve peak gradient	73.37143 ± 32.2	23.61143 ± 8.8	23.25714 ± 7.5	< 0.001	0.13
Aortic valve mean gradient	44.13158 ± 22.4	12.05263 ± 4.6	13.34211 ± 9.4	< 0.001	0.028

Note. * – upon comparison of pre-surgery and long-term ultrasound results;
** – upon comparison of post-surgery and long-term ultrasound results; see the text for abbreviation expansions.

Table 4. Comparative characteristics of the mean gradients of biological aortic prostheses made by various manufacturers [15-17]

Prosthesis	Mean gradient, mm Hg (*in vivo*)
UniLine	13.3
Carpentier-Edwards pericardial	16.3
Carpentier-Edwards porcine	17
Hancock II	11.7
St. Jude SPV	9.3

surgeries in patients > 65 years old. On the one hand, this tendency accounts for a greater share of degenerative aortic valve diseases in the structure of surgical pathologies. On the other hand, it also accounts for higher demand for biological prostheses, which are the valves of choice for this age group of patients.

There is an obvious need for aortic valve bioprostheses with good hemodynamic properties and high long-term reliability.

UniLine bioprosthesis implantation is technically undemanding. Both in combined and isolated aortic valve replacement, the time of cardiopulmonary bypass and aortic occlusion does not exceed the time reported by authors who used stented xenopericardial biological prostheses Perimount [8, 9], Trifecta [10–12], as well as xenoaortic biological prosthesis Mosaic [8, 13, 14]. The distribution and number of early postoperative complications are generally comparable with those in the references cited.

Therefore, suitable performance characteristics of UniLine should be noted: its peak and mean gradients are comparable to those of foreign stented analogs (Table 4).

For the entire follow-up period (the maximum follow-up period was 5 years), there was not a single case of reoperation regarding the inconsistency of the UniLine aortic bioprosthesis.

To sum up, the UniLine xenopericardial biological prostheses of the aortic valve adequately correct the cardiac hemodynamics and are not inferior to the best foreign analogs in terms of peak and mean transprosthetic gradients.

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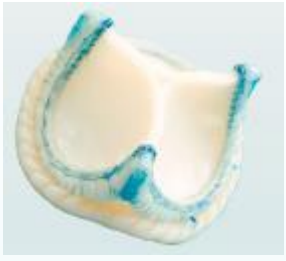
UniLine
Stented Xenopericardial Heart Valve Prosthesis

Prosthesis model	Size	Biotissue treatment
 **UniLine valve Aortic**[1, 2]	**21** **23** **25**	***By default:*** **Anticalcification**[5]
 **UniLine valve Atrioventricular**[1, 3]	**26** **28** **30** **32**	***Option to order:*** **Antithrombotic**[4] ***or*** **Antibacterial**[4]

High-Precision Leaflet Fabrication

High-precision leaflet laser-cutting prevents any separation of collagen fibers along the cut edge; Computer-aided leaflet fabrication with pericardial thickness detection prior to cutting ensures perfect coaptation[1].

Stent Materials

Flexible polymer stent and superelastic nitinol stent ensure the prosthesis durability[1].

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