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Original Research

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UNILINE NEXT-GENERATION RUSSIAN BIOLOGICAL PROSTHESIS FOR MITRAL VALVE REPLACEMENT: FIRST EXPERIENCE

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Introduction. The UniLine biological xenopericardial prosthesis has been used in the clinical practice since 2008. A number of absolutely new technologies was implemented in manufacturing of the third-generation prosthesis such as laser cutting based on biological tissue thickness, anticalcification treatment with amino bisphosphonates, spatial modeling, and a composite stent, as well as the absence of synthetic materials in the production of the prosthesis cuff. The aim of this article is to assess the immediate and mid-term results of using the UniLine biological valve in the mitral position.

Materials and methods. From January 2009 to April 2015, 215 patients got UniLine biological prostheses to replace their mitral valves. The mean follow-up time and scope were 2.3 ± 2.1 (0.1 to 5.9) years and 463.4 patient-years, respectively. The average age of the UniLine prosthesis recipients was 66.5 ± 9.7 years. The cause of the mitral valve disease was chronic rheumatic heart disease in 68.1% of all cases. The average functional class as per the NYHA Functional Classification was 2.86 ± 0.2. The heart failure class prior to the operation was IIb in 25% of the patients. The atrial fibrillation was observed in 65.1% of the patients. The reintervention occurred for 28.4% of the operated patients. Isolated mitral valve replacement was performed in 88 (41%) patients.

Results. The hospital mortality was 5.1%. Multiple organ dysfunction syndrome (54.5%) prevailed over other disorders in the hospital mortality pattern. The linearized long-term mortality was 2.6% per patient-year. The 6-year actuarial survival rate was 91%. Non-cardiac causes (41.7%) prevailed in the long-term mortality pattern.

The linearized reoperation rate was 0.86% per patient-year, and the 6-year actuarial freedom from reintervention was 96.5%. The linearized incidence of the prosthetic endocarditis and primary tissue failure accompanied by calcification was 0.65% and 0.22% per patient-year, respectively.

Seventy-four (36.3%) patients were on the anticoagulant therapy in the long-term. The linearized rate of bleedings and embolism in the study group was 0.43% and 0.22% per patient-year, respectively. The 6-year actuarial indication of the absence of bleeding was 99%, while thromboembolism – 98.5%.

Conclusion. Implantation of the UniLine biological xenopericardial prosthesis ensures a high survival rate in patients of all ages due to the adequate correction of hemodynamics, which leads to complete remodeling of the left atrium and significant decrease in the level of pulmonary hypertension. The prosthesis structure contains no synthetic components, which improves the resistance of the UniLine biological valve to prosthetic endocarditis. Implantation of the UniLine bioprosthesis is recommended to patients with low compliance to drug therapy and patients in whom adequate control of anticoagulant therapy is impossible.

Key words: biological heart valve; mitral valve disease; survival; prosthetic endocarditis.

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Introduction

The use of biological prostheses in the surgery of valvular heart diseases has long passed half a century. Each period of the bioprosthesis implantation is characterized by emergence of fundamentally new models of prosthetic valves. The distinctive feature of the first-generation bioprostheses was high-pressure preservation with glutaraldehyde. Such prostheses were made of the porcine aortic complex with or without the muscular ridge of the right coronary cusp and were mounted on a rigid or semi-rigid stent.

The key difference of the next-generation valves was that the biological tissue was preserved under low or zero pressure, the leaflet apparatus was mounted on a flexible stent, and leaflets were made of either a composite aortic complex or bovine pericardium.

The third – modern – generation of bioprostheses is characterized by the use of flexible stents made of polymer or composite materials; biological tissue treatment is also performed at low or zero pressure, but a fundamentally new approach is to use various methods of anticalcification treatment [1].

The aim of this article is to assess the immediate and mid-term results (5 years) of using the UniLine third-generation biological xenopericardial prosthesis in the mitral position.

Materials and methods

The UniLine biological xenopericardial prosthesis has been used in the clinical A distinctive feature of this third-generation prosthesis is innovative technologies including high-precision leaflet laser-cutting, which, on the one hand, prevents separation of collagen fibers along the cut edge and, on the other hand, ensures the maximum possible thickness uniformity of the material used, thus preventing fatigue-induced changes. The unique way of modeling the leaflet apparatus provides for full coaptation. Anticalcification treatment with amino biphosphonates contributes to a statistically significant reduction of calcium-binding potential, thus lowering the calcification risk of bioprosthesis dysfunction. The prosthesis has no synthetic components, so as to reduce the incidence of prosthetic endocarditis [2].

From January 2009 to April 2015, 215 patients got UniLine biological prostheses to replace their mitral valves. The mean follow-up time and scope were 2.3 ± 2.1 (0.1 to 5.9) years and 463.4 patient-years, respectively. The mean age of the UniLine prosthesis recipients was 66.5 ± 9.7 years (from 27 to 79.2 years), while the number of women (n = 169; 78.6%) was more than three times higher than the number of men; 25% of operated patients were rural residents.

In majority of cases (68.4%) the cause of the mitral valve disease was chronic rheumatic heart disease (CRHD). The mitral valve disease was much less frequently observed with papillary muscle dysfunction of ischemic origin (9.4%) and connective tissue dysplasia (8.8%), even less often the disease had a degenerative origin (7.4%). The share of infective endocarditis, both primary and secondary, accounted for no more than 6% of the cases.

The average functional class as per the NYHA Functional Classification was 2.86 ± 0.2. The heart failure class prior to the operation was IIb in 25% of the patients.

Hypertension prevailed among concomitant diseases (39%), while diabetes mellitus and chronic kidney disease accounted for 7.9% and 6.5%, respectively. It is noteworthy that in the initial population, significant coronary artery stenoses were observed in 20% of the patients, while 10.2% of the patients had suffered from a heart attack.

A significant part of operated patients (44.2%) had mitral valve stenosis. Mitral valve disease was diagnosed in 30.2% of the patients, while 25.6% of people had an equally pronounced hemodynamic type of disease.

Before surgery, the left atrium size along the long axis was 5.8 ± 1.1 cm on average. Atrial fibrillation was observed in 65.1% of the patients, while thrombosis of the left atrial appendage was found in 8.4%, and about 5% of the patients had a history of acute ischemic cerebrovascular accident.

The reintervention occurred for 28.4% of operated patients. 11.6% had had another type of biological prosthesis, 8.4% had been subject to closed mitral commissurotomy, 3.7% had had a mechanical mitral valve prosthesis, 1.9% had been subject to open mitral commissurotomy, while non-valvular interventions (percutaneous transluminal coronary intervention with coronary angioplasty and endovascular closure of an atrial septal defect) accounted for 2.8%.

Isolated mitral valve replacement was performed in 88 (41%) patients. Concomitant valve disease surgery more often included plastic surgery / replacement of the tricuspid valve (41%/3.7%). Aortic and mitral valve disease surgery (6%) and triple valve replacements (8.6%) occurred less often. Concomitant cardiac interventions were performed in 73% of the UniLine prosthesis recipients; the most frequent ones were left atrial appendage ligation (23.3%), coronary artery bypass grafting (17.2%), radiofrequency ablation (16.3%), thrombectomy of left atrial appendage thrombus (8.4%), and other interventions (7.8%).

Statistical Analysis

The statistical analysis was performed using the Statistica 6.0 software. The mean value and standard deviation were used to describe quantitative indicators. Normality of the distribution of a characteristic and differences in quantitative characteristics was carried out using the Kolmogorov-Smirnov test. The Kaplan-Meier method was used to assess the survival rate and absence of non-lethal cases. The analysis of changes in hemodynamic parameters was carried out using a paired t-test. The study results were considered statistically significant at $p < 0.05$.

This study was approved by the local ethics committee.

The databases of the Federal Migration Service of the Russian Federation and Kemerovo Cardiology Center were used in order to find patients. It was done in compliance with Law No. 152-FZ of July 27, 2006 on Personal Data.

Patients were interviewed over the telephone or during a routine screening examination. The patients gave their consent to participate in the study.

The results obtained were interpreted in accordance with recommendations for reporting morbidity and mortality in cardiac surgery [3].

The observation coverage was 100%. The end date of the study was April 22, 2015.

Results

The hospital mortality was 5.1% (n = 11). Multiple organ dysfunction syndrome (n = 6; 54.5%) prevailed over other disorders in the hospital mortality pattern. Acute heart failure developed in three patients (27.3%), while acute respiratory distress syndrome and acute posthemorrhagic anemia due to the rupture of the left ventricle posterior wall accounted for one case each (9.1% each).

In the long-term, death was observed in 12 (5.8%) patients, while the linearized long-term mortality rate was 2.6% per patient a year.

The actuarial survival rate was 91% (see figure) at the end of the fifth year of the follow-up.

Non-cardiac causes (n = 5; 41.7%) prevailed in the long-term mortality pattern. Death of four (33.3%) patients was caused by progressing chronic heart failure with normal prosthesis function (data confirmed by clinical studies and autopsy). Valve-associated death was observed in three (25%) recipients of the UniLine prosthesis, while the death of 2 patients living in remote areas and not receiving antibiotic therapy for prophylactic purposes for unknown reasons was caused by the late prosthetic endocarditis; one had an acute cerebrovascular accident due to thromboembolism with a permanent type of atrial fibrillation (AFib).

The linearized reoperation rate was 0.86% per patient-year (n = 4), and the 5-year actuarial freedom from reintervention was 96.5% (see figure).

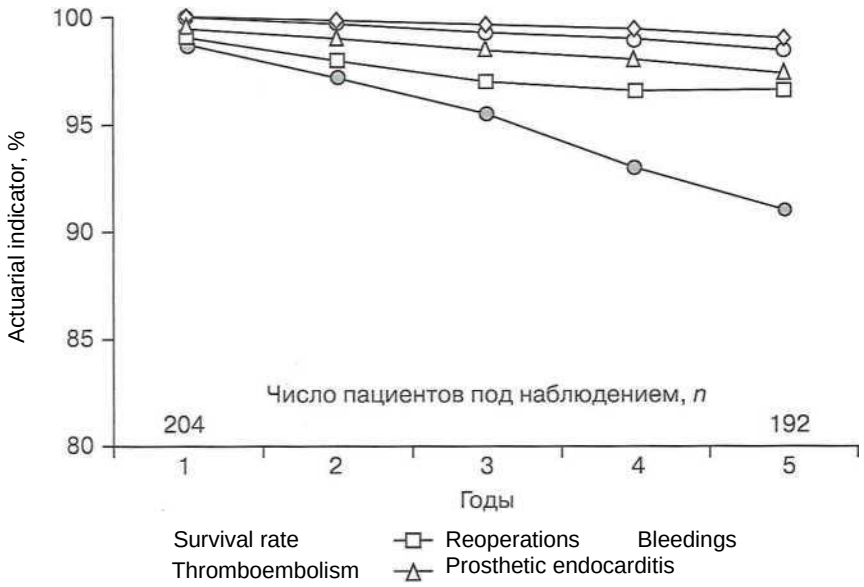
One female patient with rheumatic heart disease was reoperated a month after implantation of the UniLine bioprosthesis due to the early prosthetic endocarditis. This intervention was the third after closed mitral commissurotomy (1981) and mitral valve replacement with the KemCor bioprosthesis and De Vega tricuspid valve annuloplasty in 1999. Dysfunction of the KemCor prosthesis was caused by the primary tissue failure with calcification. Prosthetic endocarditis developed after implantation of the UniLine bioprosthesis in the early postoperative period due to the sepsis, accompanied by periprosthetic abscesses and followed by fistulas, while the prosthesis leaflets remained intact. The patient was reoperated. The death occurred a day later due to an increase in multiple organ failure.

Two more patients (with CRHD and infective endocarditis) were successfully reoperated for late prosthetic endocarditis 1.5 years after the intervention. It is worthy to note that there was no complete antibacterial therapy in both cases.

The fourth reoperation was successfully performed in a patient with bioprosthesis dysfunction due to the primary tissue failure with calcification in the third year after implantation of the UniLine bioprosthesis.

Thus, the linearized rate of prosthetic endocarditis (excluding 2 deaths) and primary tissue failure with calcification was 0.65% and 0.22% per patient a year, respectively, while hospital mortality during reoperations was 25% (n = 1).

Despite the fact that sinus rhythm was restored in 82 out of 140 patients who had AFib before the surgery, the number of patients with arrhythmias still increased up to 103 at various times after the intervention, so 74 of them received anticoagulant therapy. It is worthy to note that 45 recipients of the UniLine prosthesis with atrial fibrillation only

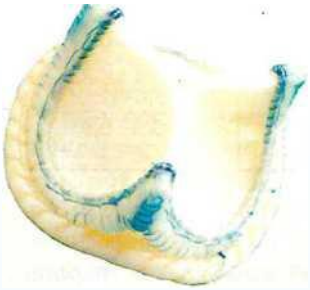


No. patients observed, *n*

Actuarial indicators of lethal and non-lethal complications in the long-term in recipients of the UniLine prosthesis

NeoCor

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[1,6].

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Original Research

Prostheses Hemodynamic Parameters

Parameter	Bore diameter, mm			
	26	28	30	32
No. prostheses under research, *n*	32	90	80	13
EOA ± SD. min-max, cm^2	3 ± 0.46 2.75–3.1	3.1 ± 0.38 2.9–3.2	3.2 ± 0.44 3–3.5	3.4 ± 0.3 3.2–3.7
Indexed EOA ± SD, cm^2/m^2	1.73 ± 0.15	1.79 ± 0.12	1.82 ± 0.10	1.86 ± 0.17
ΔPpeak ± SD, min-max, mm Hg	12.3 ± 4.2 5–16.6	10.8 ± 2.9 4.9–15.8	9.36 ± 1.5 7–11	7.2 ± 2.5 5–12
ΔPmean ± SD, min-max, mm Hg	4.86 ± 2.3 3–10	4.1 ± 1.4 2.1–7	4 ± 1.2 3–6	3.9 ± 0.9 3–6.5

Note. EOA – effective orifice area; ΔPpeak – peak pressure gradient.

had available and high-quality control of the International Normalized Ratio (INR). So, the linearized rate of bleedings and embolism in the study group was 0.43% and 0.22% per patient-year, respectively. The 5-year actuarial freedom from bleeding was 99%. The 5-year actuarial freedom from thromboembolism was 98.5% (see figure).

Hemodynamic Results

Hemodynamic parameters depending on the bore diameter of the prosthesis are shown in the table.

The mitral valve surgery was accompanied by a significant decrease in the size of the left atrium (patients who underwent atrioplasty were not taken into account when calculating the parameters) from 5.8 to 4.7 cm ($p = 0.001$) and a decrease in the pulmonary artery systolic pressure from 59 to 32 mm Hg ($p = 0.005$) with the effect persistence up to 5 years.

Discussion

The age of patients who died during the hospital period was 66.3 ± 2.5 years on average. Women predominated (n = 7). 9 out of 11 patients underwent multiple valve replacements. The reintervention was performed on four patients. For two patients it was the third intervention. Eight had a pronounced comorbidity background and thus a higher risk of death [4, 5].

However, even taking into account the above factors, hospital mortality in the study group was almost 1.5 times lower than that of patients with multiple and repeated valve replacements over the same years in Russia as a whole [6, 7].

The linearized long-term mortality rate in recipients of the UniLine prosthesis was 2.6% per patient a year, which is almost 1.5 times lower than that in recipients of earlier bioprostheses' models (PeriCor and KemCor) [8, 9].

The actuarial survival rate exceeded the results observed in the recipients of biological valves of previous generations by 5% by the end of the fifth year of the follow-up (KemCor – 84.2% and PeriCor – 84.5%) [8, 9].

The cardiac survival rate analysis of the UniLine prosthesis recipients showed that there were no deaths in patients under 60, while the survival rate in the population of 60-65 year-old patients was 99.8%, of over 65 year-old patients – 92.2% by the 5th year, which is also significantly higher than in recipients of earlier models of bioprostheses [10]. At the same time, the average age of KemCor and PeriCor prostheses recipients did not exceed 52 and the scope and frequency of interventions were significantly lower. All the above may evidence both an increase in life expectancy of the population in general and an increase in the average life expectancy among recipients of biological mitral valve prostheses in particular, which, in turn, may be due to both improved quality of life and a higher level of cardiac care.

The linearized index of prosthetic endocarditis in recipients of the UniLine prosthesis was 0.65% per patient a year, which is almost 2.5 times lower than in recipients of the KemCor prostheses (1.3%/patient-years) and PeriCor prostheses (1.5%/patient-years), which, in turn, proves a higher infection-resistance of the UniLine bioprosthesis.

However, the development of prosthetic endocarditis in this study is more related to the problem of patient compliance with therapy. Absolutely all patients receive detailed explanation regarding the need for antibiotic prophylaxis before discharge from the hospital. Besides, the Kemerovo Regional Clinical Cardiology Dispensary named after academician L.S. Barbarash also has a school for recipients of artificial heart valves, where in the course of 4 session patients are instructed, for instance, about antibiotic therapy [11]. Thus, low compliance with therapy is exclusively a patient-related factor in this case. Previous studies showed that this population accounts for an average of 5.9 to 8.8% of cardiac surgery patients with valvular heart diseases [12]. This significantly complicates the choice of the optimal type of prosthesis for this category of patients, since the implantation of a mechanical valve entails a lifelong anticoagulant therapy, and the implantation of bioprostheses requires adequate antibiotic prophylaxis. Most likely, biological valves would be preferable for this population because inadequate anticoagulant therapy in recipients of mechanical prostheses can have serious consequences.

Bleeding and thromboembolism in 6 months after implantation of a mechanical valve are associated exclusively with prolonged anticoagulant therapy prescribed, as a rule, due to heart rhythm disorders [13, 14]. The geography of the diseases presented in this article extends from the Kurgan Region to the Primorsky Krai and from the Khanty-Mansiysk Autonomous District to Kazakhstan, while the availability of high-quality INR control for residents of remote territories is still a challenge given that a quarter of the patients are rural residents. Apparently, wider use of portable INR meters, on the one

hand, and more persistent tactics of sinus rhythm recovery in case of valve disease surgery, on the other hand, would help to solve the problem, at least partly [13, 15].

The short (5-year) follow-up period does not allow us to show a complete picture of the primary tissue degeneration of the UniLine prosthesis, with and without calcification, so this issue is open for further studies.

Conclusion

Implantation of the UniLine biological xenopericardial prosthesis ensures a high survival rate in patients of all ages due to the adequate correction of hemodynamics, which leads to complete remodeling of the left atrium and significant decrease in the level of pulmonary hypertension. The prosthesis structure contains no synthetic components, which improves the resistance of the UniLine biological valve to prosthetic endocarditis. Implantation of the UniLine bioprosthesis is recommended for patients with low compliance to *drug* therapy and patients in whom adequate control of anticoagulant therapy is impossible.

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