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Effect of Implantation of a new Domestic Prosthesis in the Aortic Position on the Quality of Life of Patients With Degenerative Aortic Stenose, Survival Assessment and Development of Complications 1 Year Post-Surgery

Aim	To evaluate quality of life (QoL), general survival, and development of complications in patents one year after surgical aortic valve (AV) replacement with a MedInzh-BIO xenopericardial carcass prosthesis.
Material and methods	Degenerative AV disease is one of the most common cardiovascular diseases that gives place only to ischemic heart disease. Surgical correction of the AV defect should be aimed not only at hemodynamic outcomes but also at improvement of QoL. This study included 91 patients (48 women and 43 men), who were implanted with a MedInzh-BIO biological xenopericardial prosthesis in aortic position from January 2017 through March 2020. Mean age of patients was 69.96±4.4 years. QoL was evaluated with a standard SF-36 questionnaire. Also, survival and complications were analyzed one year after surgery.
Results	Data analysis before and one year after surgery showed a significant improvement of QoL. Postoperative one-year survival was 95.4%, and major valve-associated complications were absent in 94.5% of cases. During one year, four patients died after 1, 6, 8, and 10 months of follow-up, respectively.
Conclusion	The improvement of QoL following the AV replacement with a novel xenopericardial carcass prosthesis with the «easy change» system indicates the clinical and functional effectiveness of the used method. The results of the study demonstrated improvements of both the physical health component and the subjective emotional assessment. Postoperative one-year survival was 95.4%, and major valve-associated complications were absent in 94.5% of cases.

Keywords	Aortic valve bioprosthesis; quality of life; survival; aortic valve stenosis
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Introduction

Degenerative aortic valve disease (DAVD) is one of the most common cardiovascular diseases, second only to coronary artery disease (CAD) [1]. DAVD is most often manifested morphologically by valve stenosis and occurs mainly in older people.

Aortic stenosis significantly increases the risk of sudden cardiac death and affects the quality of life (QoL) of such patients [2]. According to the 2017 ESC/EACTS Guidelines for the management of valvular heart disease, AV replacement is the only method to correct degenerative aortic stenosis [3]. Biological prostheses are increasingly used for aortic valve (AV) replacement for several reasons. Biovalves provide central blood flow, are quiet, and do not require lifelong use of anticoagulants. The dysfunction of the biological prosthesis, unlike the mechanical one, usually develops gradually, which allows scheduling repeat surgery. Moreover, when structural degeneration of the prosthesis develops, it's possible to conduct minimally invasive transcatheter valve implantation into the prosthesis [4]. However, there is not a single ideal biological prosthesis so far. Therefore, new models should be developed and introduced into clinical practice.

In 2016, a new easy-change stented xenopericardial prosthesis MedEng-BIO was implanted for the first time. The prosthesis has a special design of the cuff with an expandable mechanism (easy change system). This design allows the suture ring to be implanted separately from the obturator.

Surgical correction of AV disease should be aimed not only at hemodynamics but also at improving the patients' QoL.

Objective

Assess QoL, overall survival and the incidence of complications in patients 12 months after the AV replacement with new stented xenopericardial prosthesis MedEng-BIO.

Material and Methods

A prospective, single-center, non-randomized study was performed in 91 patients who had a biological xenopericardial prosthesis MedInge-BIO implanted in the aortic position from January 2017 to March 2020.

Inclusion criteria: age >65 years; the need for surgical correction of DAVD (following the 2016 Russian Association of Cardiovascular Surgeons guidelines and the 2017 ESC/EACTS guidelines); severe aortic stenosis (orifice area index <0.5 cm^2/m^2, mean >40 mm Hg) without symptoms; moderate aortic stenosis (orifice area index 0.5–1 cm^2/m^2, mean gradient >20 mm Hg) requiring coronary artery bypass grafting (CABG).

Exclusion criteria: the need for surgical correction of any other valve disease or other additional cardiac surgery (other than CABG); left ventricular ejection fraction (LVEF) < 45%; CAD complications; competing diseases or concomitant pathology with a significant effect on the prognosis of QoL or the likelihood of death; severe pulmonary hypertension (right ventricular systolic pressure >60 mm Hg); the ascending aorta diameter >45 mm; patient's unwillingness to participate in the study.

The study was conducted following the Good Clinical Practice and the Declaration of Helsinki. The study protocol was approved by the ethics committee of the Institute of Cardiology, Tomsk National Research Medical Center. All subjects signed the informed consent before being inclusion in the study.

A total of 48 female and 43 male patients were operated. Mean age was 69.96±4.4 years. Detailed characteristics of patients are provided in Table 1. The main complaints presented in the group of isolated aortic stenosis were characteristic of this nosology: asthenia, dizziness, chest pain, a feeling of irregular heartbeats. Patients with DAVD and CAD were more likely to complain of angina pectoris and irregular heartbeats.

All patients underwent AV replacement. A new stented xenopericardial prosthesis MedEng-BIO was used as a prosthetic valve. The new biovalve lies in the unique design of the cuff, which allows implanting suture ring separately from the obturator (Figure 1). This replacement techniques provides better visual control of subvalvular structures and fixation of the prosthesis to the fibrous ring. Moreover, delayed implantation of the biological element itself reduces the risk of its damage when suturing or tying threads.

The structure of the surgical intervention scope is as follows. Group 1 included 59 patients with isolated aortic stenosis, 9 of whom underwent AV replacement with aortic annuloplasty. That was necessary to prevent the mismatch of the prosthesis for a specific patient, since the aortic annulus was 20 mm or less in those patients. The Manouguian aortic annuloplasty was performed in all cases and AV prosthesis sizes 23 and 25 were implanted. The remaining 50 patients underwent isolated AV replacement using cardiopulmonary bypass and Custodiol cardioplegia.

Table 1. Main preoperative patient characteristics

Parameter	Value
Number of patients	91
Age, years	69.96±4.4
Sex, n (%)	
• Male	48 (52.7)
• Female	43 (47.3)
Body mass index, kg/m2	30.02±5.0
CHF NYHA class, n (%)	
• I	3 (3.3)
• II	28 (30.7)
• III	60 (65.9)
DM type 2, n (%)	23 (25.3)
CAD, n (%)	32 (35.2)
HHD stage III, n (%)	88 (96.7)
Hypercholesterolemia, n (%)	7 (7.7)
COPD, n (%)	11 (12.1)

CHF, chronic heart failure; NYHA, New York Heart Association; DM, diabetes mellitus; CAD, coronary artery disease; HHD, hypertensive heart disease; COPD, chronic obstructive pulmonary disease.

CABG was also performed in patients with DAVD and CAD and with hemodynamically significant coronary stenosis. A total of 32 AV replacement + CABG surgeries were performed. Of all cases of revascularization, 21 (65.6%) patients underwent two-vessel CABG.

Warfarin was administered to all patients after surgery for 3 months under the control of the international normalized ratio (INR).

All patients underwent echocardiography and Doppler imaging before and after surgery, including 12 months later. The left ventricular volumes, the degree of hypertrophy, and intracardiac hemodynamics were evaluated.

The standard SF-36 questionnaire was used to assess QoL. Eight parameters were assessed: Physical Functioning (PF), Role – Physical Functioning (RP), Bodily Pain (BP), General Health (GH), Vitality (VT), Social Functioning (SF), Role Emotional (RE), Mental Health (MH). Each parameter was scored from 0 to 100: the higher the score, the better the QoL. There were from 2 to 6 possible answers to the questions.

Analysis of survival and complications was also performed within 12 months after the MedEng-BIO prosthesis implantation in the aortic position.

Statistical processing of the data obtained was performed using SPSS 23.0 and the R package for Windows. The Shapiro–Wilk test was used to assess the normality of distribution of

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Figure 1. New easy-change stented xenopericardial prosthesis MedEng-BIO

quantitative variables. Normally distributed variables were expressed described by the mean values (M) and the standard deviations (SD) as M±SD, and non-normally distributed variables as the medians (Me) and the interquartile ranges [Q1; Q3]. The qualitative data were presented using the absolute and relative rates (percentages).

The t-test for dependent samples were used for normally distributed quantitative indicators and the Wilcoxon rank test was used for non-normally distributed quantitative indicators. The chi-square test or the exact Fisher test was used to verify the significance of differences in qualitative data.

The Pearson correlation coefficient (r) (for normally distributed quantitative indicators) and the Spearman correlation coefficient (for non-normally distributed quantitative indicators and qualitative indicators measured on ordinal scale) were calculated to find statistical dependencies, determine their strength and direction. The analysis of survival and complication rates used the Kaplan–Meier method and lifetime distribution and tables, as well as univariate and multivariate regression analyses.

The differences were considered to be statistically significant with $p < 0.05$.

Results

Echocardiogram performed before surgery and 12 months after surgery showed a decrease in the degree of hypertrophy: interventricular septum (IVS) thickness decreased by 1.5 mm, myocardial mass index (MMI) decreased by 21 g/m^2, and hemodynamic parameters improved. The detailed data are provided in Table 2.

Analysis of data before and 12 months after surgery showed a significant positive trend in QoL (Table 3).

Linear regression analysis was used to assess the factors affecting the patients' QoL 12 months after surgery. In the univariate analysis, a statistically significant effect on PF was exerted by sex (p=0.001), performance of CABG (p=0.043), and echocardiographic findings 12 months after surgery – a 1mm decrease in IVS thickness increased the score by 0.04 (p=0.023), a 1 g/m^2 decrease in MMI increased the score by 0.12 (p=0.009). Male sex (p=0.001) increased mean RP, the indicators of myocardial hypertrophy also had a positive effect in 12 months – a 1 mm decrease in IVS thickness increased the mean score by 1.62 (p=0.041), a decrease in MMI increased the mean score by 0.17 (p=0.013). Bodily pain of the SF-36 questionnaire was lower in male patients (p=0.001). The mean score of the General Health (GH) measure increased by 0.13 as MMI decreased by 1 g/m^2 in 12 months (p=0.011). Lower chronic heart failure (CHF) class and male sex also had a positive effect on GH. The mean score of Social Functioning (SF) was higher in male patients and increased by 0.62 with a decrease in patient's age by 1 year. The mean Vitality score was influenced 12 months after surgery by changes in MMI (p=0.042) and left ventricular ejection fraction (LVEF) (p=0.022).

Sex turned out to be the most significant factor in a multivariate model: the mean score for PF, RP, SF was higher in male patients. Social functioning (SF) was influenced not only by sex but by patient's age (Table 4). There were no correlations with such indicators of QoL as MH and RE.

Survival within 12 months from the date of valve replacement was 95.4%. During 12 months of follow-up, 4 people died in 1, 6, 8 and 10 months, respectively.

The death in month 1 after surgery was due to major internal bleeding caused by warfarin overdose – the patient did not self-monitor the INR. Major internal bleeding caused fatal hemorrhagic shock. Cancer found after surgery was the most common non-AV-related causes of death (n=2). In month 10, a female patient died of hemorrhagic stroke (warfarin was discontinued in month 6). Figure 2 shows the Kaplan–Meier survival curve after the MedEng-BIO implantation.

The postoperative complications included stroke, prosthetic endocarditis, bleeding, myocardial infarction, pacemaker implantation due to grade 3 atrioventricular (AV) block.

No cases of prosthetic endocarditis were reported. Cerebrovascular accident (CVA) occurred in 4 patients. One case was fatal (described above). The remaining cases of ischemic CVA occurred in month 6 (n=1) and month 10 (n=2). The patients had no signs of prosthetic dysfunction. One patient had a pacemaker implanted in month 3 due to grade 3 AV block. No other adverse events were reported within 12 months of follow-up. Thus, there were no valve-associated complications in 94.5% of cases (Figure 3).

Discussion

During the study, we observed a statistically significant improvement in QoL according to the SF-36 questionnaire 12 months after the implantation of the new easy-change biological prosthesis MedEng-BIO in the aortic position.

According to Molchanova et al. [5], surgical correction of aortic stenosis in patients of 70 years and older improves their QoL. Demidov et al. [6] compared the QoL scores of the SF-

Table 2. Echocardiographic parameters before surgery and 12 months after surgery

Parameter	Before surgery	12 months after surgery	p*
IVS thickness, mm	14 [12.5; 15]	12.5 [11; 14]	0.001
MM, g	241 [168; 226]	194 [168; 228]	0.001
MMI, g/m2	128 [114; 147]	107 [96; 121]	0.001
LVEF, %	66 [61; 69]	67 [65; 72]	0.001
Peak pressure gradient, mm Hg	74.1±25.3	34.7±10.8	0.001
Mean pressure gradient, mm Hg	42.7±16.2	17.65±5.9	0.001
EA (cm2)	0.69±0.2	1.16±0.3	0.001

* Wilcoxon test. IVS, interventricular septum; MM, myocardial mass; MMI, myocardial mass index; LVEF, left ventricular ejection fraction; EA, effective area.

Table 3. Changes in quality of life before and 12 months after surgery, score

Parameter	Before surgery	12 months after surgery	p*
PF	34.4 [31.2; 41.8]	45.3 [41.1; 51.7]	0.001
RP	32.5 [30.4; 39.5]	39.3 [33.9; 46.3]	0.001
BP	38.1 [31.4; 45.5]	42.0 [38.2; 48.9]	0.001
GH	36.5 [33.3; 45.6]	49.8 [42.5; 53.6]	0.001
VT	35.2 [32.5; 41.2]	46.3 [41.2; 52.5]	0.001
SF	36.5 [32.5; 42.3]	46.1 [42.6; 54.8]	0.001
RE	36.2 [33.1; 42.9]	45.6 [41.2; 51.2]	0.001
MH	43.2 [36.3; 48.6]	51.2 [44.8; 51.2]	0.001

* Wilcoxon test. PF, Physical Functioning; RP, Role-Physical; BP, Bodily Pain; GH, General Health; VT, Vitality; SF, Social Functioning; RE, Role-Emotional; MH, Mental Health.

Table 4. Analysis of factors affecting the SF-36 quality of life measures (linear regression analysis)

Parameter	Factor	Univariate analysis		Multivariate analysis	
		HR (95 %CI)	p	HR (95 %CI)	p
PF	Sex	6.56 (3.3–9.8)	0.001	4.57 (0.87–8.27)	0.017
	Age	0.42 (–0.01–0.85)	0.055	–	–
	CHF NYHA class, 12 months	–1.98 (–4.66–0.69)	0.143	–	–
	EF before surgery	–0.07 (–0.28–0.14)	0.48	–	–
	CABG	3.85 (0.12–7.57)	0.043	1.98 (–1.71–5.67)	–
	Time of CPB	0.05 (–0.02–0.12)	0.145	–	0.284
	Time of AO	0.07 (–0.01–0.15)	0.099	–	–
	Repeat surgery	10.2 (–2.21–22.6)	0.105	–	–
	Complicated postoperative period	1.75 (–3.77–7.28)	0.525	–	–
	AF in the long-term period	1.75 (–3.77–7.28)	0.525	–	–
	IVS thickness	0.04 (0.01–0.08)	0.023	–	–
	EF in 12 months	–0.34 (–0.62 – –0.06)	0.018	–	0.328
	MMI in 12 months	0.12 (0.03–0.21)	0.009	–0.78 (–2.38–0.82)	0.504
	EA in 12 months	6.85 (–0.05–13.7)	0.052	0.385 (–3.91–0.68)	0.04
	Mean gradient in 12 months	–0.2 (–0.53–0.12)	0.214	0.12 (–0.02–0.27)	–
RP	Sex	8.46 (3.47–13.5)	0.001	6.03 (0.30–11.8)	–
	Age	0.24 (–0.41–0.89)	0.465	–	–
	CHF NYHA class, 12 months	–2.66 (–6.54–1.22)	0.173	–	–
	EF before surgery	–0.21 (–0.51–0.09)	0.159	–	–
	CABG	4.58 (–0.98–10.2)	0.104	–	–
	Time of CPB	0.01 (–0.09–0.12)	0.791	–	–
	Time of AO	0.01 (–0.12–0.13)	0.879	–	–
	Repeat surgery	17.4 (–0.62–35.3)	0.052	–	–
	Complicated postoperative period	6.44 (–1.47–14.3)	0.108	–	–
	AF in the long-term period	0.76 (–5.24–6.76)	0.80	–	0.550
	IVS thickness	1.62 (0.07–3.18)	0.041	–	–
	EF in 12 months	–0.38 (–0.79–0.03)	0.071	–	0.576
	MMI	0.17 (0.04–0.3)	0.013	0.68 (–1.59–2.94)	–
	EA in 12 months	3.52 (–6.84–13.9)	0.497	–	–
	Mean gradient in 12 months	0.003 (–0.48–0.48)	0.989	0.06 (–0.15–0.27)	–
BP	Sex	7.369 (3.16–11.6)	0.001	–	–
	Age	0.283 (–0.27–0.83)	0.305	–	–
	CHF NYHA class, 12 months	–2.26 (–5.57–1.04)	0.174	–	–

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Table 4 (continuation). Analysis of factors affecting the SF-36 quality of life measures (linear regression analysis)

Parameter	Factor	Univariate analysis		Multivariate analysis	
		HR (95 %CI)	p	HR (95 %CI)	p
BP	EF before surgery	0.011 (–0.25–0.27)	0.933	–	–
	CABG	0.998 (–3.87–5.86)	0.681	–	–
	Time of CPB	0.029 (–0.06–0.012)	0.526	–	–
	Time of AO	0.054 (–0.05–0.16)	0.301	–	–
	Repeat surgery	13.7 (–1.65–29.1)	0.079	–	–
	Complicated postoperative period	4.95 (–6.35–16.2)	0.382	–	–
	AF in the long-term period	0.725 (–4.37–5.82)	0.775	–	–
	IVS thickness	0.373 (–1.02–1.76)	0.591	–	–
	EF in 12 months	–0.149 (–0.51–0.22)	0.414	–	–
	MMI	0.043 (–0.08–0.16)	0.474	–	–
	EA in 12 months	5.67 (–3.03–14.4)	0.196	–	–
	Mean gradient in 12 months	–0.25 (–0.65–0.16)	0.222	–	–
GH	Sex	3.827 (–0.03–7.69)	0.050	–1.11 (–5.71–3.49)	0.628
	Age	–0.222 (–0.69–0.24)	0.340	–	–
	CHF NYHA class, 12 months	–3.76 (–6.45 – –1.07)	0.007	–3.75 (–6.65 – –0.84)	0.013
	EF before surgery	–0.07 (–0.29–0.15)	0.519	–	–
	CABG	–0.372 (–4.48–3.74)	0.856	–	–
	Time of CPB	–0.031 (–0.11–0.05)	0.421	–	–
	Time of AO	–0.05 (–0.14–0.04)	0.260	–	–
	Repeat surgery	6.964 (–6.29–20.2)	0.295	–	–
	Complicated postoperative period	2.01 (–7.57–11.6)	0.674	–	–
	AF in the long-term period	0.385 (–3.91–4.68)	0.857	–	–
	IVS thickness	0.98 (–0.19–2.15)	0.099	–	–
	EF in 12 months	–0.208 (–0.52–0.11)	0.188	–	–
	MMI	0.13 (0.03–0.23)	0.011	0.13 (0.02–0.23)	–
	EA in 12 months	2.57 (–5.13–10.3)	0.504	–	0.017
	Mean gradient in 12 months	0.13 (–0.34–0.37)	0.943	–	–
SF	Sex	6.291 (1.675–10.9)	0.009	5.857 (1.44–10.3)	0.011
	Age	0.641 (0.09–1.19)	0.023	–	–
	CHF NYHA class, 12 months	–0.97 (–4.58–2.65)	0.591	0.582 (0.07–1.09)	0.027
	EF before surgery	–0.002 (–0.27–0.27)	0.985	–	–
	CABG	3.48 (–1.5–8.47)	0.166	–	–
	Time of CPB	0.007 (–0.09–0.1)	0.878	–	–
	Time of AO	0.022 (–0.09–0.13)	0.694	–	–
	Repeat surgery	8.756 (–7.69–25.2)	0.289	–	–
	Complicated postoperative period	2.317 (–9.59–14.2)	0.696	–	–
	AF in the long-term period	3.794 (–1.41–8.99)	0.148	–	–
	IVS thickness	0.374 (–1.12–1.87)	0.615	–	–
	EF in 12 months	–0.216 (–0.6–0.17)	0.266	–	–
	MMI	0.091 (–0.04–0.22)	0.153	–	–
	EA in 12 months	4.72 (–4.69–14.1)	0.317	–	–
	Mean gradient in 12 months	–0.19 (–0.63–0.24)	0.364	–	–
VT	Sex	4.248 (–0.53–9.02)	0.080	–	–
	Age	–0.171 (–0.74–0.4)	0.551	–	–
	CHF NYHA class, 12 months	–3.0 (–6.47–0.47)	0.088	–	–
	EF before surgery	–0.057 (–0.33–0.21)	0.670	–	–
	CABG	–0.73 (–5.77–4.31)	0.771	–	–
	Time of CPB	–0.056 (–0.15–0.04)	0.225	–	–
	Time of AO	-0.069 (0.18–0.04)	0.202	–	–
	Repeat surgery	9.667 (–6.52–25.9)	0.235	–	–
	Complicated postoperative period	4.78 (–6.9–16.5)	0.414	–	–
	AF in the long-term period	–1.208 (–6.46–4.04)	0.645	–	–

Table 4 (ending). Analysis of factors affecting the SF-36 quality of life measures (linear regression analysis)

Parameter	Factor	Univariate analysis		Multivariate analysis	
		HR (95 %CI)	p	HR (95 %CI)	p
VT	IVS thickness	1.083 (–0.36–2.53)	0.138	–0.245 (–0.65–0.16)	0.227
	EF in 12 months	–0.387 (–0.76 – –0.02)	0.042	–	–
	MMI	0.142 (0.02–0.26)	0.022	–	–
	EA in 12 months	3.87 (–5.51–13.2)	0.409	0.107 (–0.03–0.24)	0.110
	Mean gradient in 12 months	0.19 (–0.24–0.63)	0.367	–	–

HR, hazard ratio; CI, confidence interval; CHF, chronic heart failure; EF, ejection fraction; CABG, coronary artery bypass graft; CPB, cardiopulmonary bypass; AO, aortic occlusion; AF, atrial fibrillation; MMI, myocardial mass index; EA, effective area.

Figure 2. Survival curve of patients after MedEng-BIO implantation

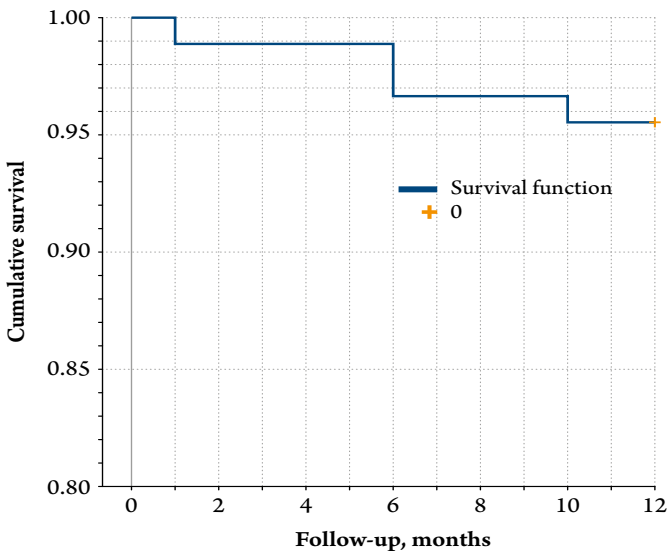
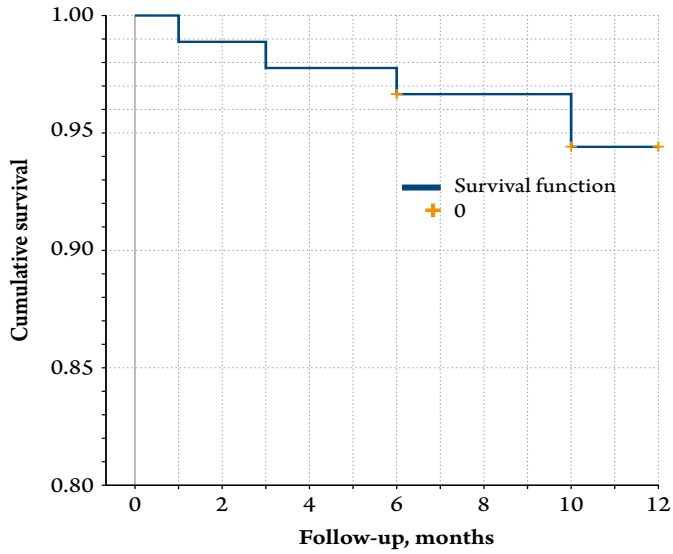


Figure 3. Long-term complication curve (Kaplan-Meier)



36 questionnaire in patients who had stented and non-stented bioprosthesis implanted. According to the study results, the improvement in QoL after surgery did not depend on the gradient or the design of the prosthesis.

In 2020, Wang et al. [7] published the study, in which they compared the influence of the mechanical and biological aortic prostheses on the QoL of 60–70-year-old patients. The authors showed that the SF-36 scores were higher in patients who had an aortic bioprosthesis implanted.

The multivariate analysis revealed the influence of the patient's sex on 3 measures of the SF-36 questionnaire: PF, RF, and SF. The latter also depended on the patient's age. MMI influenced the General Health. According to the literature, the QoL indicators depended the most on CHF class [8]. In our study, the CHF class affected he General Health.

Thus, the implantation of the MedEng-BIO biological prosthesis was not inferior in improving the patients' QoL than the known xenopericardial prosthesis models.

The overall survival rate was 95.4% within 12 months after the implantation of the MedEng-BIO prosthesis. According to the foreign literature, the overall survival after AV replacement using the Hancock II biological prostheses was 93.2% [9].

The postoperative complications after AV replacement include both valve-associated and infectious complications. Infectious complications are more common in the early postoperative period [10]. There were no major valve-associated complications in 94.5% of cases in the 12-month postoperative period after the implantation of MedEng-BIO in the aortic position.

Conclusion

Improved quality of life after aortic valve replacement using the new easy-change stented xenopericardial prosthesis MedEng-BIO is indicative of the clinical and functional efficacy of the technique. The study showed improvements in the physical components of health and the subjective emotional assessment. The 12-month survival rate after the valve replacement was 95.4%, there major valve-dependent complications were absent in 94.5% of cases.

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