Quality of life after aortic valve replacement with biological prostheses in elderly patients

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Aim	The paper aims to assess the quality of life of patients subjected to aortic valve replacement with a stented/stentless biological prosthesis.
Methods	The research was done at the Acquired Heart Disease Department of Meshalkin National Medical Research Center. The inclusion criteria were patient age older than 65 years and severe stenosis of the aortic valve. 114 patients were randomized 1:1 in two groups: group I patients received stentless biological prostheses, while group II patients—stented xenopericardial ones. All patients underwent aortic valve replacement under normothermic cardiopulmonary bypass. Mean follow-up was 3.9 [2.77; 4.55] years, mean age 71.5±4 (65–84) years, mean left ventricle ejection fraction 65.5 (40–86) % and mean preoperative Log.Euroscore 5.4±1.3 (1.4–12.4). The quality of life was assessed by using a standard questionnaire SF-36.
Results	Peak transprosthetic gradients at 1-year follow-up amounted to 16.22±4.34 and 24.66±4.74 mm Hg for group I and group II respectively. The 5-year survival rate was 90 [81; 99] % and 96 [90; 100] % for the two groups respectively and did not differ statistically (log rank test, p = 0.226). A statistically significant improvement of quality of life among patients in both groups was observed at 1-year follow-up, as compared to the preoperative values, however, marked intergroup differences in any of the parameters were not recorded.
Conclusion	Conclusion. The quality of life after aortic valve replacement with stented and stentless biological prostheses in elderly patients confirms clinical and functional efficiency of both methods, does not show sound advantages of any of them and improves both the physical component of health and subjective emotional level.
Keywords	aortic valve disease; aortic valve replacement; biological prosthesis; heart failure

Introduction

Undoubtedly, cardiac surgery intervention has a huge impact on a patient's quality of life in the long-term follow-up [1, 2]. Even if the cardiac insufficiency symptoms are removed during a successful and timely operation, permanent application of anticoagulant therapy in elderly patients during the long-term follow-up reduces the acceptable subjective level of quality of life [3–7]. For elderly patients with degenerative aortic
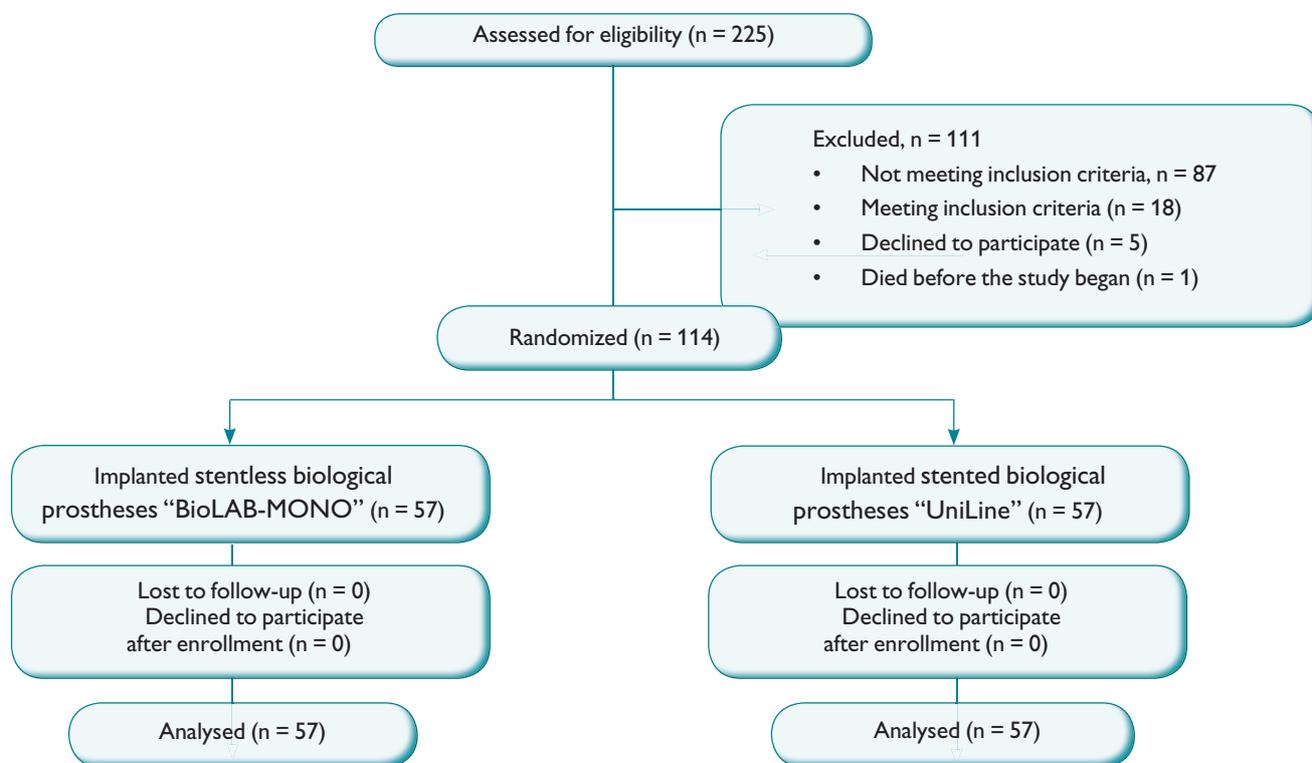
Fig. 1. CONSORT flow diagram

valve disease, replacing the aortic valve with a frame-mounted biological implant is a standard method of therapy [8]. Its relative simplicity and reproducibility, as well as a sustainable and anticipated outcome turn this surgery into one of the widely spread procedures in routine surgical practice [9]. Aortic valve replacement with frameless bioprostheses is considered as an alternative method of treatment. The use of frameless bioprostheses, demanding smarter implantation tools on the one hand and resulting in better hemodynamic characteristics on the other hand, is becoming a procedure of choice when treating senile aortic diseases [10–13].

The aim of our study was to compare the quality of life of elderly patients who had undergone aortic valve replacement by using frame-mounted/frameless bioprostheses.

Methods

The study included 114 patients aged 65 to 84 years old with hemodynamically significant stenosis of the aortic valve, who had undergone surgery at the Acquired Heart Diseases Department of Meshalkin National Medical Research Center over a period from December 2011 to June 2015.

The primary endpoint was the value of peak transprosthetic gradient at 1 year of follow-up, the secondary endpoints were dysfunction of the bioprosthesis implanted, a patient's death and quality of life during long-term follow-up. With study power equal to 80%, the estimated sample amounted to 114 patients (57 patients in each group). The results were evaluated every year after implantation, with intermediate analysis done at 30 days after surgery.

In accordance with the 2014 American Heart Association / American College of Cardiology Guidelines on management of patients with valvular heart diseases, the inclusion criteria were a patient's age and hemodynamically significant stenosis of the aortic valve being the main indication for surgery [8].

Patients in need of replacement of two and more valves, left ventricular contractility less than 40%, reintervention on the heart, infective endocarditis and unwillingness to participate in the study were accepted as exclusion criteria. The study was approved by the Ethics Committee. All patients signed up the consent form.

The data on the first and second postoperative long-term endpoints were obtained by direct contact with patients during their outpatient visits or by phone.

Statistical analysis

Empirical distributions of quantitative indicators were tested for compliance with a normal distribution law by using Shapiro–Wilk test. The results are presented as a mean value ± standard deviation for normally distributed indicators, a median (first quartile–third quartile) for abnormally distributed indicators, quantity (per cent) for qualitative (categorical) indicators. Comparative analysis of quantitative indicators was done by Student's t-test for normally distributed data, Mann–Whitney U-test for abnormally distributed data and two-tailed Fisher's exact test for qualitative indicators.

The survivorship functions were calculated by a Kaplan–Meier method, the results are presented as graphs with 95% confidence intervals for survival probability. To compare the survival between the groups, a log-rank test was applied. Statistical hypotheses were verified with a critical significance value p = 0.05. The deviation was considered a statistically significant at $p < 0.05$. The RStudio program (version 0.99.879, © 2009–2016 RStudio, Inc., USA) was used to perform statistical estimates.

The standard SF-36 questionnaire was used to evaluate the quality of life. A mean observation period was 3.9

Table 1 Patients' preoperative indicators

Indicator	"Bio-Lab-MONO" group (n = 57)	"UniLine" group (n = 57)	p
Age (years)	71 [66; 74]	72 [69; 77]	0,054U
Sex (female)	40 (70%)	31 (54%)	0,018F
BMI (kg/m^2)	28,8 [25,21; 30,8]	27,88 [25,46; 31,1]	0,598U
BSA (m^2)	1,82 [171; 192]	1,86 [175; 191]	0,287U
Diabetes mellitus	11 (1,9%)	11 (1,9)	0,961F
Arterial hypertension	37 (64,9%)	41 (71,9)	0,423F
ACVE/CCVE	8 (14%)	4 (7)	0,622F
COPD	4 (7%)	2 (3,5)	0,467F
IHD	6(10,5%)	7 (12,3)	0,251F
Peripheral arterial disease	29 (50,9%)	28 (49)	0,071F
Peak gradient across the valve	106 [85,4; 123]	103 [87; 120]	0,872U
Aortic valve area	0,7 [0,5; 0,78]	0,7 [0,56; 0,78]	0,654U
NYHA CHF			
II	50 (87,7%)	6 (10,5)	0,091F
III	50 (87,7%)	51 (89,5)	0,063F
LVEF (%)	67 [58; 74]	68 [56; 74]	0,596F
LVMMI (g/m^2)	210,01 [182,02; 248,26]	182,55 [160,02; 209,11]	0,077U
Logistic Euroscore	5,5±1,2	5,3±1,5	0,553T

BMI, body mass index; *BSA*, body surface area; *ACVE/CCVE*, acute cerebrovascular event / chronic cerebrovascular event; *COPD*, chronic obstructive pulmonary disease; *IHD*, ischemic heart disease; *CHF*, congestive heart failure; *NYHA*, New York Heart Association; *LVEF*, left ventricular ejection fraction; *LVMMI*, left ventricular myocardium mass index; *U*, Mann-Whitney U-test; *F*, Fisher's exact test; *T*, Student's t-test

[2.77; 4.55] and 3.25 [2.8; 4.2] for "BioLAB-MONO" and "UniLine" groups respectively.

Results

The CONSORT chart was designed on the basis of inclusion and exclusion criteria (Fig. 1).

No statistically significant differences in preoperative demographic and clinical characteristics of both groups were revealed (Table 1).

In the long-term follow-up, the data were obtained for 100% operated patients from both groups. When analyzing the primary endpoint, a significant intergroup

difference in transprosthetic gradient values with lower values for frameless prostheses both in hospital and 1 year after surgery was obtained (Fig. 2).

No statistically significant differences in 5-year survival indicators amounting to 96 [90; 100] and 90 [81; 99] % in the "UniLine" and "BioLAB-MONO" groups respectively (log-rank test, p = 0.0226, Fig. 3) were not observed.

The cause of mortality among the patients who died during the long-term follow-up was a concomitant pathology. One of the "BioLAB-MONO" group patients died because of secondary septic complications following acute ischemic stroke.
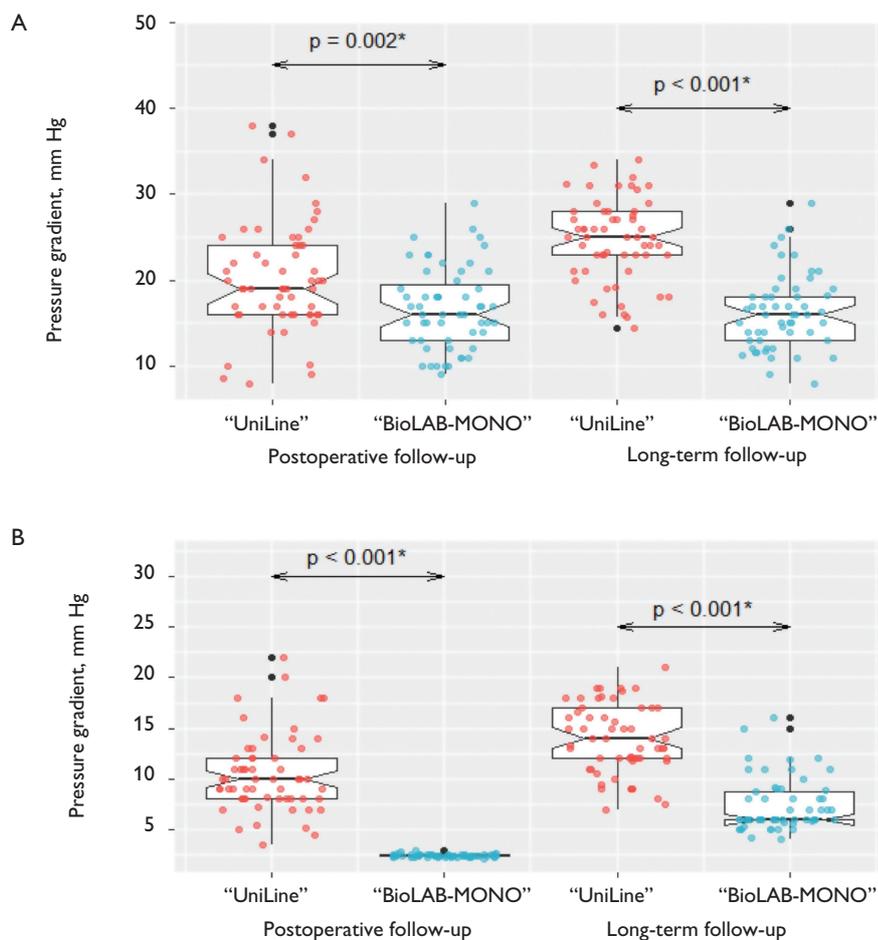

Fig. 2. Comparison of bioprosthetic pressure gradients of "UniLine" and "BioLAB-MONO" groups: peak transprosthetic gradient values (*A*); mean transprosthetic gradient (*B*)
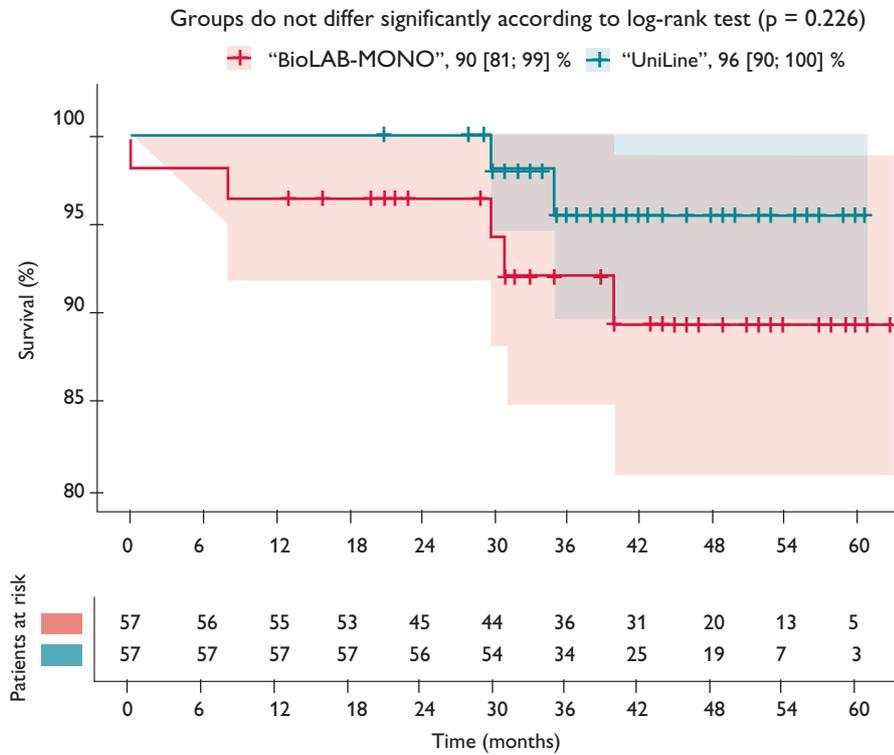
Fig. 3. Kaplan–Meier 5-year survival curve for "BioLAB-MONO" and "UniLine" groups

8 parameters were studied: physical functionality (PF), role playing determined by physical state (RP), bodily pain (BP), general health (GH), vitality (VT), social functionality, adaptation (SF), role playing determined by emotional health (RE), mental health (MH). Each indicator had limits from 0 to 100: the higher the value, the better the health. Possible answers varied from 2 to 6.

When carrying out a comparative analysis of quality of life indicators 1 year after operation, no significant differences between the groups were recorded (Table 2). The value of subjective physical functionality of "UniLine" respondents was slightly higher, however, it did not reach a significance point ($p = 0.053$).

Table 2 QoL analysis of patients of both groups 1 year after surgery (according to SF-36 questionnaire data)

| Quality of life indicators	"BioLab-MONO" group (n = 57)	"UniLine" group (n = 57)	Mann–Whitney U-test, p
Physical functionality (PF)	61,7 [54,3; 67,2]	69,8 [57,5; 71,4]	0,053
Role playing determined by physical state (RP)	57,3 [51,2; 64,7]	56,9 [49,1; 62,5]	0,865
Bodily pain (BP)	58,4 [50,6; 61,3]	63,3 [56,1; 62,7]	0,617
General health (GH)	45,2 [41,3; 50,5]	49,1 [43,5; 56,8]	0,332
Vitality (VT)	55,7 [51,3; 58,4]	52,6 [47,9; 57,4]	0,763
Social functionality, adaptation (SF)	44,2 [41,7; 8,6]	43,4 [41,1; 45,2]	0,442
Role playing determined by emotional health (RE)	53,3 [45,4; 54,7]	56,5 [51,2; 58,4]	0,731
Mental health (MH)	65,9 [61,3; 67,1]	62,8 [56,8; 65,4]	0,834

A

B
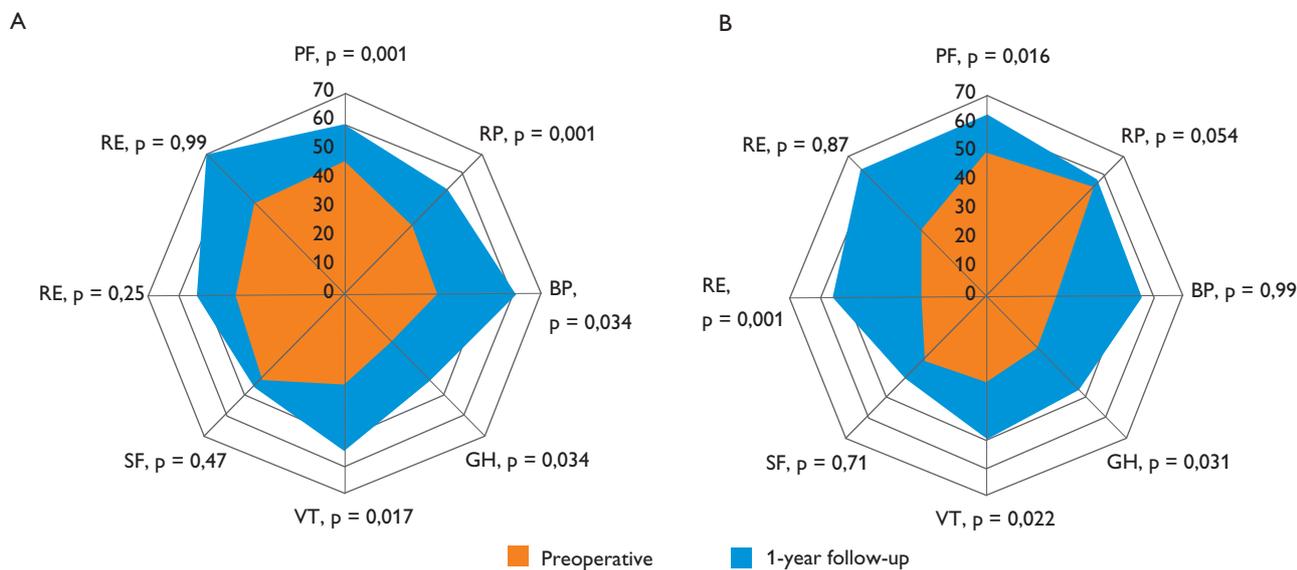
Fig. 4. Changes of quality of life dimensions in "BioLAB-MONO" (*A*) and "UniLine" (*B*) groups before and one year after operation according to SF-36 questionnaire results

PF, physical functioning; *RP*, roleplaying; *BP*, bodily pain; *GH*, general health; *MH*, mental health; *RE*, role-emotional functioning; *VT*, vitality

When doing an intergroup analysis of quality of life and comparing it with the preoperative one, a considerable improvement was observed for all indicators (Fig. 4).

Discussion

The results of our study on long-term mortality level indicators are comparable to those described by other authors [14, 15]. The analysis of morbidity/lethality rates during a long-term follow-up after cardiac surgery interventions is a standard tool to evaluate the efficiency and success of treatment. However, it is unlikely that these parameters reflect a patient's subjective status and postoperative standard living, especially when we deal with such a vulnerable social category as elderly and senile people. Given that the number of operative interventions in elderly patients is steadily growing, there is a need to analyze both the social-adaptive and psychological/physical state of treated patients. Improvement of quality of life of elderly patients who underwent aortic valve replacement has been demonstrated by many authors [16–18].

The analysis of a patient's quality of life necessitates his/her treatment and not a disease. Our study demonstrates a true improvement of quality of life in the majority of patients' characteristics as compared to the preoperative ones in both groups. However, the study has not revealed a statistically significant intergroup difference in the quality of life indicators, despite a true difference in the primary endpoint—the peak transprosthetic gradient level. This can be explained by the fact that a statistically significant difference in the gradient between the groups has no impact on the clinical and subjective status of patients because of basically the same hemodynamic effects of the technologies used.

Study limitations

The main limitations are a single-center enrollment of patients and a short period of observation.

A longer follow-up might demonstrate that the use of frameless aortic valve prostheses having lower transvalvular gradients will result in a higher level of freedom from reoperations. Nowadays, however, because of more sophisticated techniques for

implantation of frameless prostheses and a lack of a statistically significant difference in patients' quality of life, the advantages of this technology can only be seen in specific anatomic conditions, such as a narrow aortic root.

Conclusion

Repairing aortic diseases by means of frame-based/frameless bioprostheses shows similar improvement of the parameters of elderly's quality of life as compared to the preoperative ones. With 5-year cumulative survival indicators comparable in both groups, a statistically significant increase of both physical characteristics of the health level and a subjective emotional component of the quality of life level of treated elderly patients.

Funding

Conflict of interest

The authors declare no conflict of interest.

References

1. Chocron S., Etievent J., Viel J., Dussaucy A., Clement F., Alwan K., Neidhardt M., Schipman N. Prospective study of quality of life before and after open heart operations. *Ann Thorac Surg.* 1996;61(1):153-7. PMID: 8561543. http://dx.doi.org/10.1016/0003-4975(95)00936-1

2. Myken P., Larsson S., Berggren H., Caidahl K. Similar quality of life after heart valve replacement with mechanical or bioprosthetic valves. *J Heart Valv Dis.* 1995;4(4):339-45. PMID: 7582138

3. Babenko S.I., Muratov R.M., Soboleva N.N. Results of aortic valve replacement stented and stentless bioprostheses series BioLAB. *Klinicheskaja fiziologija krovoobrashhenija = Clinical Physiology of Blood Circulaiton.* 2015;(1):30-5. (In Russ.) Available at: https://cfc-journal.com/EN/catalog/detail.php?SECTION_ID=4013&ID=47368

4. Perchinsky M., Henderson C., Jamieson W., Anderson W. Jr, Lamy A., Lowe N., de Guzman S. Quality of life in patients with bioprostheses and mechanical prostheses. Evaluation of cohorts of patients aged 51 to 65 years at implantation. *Circulation.* 1998;98(Suppl II):81-6. discussion II86-7. PMID: 9852886

5. Aleksi-Meshishvili V.V., Dzemeshkevich S.L., Stivenson L.U. Bolezni aortalnogo klapana. Funktsiya. Diagnostika. Lechenie. Moscow, Geotar Media Publ.; 2004. 328 p.

6. Astapov D.A., Demidov D.P., Semenova E.I. Aortic valve replacement with stentless bioprosthesis. Khirurgiya. *Zhurnal imeni N.I. Pirogova = Journal Surgery named after N.I. Pirogov.* 2016(5):4-12. (In Russ.) http://dx.doi.org/10.17116/hirurgia201654-12

7. Astapov D.A., Demidov D.P., Semenova Ye.I., Zheleznev S.I., Zorina I.G., Syrtseva Ya.V. The first experience with the implantation of the prosthesis xenopericardial frame variable stiffness "Tiara" in the aortic position. *Patologiya krovoobrashcheniya i kardiokhirurgiya = Circulation Pathology and Cardiac Surgery.* 2013;17(2):73-75. (In Russ.) http://dx.doi.org/10.21688/1681-3472-2013-2-73-75

8. Nishimura R.A., Otto C.M., Bonow R.O., Carabello B.A., Erwin J.P., Fleisher L.A., Jneid H., Mack M.J., McLeod C.J., O'Gara P.T., Rigolin V.H., Sundt T.M., Thompson A. 017 AHA/ACC Focused Update of the 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines. *Circulation.* 2017;136(13). https://doi.org/10.1161/CIR.0000000000000503

9. Karas'kov A.M., Zhuravleva I.Ju., Astapov D.A. Stasev A.N., Demidov D.P., Odarenko Ju.N., Barbarash L.S Clinical and hemodynamic results of bioprostheses UniLine using in aortic position. *Kardiologiya i serdechno-sosudistaya khirurgiya = Cardiology and Cardiovascular Surgery.* 2014;(4):87-91. (In Russ.) Available at: https://www.mediasphera.ru/issues/kardiologiya-i-serdechno-sosudistaya-khirurgiya/2014/4/031996-63852014414

10. Astapov D.A., Karaskov A.M., Semenova Ye.I., Demidov D.P., Isayan M.V., Open A.B. Aortic valve replacement with stentless bioprosthesis "Kemerovo-AB-Neo". *Patologiya krovoobrashcheniya i kardiokhirurgiya = Circulation Pathology and Cardiac Surgery.* 2012;16(1):23-26. (In Russ.) http://dx.doi.org/10.21688/1681-3472-2012-1-23-26

11. Bockeria L.A., Muratov R.M., Babenko S.I., Soboleva N.N., Semenova E.V. A new xenopericardial stentless bioprosthesis «BioLAB» in the surgery of aortic valve. *Grudnaja i serdechno-sosudistaja hirurgija = Russian Journal of Thoracic and Cardiovascular Surgery.* 2015;57(1):25-31. (In Russ.). Available at: https://tcs-journal.com/EN/catalog/detail.php?SECTION_ID=3936&ID=44878

12. Glauber M, Solinas M, Karimov J. Technique for implant of the stentless aortic valve Freedom Solo. *Multimed Man Cardiothorac Surg.* 2007;1:002618. PMID: 24415056. http://dx.doi.org/10.1510/mmcts.2007.002618

13. Repossini A., Kotelnikov I., Bouchikhi R., Torre T., Passaretti B., Parodi O., Arena V. Single-suture line

placement of a pericardial stentless valve. *J Thorac Cardiovasc Surg.* 2005;130(5):1265-9. PMID: 16256777. http://dx.doi.org/10.1016/j.jtcvs.2005.07.045

14. van der Straaten E.P., Rademakers L.M., van Straten A.H., Houterman S., Tan M.E., Soliman Hamad M.A. Mid-term haemodynamic and clinical results after aortic valve replacement using the Freedom Solo stentless bioprosthesis versus the Carpentier Edwards Perimount stented bioprosthesis. *Eur J Cardiothorac Surg.* 2016;49(4):1174-80. PMID: 26224338. http://dx.doi.org/10.1093/ejcts/ezv255

15. Beholz S., Repossini A., Livi U., Schepens M., Gabry M., Matschke K., Trivedi U., Eckel L., Dapunt O., Zamorano J. The Freedom SOLO valve for aortic valve replacement: clinical and hemodynamic results from a prospective multicenter trial. *J Heart Valve Dis.* 2010;19(1):23. PMID: 20329497.

16. Vicchio M., Della Corte A., De Santo L., De Feo M., Caianiello G., Scardone M., Cotrufo M. Prosthesis patient mismatch in the elderly: survival, ventricular mass regression, and quality of life. *Ann Thorac Surg.* 2008;86(6):1791-7. PMID: 19021978. http://dx.doi.org/10.1016/j.athoracsur.2008.09.005

17. Salizzoni S. Quality of life in patients with prosthesis–patient mismatch. *J Thorac Cardiovasc Surg.* 2009;138(3):786-7. http://dx.doi.org/10.1016/j.jtcvs.2009.04.036

18. Sportelli E., Regesta T., Salsano A., Ghione P., Brega C., Bezante G., Passerone G., Santini F. Does patient-prosthesis mismatch after aortic valve replacement affect survival and quality of life in elderly patients? *J Cardiovasc Med (Hagerstown).* 2016;17(2):137-43. http://dx.doi.org/10.2459/JCM.0000000000000292