REMOTE RESULTS OF FLORIDA SLEEVE TECHNIQUE IN PATIENTS WITH ASCENDING AORTIC ANEURYSMS AND AORTIC INSUFFICIENCY

KHVAN D.S., SIROTA D.A., ZHULKOV M.O., LYASHENKO M.M., CHERNYAVSKY A.M.

Centre for Surgery of the Aorta, Coronary and Peripheral Arteries, National Medical Research Centre named after Academician E.N. Meshalkin under the RF Ministry of Public Health, Novosibirsk, Russia

Objective. The aim of our investigation was to assess the remote results of valve-sparing aortic root reimplantation into the graft (Florida Sleeve technique) compared with reimplantation of the aortic valve into the graft (David technique) during surgical correction of ascending aortic aneurysms accompanied by concomitant aortic insufficiency.

Patients and methods. Our single-centre, blind, prospective, randomized study carried out from 2011 to 2015 included a total of 64 patients with ascending aortic aneurysms and aortic insufficiency. The patients were randomized into 2 groups: group I – aortic root reimplantation according to the Florida Sleeve technique (FS group) and group II – reimplantation of the aortic valve according to the T. David technique in David I modification (D group). The groups did not statistically differ by the baseline clinical profile.

Results. The overall 7-year survival for the FS group and D group amounted to 83% and 85.6%, respectively (p=0.98). Assessing the competing risks of mortality related to cardiovascular or other causes revealed no differences. Freedom from prosthetic repair of the aortic valve in the remote follow-up period amounted to 92.8% and 85.8% for the FS group and D group, respectively (p=0.4). According to the obtained findings, the technique of a valve-sparing operation is not a predictor of either lethality (RR 0.98 (95% CI 0.23–4.15), p=0.98) or prosthetic repair of the aortic valve (RR 2.03 (95% CI 0.40–14.63), p=0.40) in the remote period of follow up.

Conclusion. Aortic root reimplantation inside the prosthesis according to the Florida Sleeve technique makes it possible to simplify and accelerate the procedure of aortic root reconstruction in patients with aortic root aneurysms and concomitant aortic insufficiency, demonstrating long-term results comparable with those of the David technique.

Key words: *aortic insufficiency, ascending aortic aneurysm, aortic root aneurysm, valve-sparing operations, David operation, Florida Sleeve operation.*

INTRODUCTION

Surgical treatment of patients presenting with ascending aortic aneurysms and concomitant aortic insufficiency is one of the most complicated fields of cardiovascular surgery. An increased understanding of the functional anatomy of the aortic root and studying the mechanism of formation of aortic insufficiency in ascending aortic aneurysms favourably contribute to a differentiated approach towards selecting an appropriate technique of reconstructive surgery for this pathology. Despite progress in treatment of patients with aortic root aneurysms there are a number of hitherto unsolved problems. Probably, the most important one consists in what method should be chosen for surgical correction in this cohort of patients [1].

The results of valve-sparing techniques as compared with complete replacement of the aortic valve with a valve-containing conduit are suggestive of high quality of life of patients and appear to influence the surgeon's therapeutic decision-making concerning preservation of the native valve [2, 3]. Proposed in 1992 by T.E. David, the technique of reimplantation of the aortic valve inside a synthetic prosthesis for an ascending aortic aneurysm with concomitant aortic insufficiency has become the «gold standard».

Despite success and progress of valve-sparing operations, the proportion of their application in the structure of aortic root surgery still remains low. Operations preserving the native aortic valve are performed in large centres possessing sufficient experience with this type of surgical interventions. The main problems for wide implementation of valve-sparing operations are as follows: their complexity, long duration, and certain unpredictability, whereas the selection of a prosthesis and visual assessment of the quality of the correction performed are to a larger extent based upon the operating surgeon's experience [4–7].

In 2005, P. Hess, et al. proposed the so-called Florida Sleeve technique, offering a new mode of view on preservation of the aortic valve [8]. This technique

Table

Preoperative characteristic of the patients

Clinical characteristics of the patients	FS group n = 32	D group n = 32	p-value
Age, years (M ± δ)	58±52	55±11	0.54
Men, n (%)	25 (78%)	25 (78%)	>0.99
Body surface area (m^2)	1.95±0.23	1.99±0.19	0.25
Marfan syndrome, n (%)	2 (6%)	3 (9%)	>0.99
Aortic arch aneurysm	9 (28%)	7 (22%)	>0.99
Type A aortic dissection, n (%)	4 (13%)	2 (6%)	0.67
AH, stage (M ± δ)	2.3±1.2	2±1.3	0.18
NYHA FC (M ± δ)	2.4±0.7	2.4 ± 0.7	0.92
Pronounced MI, n (%)	0	2 (6%)	0.49
Significant lesion of CA, n (%)	7 (22%)	5 (16%)	0.75
EuroSCORE II	2.5±1.6	2.7±1.7	0.48
EchoCG parameters (M ± δ)			
AV annulus diameter, mm	27±2	27±3	0.94
Valsalva sinus diameter, mm	51±7	56±10	0.09
STJ diameter, mm	49±6	55±12	0.08
Ascending aortic diameter, mm	57±11	59±16	0.54
Aortic regurgitation (+)	2.6±0.7	2.8±0.8	0.15
1+	1 (3%)	1 (3%)	>0.99
2+	13 (41%)	9 (28%)	0.43
3+	16 (50%)	16 (50%)	>0.99
4+	2 (6%)	6 (19%)	0.26
LV EF, %	62±7	60±10	0.23
LV EDD, cm	5.5±0.7	5.9±1.0	0.09
Accompanying interventions			
Intervention on the arch, n (%)	11 (34%)	7 (22%)	0.40
CABG, n (%)	7 (22%)	5 (16%)	0.75
MV plasty, n (%)	0	2 (6%)	0.49
RFA, n (%)	0	2 (6%)	0.49

Note: AH – arterial hypertension; FC – functional class; MI – mitral insufficiency; CA – coronary artery; EchoCG – echocardiography; AV – aortic valve; STJ – sinotubular junction; LV EF – left ventricular ejection fraction; LF EDD – left ventricular end-diastolic dimension; CABG – coronary artery bypass grafting; MV – mitral valve; RFA – radiofrequency ablation.

implies reimplantation of the whole aortic root inside a Dacron graft appropriately sized to achieve adequate competence of the aortic valve, without reimplantation of ostia of coronary arteries. Such an approach makes it possible to reduce the duration of the operation, to decrease the complication rate, as well as to avoid a series of errors inherent to valve-sparing techniques with reimplantation of coronary arteries, and is an alternative to more widespread techniques [8, 9].

Presented in this study are the remote results regarding reimplantation of the root of the aorta inside the prosthesis (Florida Sleeve technique) compared with reimplantation of the aortic valve (T. David procedure) in patients with ascending aortic aneurysms and concomitant aortic insufficiency.

PATIENTS AND METHODS

Our single-centre simple blind prospective randomised study was aimed at comparative evaluation of efficacy of the technique of aortic root reimplantation inside the prosthesis. Form 2011 to 2015, a total of 64 patients with ascending aortic aneurysms and aortic insufficiency underwent valve-sparing interventions. The patients were blindly randomised into 2 groups: group I – reimplantation of the aortic root according to the modified Florida Sleeve technique (FS group) and group II – reimplantation of the aortic valve according to the T. David technique in David I modification (D group).

All data were acquired and analysed preoperatively, postoperatively and in the remote follow-up period using instrumental methods of examination, observation, interviewing.

The comparative preoperative characteristics of the patients are shown in the Table below. No statistically significant differences by age, gender, anthropometric and echographic parameters between the groups were revealed.

In all patients of this study, the aneurysms of the ascending portion of the aorta belonged to types I and IIB according to the Yu.V. Belov's classification [10]. In 16 (25%) patients, the ascending aortic aneurysm extended to the aortic arch.

All operations were performed electively, in accordance with the standard protocol and routine provision accepted in our Clinic. The valve-sparing interventions were carried out either in an isolated manner or in a combination with other interventions on the heart. No statistically significant differences between the groups by the spectrum of concomitant interventions were revealed (Table).

STATISTICAL PROCESSING

The obtained data were statistically processed using the JMP 7 programme. The electronic database was maintained with the help of the MS Office 2016 in the Excel format.

The presentation of the sample was made up using methods of descriptive statistics. Continuous data were expressed as mean values ± δ, with categorical and discrete data expressed as percentage. The significance of differences between the compared

groups (p-value) for continuous data was calculated using the nonparametric Mann-Whitney U test for independent variables and the Wilcoxon test for dependent ones, for categorical variables – with the help of contingency tables using the two-tailed exact Fisher test. Differences between the compared groups were regarded as significant if $p<0.05$, which corresponds to the criteria accepted in biomedical studies.

Survival curves were constructed based on the Kaplan-Meier method. Significance was assessed by the log-rank test. Predictors of mortality and prosthetic repair of the aortic valve were assessed by means of univariate and multivariate analyses. Survival analysis in the presence of competing risks of cardiovascular mortality and death from other causes was performed using the statistical programme R.

RESULTS

The overall 7-year survival in both groups of follow-up turned out comparable, amounting to 83% and 85.6% for the FS group and D group, respectively (Fig. 1).

In assessment of the competing risks of cardiovascular mortality and other causes of death, no differences were revealed (Fig. 2).

Aortic insufficiency exceeding grade 2 was considered as an indication for prosthetic repair of the aortic valve. Freedom from prosthetic repair of the aortic valve in the remote period of follow-up turned out to be comparable and amounted to 92.8% and 85.8% in the FS group and D group, respectively (Fig. 3).

According to the obtained findings, the technique of a valve-sparing operation is not a predictor of either mortality (RR 0.98 (95% CI 0.23–4.15), p=0.98) or prosthetic repair of the aortic valve (RR 2.03 (95% CI 0.40–14.63), p=0.40) in the remote period of follow up.

The univariate analysis of predictors of mortality demonstrated that the presence of combined interventions in performing valve-sparing operations appeared to be a significant parameter and was associated with a 4-fold increase in the risk of a lethal outcome (HR 4.19 (95% CI 1.02–20.53), p=0.046), a 7-fold increased risk of stroke (HR 7.14 (95% CI 1.04–31.35), p=0.046), and a 32-fold increase in the risk of acute postoperative heart failure (HR 31.57 (95% CI 7.54–156.82), p=0.001). At the same time, analysing the EF before the operation revealed that the higher the EF, the lower the risk of a lethal outcome (RR 0.92 (95% CI 0.86–0.97), p=0.0032). After construction of a multivariate model, significant predictors of mortality in performing valve-sparing operations turned out to be the preoperative EF and acute postoperative heart failure. A 5% increase of the EF was associated with a 68% decrease of the risk of a lethal outcome (HR 0.42 (95% CI 0.24–0.77), p=0.0008), whereas the presence of acute postoperative heart failure with a 102-fold increase of the risk (HR 102.27 (95% CI 14.02–2214.33), p<0.0001).

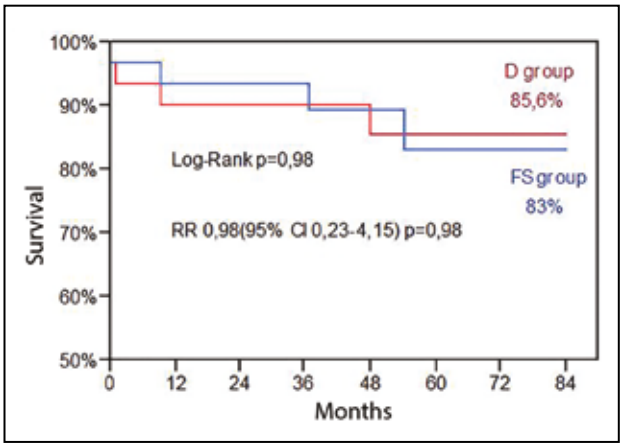

Fig. 1. Survival during 7-year period of follow up. Above and in Figures 2 and 3 hereunder: D group – David operation; FS group – operation according to the Florida Sleeve technique

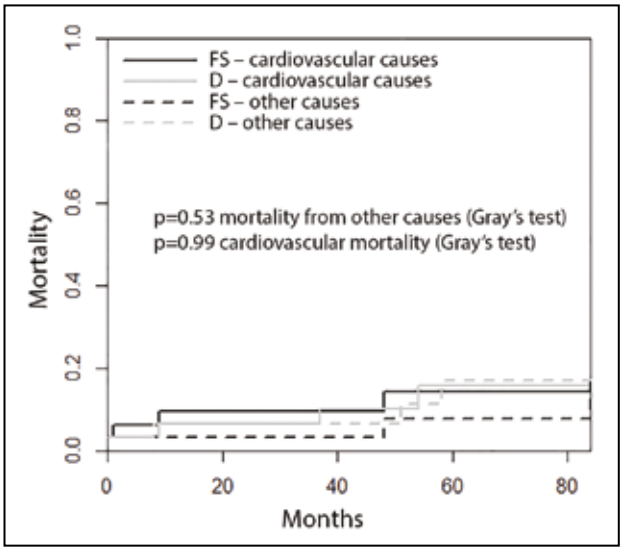

Fig. 2. Mortality related to competing risks of cardiovascular or other causes of death

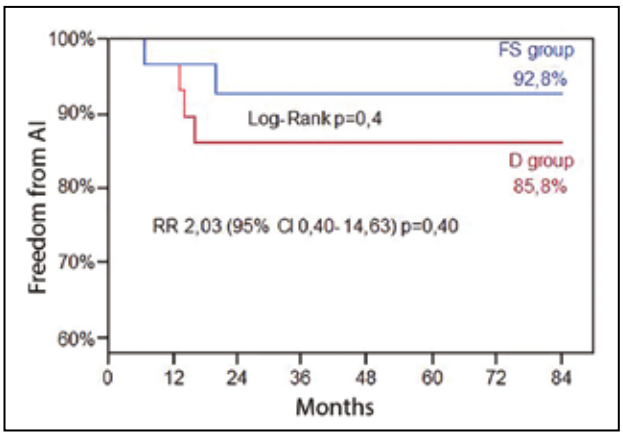

Fig. 3. Freedom from aortic valve insufficiency greater than grade 2 during 7-year follow-up period

There were no cases of valve-related thromboembolism, haemorrhage or endocarditis registered in either group.

The univariate analysis of predictors of the development of aortic insufficiency leading to prosthetic repair of the aortic valve demonstrated that the presence of postoperative aortic insufficiency exceeding grade 1+ was associated with a more than 20-fold increase of the risk for further progression of aortic regurgitation and prosthetic repair of the aortic valve (HR 20.94 (95% CI 3.35–402.11), p=00007). Besides the valve structure, the development and progression of aortic insufficiency were influenced by the functional state of the leaflets. Thus, an increase in the time of leaflet opening of the aortic valve by 1 ms was associated with a 93% decrease in the risk (HR 0.07 (95% CI 1–0.92), p=0.0037), whereas an increase in the velocity of leaflets opening by 1 cm/s with a 2-fold increase of the risk (HR 2.16 (95% CI 0.24–0.77), p=0.0008). An insufficient number of unfavourable events in the remote postoperative period does not allow of performing a multivariate analysis in order to reveal the predictors associated with progression of aortic insufficiency requiring prosthetic repair of the aortic valve.

DISCUSSION

In our study we did not reveal a statistically significant difference in mortality between the groups of the patients subjected to either David operation or Florida Sleeve technique. Neither did analyzing the competing risks – cardiac (sudden death, stroke, infarction, acute heart failure) versus noncardiac (death from other causes) reveal significant differences between the groups. These results confirm safety of the technique of aortic root reimplantation in the remote period of follow-up. As in any cardiosurgical operation, a favourable outcome depends on the patient's condition and compensatory capabilities of the body, which is confirmed by the obtained findings. Thus, two main predictors of mortality were indentified, i.e., the preoperative LVEF and the presence of acute postoperative insufficiency. The higher the EF, the more chances of a favourable outcome. However, if a patient has developed acute postoperative cardiovascular insufficiency, his or her chances for a favourable outcome dramatically decrease.

The main problems to be addressed during valve-sparing operations include long-term efficacy and durability of the native valve. The results of freedom from aortic insufficiency for both techniques are comparable, thus suggesting efficacy of reimplantation of the aortic root in the remote period of follow-up, comparable with that of the David operation. The main reason for prosthetic repair of the aortic valve was progression of the pathological process. Thus, in all patients subjected to reoperation, visual examination demonstrated thickening and prolapse of one or several leaflets, and histological examination revealed events of fibrosis, sclerosis, round-cell infiltration and myxomatous degeneration of tissues of the leaflets. There was no probability of injuring the leaflets for both techniques, since in all cases we used prostheses with artificial sinuses of Valsalva and while performing aortic root reimplantation the prosthesis was excluded from the vascular bed. However, the univariate analysis of predictors of aortic valve prosthetic repair showed that the type of the valve-sparing technique was not associated with aortic valve prosthetic repair in the remote period, but revealed predictors influencing the progression of aortic insufficiency such as residual aortic regurgitation of grade 2 and higher, as well as the velocity and time of opening of leaflets of the aortic valve.

Hence, performing a valve-sparing operation, special attention should be paid to all factors of incompetence of a valve-sparing operation and to take into account the effect of a particular technique on biomechanics of the reconstructed valve. Our study also demonstrated the influence of biomechanical changes, i. e., velocity and time of opening of the aortic valve on the remote results of a valve-sparing operation. In aortic valve reimplantation, stabilization of the fibrous annulus makes it possible to avoid recurrent aortic regurgitation in the remote period [11]. The goal of the technique of aortic root reimplantation, like that of the David operation, is to achieve stabilization of the aortic valve fibrous annulus [12]. We do not think that the use of the modified Florida Sleeve technique can lead to long-term dilatation of the fibrous annulus, since a greater circumference of the annulus is attached to the prosthesis and, in total, only 3–5 mm of the circumference underneath the coronary arteries remain intact, however, it is the subject of further study. Reinforcement the wall of the aortic root makes it possible to prevent further expansion of the elements of the aortic root, including in patients with Marfan syndrome.

The advantages of the new technique should also include no need for coronary artery reimplantation, tailoring of sinuses and attachment of commissural struts, thus decreasing the risk of both haemorrhage and possible deformation of coronary arteries during reimplntation. In isolated interventions on the aortic root this technique makes it possible to completely isolate the prosthesis from the vascular bed and to exclude the contact of leaflets with the prosthesis's wall. Therefore, one of the areas where some authors envisage the use of the Florida Sleeve technique is a situation with acute aortic dissection, especially in elderly patients of about 70 years without expansion of the aortic root for the purpose of preventing its dilatation and reducing the time of myocardial ischaemia. However, there are no comprehensive data for such patient cohort, and the

cases themselves are rather sporadic. Thus, the authors of the original technique possess experience of three cases with 100% mortality in initially severe patients, but no detailed analysis was reported [8, 9]. In other series, A. Gamba, et al. and W. Heo, et al. each described two interventions in patients with acute aortic dissection [13, 14]. Our experience includes only one successful case of using this technique. In the largest series reported, M. Shrestha, et al. described 14 cases with satisfactory results in the immediate period. The authors used a similar methodology for reinforcement of the non-dilated aortic root in acute aortic dissection as prevention of further expansion. There were neither valve-associated complications nor aortic insufficiency, with the mean duration of follow-up amounting to 17 months [15]. The paucity of data on the durability of the repairs has served to further limit their widespread use, which can be explained. Operative interventions in acute aortic dissection are always operations of saving the patient's life, requiring reduction of the time of aortic occlusion, and performing a valve-sparing procedure especially in centres with small experience is of tremendous risk, because they require scrupulous exposure of the aortic root and experience with such interventions [13]. Besides, very often in aortic root dissection there are fenestrations in the intima at the level of the aortic root, thus immediately excluding the use of a valve-sparing operation in these patients. Hence, there remains only one cohort of patients, where root dissection has no fenestrations and does not extend, as a rule, deeper than coronary arteries, in whom it is possible to use this technique. However, the majority of surgeons prefer to use in this situation the «sandwich» technique with supracoronary repair of the aorta, which is frequently justified in conditions of limited time in acute aortic dissection. Despite the fact that the technique potentially has advantages for prevention of the development of aortic root aneurysms, the use of the Florida Sleeve technique in acute dissection at this stage requires studying on a larger patient cohort, since it also bears certain risks related to the absence of data on what happens to the wrapped wall of the dissected aortic root in the remote period. So, there is no unanimity of views of the authors on this problem, with the choice and preference currently based upon the surgeon's experience.

Thus, aortic root reimplantation inside the prosthesis according to the Florida Sleeve technique makes it possible to simplify and accelerate the procedure of reconstruction of the aortic root in patients with aortic root aneurysms and accompanying aortic insufficiency, demonstrating comparable results with those of aortic valve reimplantation inside the prosthesis according to the David technique in the remote period of follow-up.

Conflict of interest: none declared.

ЛИТЕРАТУРА/REFERENCES

1. ***Rahnavardi M, Yan TD, Bannon PG, Wilson MK*** Aortic valve-sparing operations in aortic root aneurysms: remodeling or reimplantation? Interact. Cardiovasc. Thorac. Surg. 2011; 13: 2: 189–197. doi:10.1510/icvts.2011.267401.
2. ***Kallenbach K, Pethig K, Schwarz M, et al.*** Valve sparing aortic root reconstruction versus composite replacement – perioperative course and early complications. Eur. J. Cardiothorac. Surg. 2001; 20: 1: 77–81. doi:10.1016/S1010–7940%2801%2900750–3.
3. ***Patel ND, Weiss ES, Alejo DE, et al.*** Aortic root operations for Marfan syndrome: a comparison of the Bentall and valve-sparing procedures. Ann. Thorac. Surg. 2008; 86: 6: 2003–2010. doi:10.1016/j.athoracsur.2008.01.032.
4. ***David TE, Feindel CM, Webb GD, et al.*** Long-term results of aortic valve-sparing operations for aortic root aneurysm. J. Thorac. Cardiovasc. Surg. 2006; 132: 2: 347–354. doi:10.1016/j.jtcvs.2006.03.053.
5. ***Hiratzka LF, Bakris GL, Beckman JA, et al.*** 2010 ACCF/AHA/AATS/ACR/ASA/SCA/SCAI/SIR/STS/SVM guidelines for the diagnosis and management of patients with thoracic aortic disease: a report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. Circulation. 2010; 121: 13: 266–369. doi:10.1161/CIR.0b013e3181d4739e.
6. ***Carr JA, Savage EB*** Aortic valve repair for aortic insufficiency in adults: a contemporary review and comparison with replacement techniques. Eur. J. Cardiothorac. Surg. 2004; 25: 1: 6–15. doi:10.1016/j.ejcts.2003.09.018.
7. ***Volguina IV, Miller DC, LeMaire SA, et al.*** Valve-sparing and valve-replacing techniques for aortic root replacement in patients with Marfan syndrome: analysis of early outcome. J. Thorac. Cardiovasc. Surg. 2009; 137: 5: 1124–1132. doi:10.1016/j.jtcvs.2009.03.023.
8. ***Hess PJ Jr, Klodell CT, Beaver TM, Martin TD*** The Florida Sleeve: a new technique for aortic root remodeling with preservation of the aortic valve and sinuses. Ann. Thorac. Surg. 2005; 80: 2: 748–750. doi:10.1016/j.athoracsur.2004.02.092.
9. ***Hess PJ Jr, Harman PK, Klodell CT, et al.*** Early outcomes using the Florida Sleeve repair for correction of aortic insufficiency due to root aneurysms. Ann. Thorac. Surg. 2009; 87: 4: 1161–1168. doi:10.1016/j.athoracsur.2009.01.016.
10. ***Belov YuV, Charchan ER*** Valve-sparing operations in patients with ascending aortic aneurysms accompanied by aortic insufficiency. Thoracic and Cardiovascular Surgery. 2004; 1: 59–64 [in Russian].
11. ***Chernyavsky AV, Khvan DS, Alsov SA, et al.*** Results of aortic root reimplantation inside the prosthesis in patients with ascending aortic aneurysms and aortic valve insufficiency. Circulation Pathology and Cardiac Surgery. 2015; 19: 4: 38–47 [in Russian].
12. ***Hopkins RA*** Aortic valve leaflet sparing and salvage sur-

gery: evolution of techniques for aortic root reconstruction. Eur. J. Cardiothorac. Surg. 2003; 24: 6: 886–897. doi:10.1016/s1010–7940(03)00619–5.

13. ***Gamba A, Tasca G, Giannico F, et al.*** Early and medium term results of the sleeve valve-sparing procedure for aortic root ectasia. Ann. Thorac. Surg. 2015; 99: 4: 1228–1233. doi:10.1016/j.athoracsur.2014.10.044
14. ***Heo W, Min HK, Kang DK, et al.*** A modified root reinforcement technique for acute aortic dissection with a weakened aortic root: a modified Florida Sleeve technique and two cases report. J. Cardiothorac. Surg. 2013; 8: 203. doi:10.1186/1749–8090-8–203.
15. ***Shrestha M, Khaladj N, Hagl C, Haverich A*** Valve-sparing aortic root stabilization in acute type A aortic dissection. Asian. Cardiovasc. Thorac. Ann. 2009; 17: 1: 22–24. doi: 10.1177/0218492309102483.

Адрес для корреспонденции:
Хван Д.С.
Тел.: +7 (383) 332-30-49
E-mail: dmhvan@mail.ru

Correspondence to:
Khvan D.S.
Tel.: +7 (383) 332-30-49
E-mail: dmhvan@mail.ru