OPEN TRANSAORTIC IMPLANTATION OF "MEDLAB-KT" PROSTHESIS

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Objective. The study was aimed at comparing the immediate clinical and haemodynamic results of open implantation of the balloon-expandable aortic prosthesis "MedLab-KT" with the respective parameters of standard replacement of the aortic valve by a mechanical prosthesis in high-risk surgical patients.

Patients and methods. We analysed a total of 209 cases of prosthetic repair of the aortic valve. The Study Group comprised 28 patients subjected to open implantation of the "MedLab-KT" prosthesis in conditions of extracorporeal circulation and myocardial ischaemia and belonging to a high-surgical risk cohort. The Comparison Group included 181 patients who endured standard open prosthetic repair of the aortic valve with a mechanical prosthesis. Using the ppropensity score matching method, we selected 28 patients from the Comparison Group, followed by assessing the incidence of adverse clinical events and haemodynamic parameters of the aortic valve prosthesis at the in-hospital stage.

Results. There were no lethal outcomes in the study group, with one in the group of standard aortic valve repair – 3.6%. The mean operative time in the Study and Comparison Group patients amounted to 121.5±51. 2 and 274.2±55.3 min (p=0.04), the duration of extracorporeal circulation to 56.1±19.5 and 119.9±23.4 min (p=0.04), that of myocardial ischaemia to 38.4±17.1 and 96.7±20.8 (p=0.03), respectively. The mean gradient on the aortic valve in the "MedLab-KT" group was less (7.5±3.2 mm Hg) than in those of the second group (9±3.5 mm Hg), with no statistically significant differences in the parameters revealed (p=0.096). All patients of the study group were discharged from hospital in a satisfactory condition, with the haemodynamic result of the operation regarded as satisfactory.

Conclusions. Comparing the main clinical characteristics and haemodynamic parameters in the groups of «MedLab-KT» and aortic valve prosthetic repair at the hospital stage revealed no statistically significant differences. Open implantation of the "MedLab-KT" prosthesis proved safe and effective.

Key words: *transcatheter aortic valve replacement, MedLab-KT, aortic valve prosthetic repair, high-risk surgical patient, aortic valve stenosis.*

INTRODUCTION

In developed countries, a degenerative lesion of the aortic valve (AV) leading to severe stenosis is the most prevalent of all valvular heart diseases [1]. Surgical replacement appears to be a reliable and effective method of treatment of AV pathology, remaining a method of choice for the majority of patients and is associated with improved quality of life and prolonged lifespan [2]. The transcatheter technique of implanting an AV prosthesis has been implemented into clinical practice since 2002, possessing a series of evidence-based advantages: significant reduction of the duration of the procedure at the expense of decreasing the scope of surgical intervention, shorter length of hospital stay, as well as a low risk of haemorrhage and infectious complications [3, 4]. Since February 2016, specialists of the Federal Centre of Cardiovascular Surgery of the RF Ministry of Public Health, Penza, have been performing transcatheter replacement of the AV using the first Russian-made prosthesis "MedLab-KT", yielding good in-hospital and mid-term clinical results [5, 6].

Transcatheter replacement of the AV is indicated for high-risk patients in order to mitigate adverse events (lethal outcome, neurological complications, acute renal failure, etc.) associated with open operations [3, 4, 7–9]. In combination with degenerative AV defect in surgical practice often encountered are severe lesions of the coronary bed, left ventricular dysfunction, insufficiency of other heart valves, pathology of major vessels. Due to progressing concomitant pathology, isolated intervention on the AV in this cohort of patients does lead to the desired effect. At the same time, total surgical correction is accompanied by an utterly severe risk. Patients who were refused surgical treatment have an unfavourable prognosis with an estimated mortality rate of 50% within a year after surgical assessment [10].

We report herein the results of open implantation of the Russian-made balloon-expandable valve "MedLab-KT" into the aortic position in conditions of extracorporeal

Table 1

Clinical and demographic characteristics of patients before the PSM procedure

Parameters	MedLab-KT (n=28)	% (95% CI)	AVR (n=181)	% (95% CI)	P
Age, years	65.2±11.9	(60.5–69.8)	54.62±11.9	(52.8–56.3)	0.0001
Women (n=59)	15	53.5(35.8–70.4)	44	24.3 (18–31)	0.001
BMI	29.8±8	(26.6–32.9)	28.6±5	(27.8–29.3)	0.287
NYHA FC					
II	10	35.7 (20.7–54.1)	106	58.5 (51.2–65.4)	0.024
III	17	60.7 (42.4–76.4)	73	40.3 (33.4–47.6)	0.043
IV	1	3.5 (0.06–17)	2	1.1 (0.3–3.9)	0.307
EuroSCORE II	11.5±2.8	(10.4–12.5)	3.1±2.9	(2.6–3.5)	0.038
COPD (n=18)	2	7.14 (1.9–22.6)	16	8.8 (5.5–13.8)	0.805
DM (n=31)	10	35.7 (20.7–54.1)	21	11.6 (7.7–17)	0.001
HD (n=150)	17	60.7 (42.4–76.4)	133	73.4 (66.6–79.3)	0.0001
History of arrhythmia (n=63)	7	25 (12.6–43.3)	56	30.9 (24.6–38)	0.746
History of stroke (n=12)	2	7.14 (1.9–22.6)	10	5.5 (3–9.8)	0.732
Multifocal atherosclerosis (n=44)	20	71.4 (52.9–84.7)	24	13.2 (9–18.9)	0.0001
CKD (n=65)	10	35.7 (20.7–54.1)	55	30.3 (24.1–37.4)	0.571

Note: Herein above and in Table 2: PSM – Propensity Score Matching; CI – confidence interval; AVR – aortic valve repair; BMI – body mass index ; NYHA FC –functional class according to the New York Heart Association classification; EuroSCORE – European System for Cardiac Operative Risk Evaluation; COPD – chronic obstructive pulmonary disease; DM – diabetes mellitus; CKD – chronic kidney disease.

Table 2

Clinical and demographic characteristics of patients after the PSM procedure

Parameters	MedLab-KT (n=28)	% (95% CI)	AVR (n=28)	% (95% CI)	P
Age, years	65.2±11.9	(60.5–69.8)	60.7±10.4	(56.6–64.7)	0.143
Women (n=59)	15	53.5 (35.5–70.4)	13	46.4 (29.5–64.1)	0.593
BMI	31.1±5.6	(28.9–33.2)	29.5±6.2	(27–31.9)	0.317
NYHA FC					
II	10	35.7 (20.7–54.1)	12	42.8 (26.5–60.9)	0.584
III	17	60.7 (42.4–76.4)	16	57.1 (39–73.4)	0.786
IV	1	3 (0.6–17)	0	-	0.313
EuroSCORE II	11.5±2.8	(10.4–12.5)	3.6±2.8	(2.5–4.6)	0.051
COPD (n=18)	2	7.14 (1.9–22.6)	4	14.2 (5.7–31.4)	0.413
DM (n=31)	10	35.7 (20.7–54.1)	9	32.1 (17.9–50.6)	0.778
HD (n=150)	17	60.7 (42.4–76.4)	23	82.1 (64.4–92.1)	0.076
History of arrhythmia (n=63)	7	25 (12.6–43.3)	10	35.7 (20.7–54.1)	0.383
History of stroke (n=12)	2	7.14 (1.9–22.6)	3	10.7 (3.7–27.2)	0.639
Multifocal atherosclerosis (n=44)	20	71.4 (52.9–84.7)	19	67.8 (49.3–82)	0.771
CKD (n=65)	10	35.7 (20.7–54.1)	14	50 (32.6–67.3)	0.280

circulation (ECC) and myocardial ischaemia (MI) in combination with correction of accompanying pathology in a cohort of high-risk surgical patients.

PATIENTS AND METHODS

We retrospectively studied the results of treatment of patients operated on during 2018—2020 at the Clinic of the Federal Centre of Cardiovascular Surgery of the RF Ministry of Public Health, Penza, analysing the outcomes of 209 operations of AV replacement. The patients were divided into two groups. Group One (Study Group, "MedLab-KT") included 28 patients subjected to implantation of the balloon-expandable prosthesis "MedLab-KT" into the aortic position and Group Two [Comparison Group, standard aortic valve repair (AVR)] consisting of 181 patients undergoing replacement of the AV with the mechanical full-flow prosthesis "MedEng-ST". The characteristics of patients are shown in Table 1.

Patients in the Study Group had high risk of surgical intervention according to the EuroSCORE II. Intergroup statistically significant differences were revealed by the following parameters: age, gender, NYHA functional class II and III, diabetes mellitus, multifocal atherosclerosis, EuroSCORE II. The propensity score matching method was used, resulting in formation of the Comparison Group consisting of 28 participants (Table 2).

There were no statistically significant differences between the groups.

PECULIARITIES OF OPERATIVE INTERVENTION

All operations were performed under combined endotracheal anaesthesia with connection of a heart-lung machine (HLM) and antegrade cardioplegia. The surgical approach depended on the scope of the expected intervention. The prosthesis size was selected by the surgeon based

on the findings of the following examinations: echocardiography, computed tomography of the aortic root, and intraoperative direct measurement of the AV fibrous ring. Isolated open AVR using the "MedLab-KT' prosthesis was carried out in cases when the aortic root anatomy did not allow performing AV transcatheter implantation due to a high risk of occlusion of the coronary arteries ostia (low location of coronary artery ostia relative to the AV fibrous ring, presence of large calcinates of the cusps of the native valve). Such being the case, the operations were performed from the right-sided minithoracotomy in the 2nd intercostal space, with peripheral connection of HLM according to the scheme: "femoral artery – femoral vein" or via the partial superior J-shaped sternotomy with connecting the HLM: "right atrium – aorta". In the remaining cases envisaging combined interventions on the heart, operations were performed from median sternotomy, with HLM connected according to the scheme: "venae cavae–aorta". The approach to the AV was achieved by means of transverse aortotomy. If necessary, during revision we performed local decalcification and/or partial resection of AV cusps in the projection of coronary artery ostia. Implantation of the balloon-expandable prosthesis was performed in full visualization of all anatomical structures of the aortic root. Implantation of the mechanical prosthesis according to the standard technique with total dissection of the cusps of the native AV and decalcification of the fibrous ring using separate U-shaped sutures with Teflon gaskets.

Table 3

Intraoperative characteristics of the procedure

Parameters	MedLab-KT (n=28)	% (95% CI)	AVR (n=28)	% (95% CI)	P
Duration of operation, min.	121.5±51.2	(101.6–141.3)	274.2±55.3	(252.7–295.6)	0.04
ECC, min.	56.1±19.5	(48.5–63.6)	119.9±23.4	(110.8–128.9)	0.04
MI, min.	38.4±17.1	(31.7–45)	96.7±20.8	(88.6–104.7)	0.03
Use of inotropic drugs	7	25 (12.6–43.3)	13	46.4 (29.5–64.1)	0.94
Combined interventions on the heart	17	60.7 (42.4–76.4)	15	53.5 (35.8–70.4)	0.589
CABG	14	50 (32.6–67.3)	11	39.2 (23.5–57.5)	0.420
Surgery of heart valves (MV, TV)	2	7.1 (1.9–22.6)	4	14.2 (5.7–31.4)	0.388
LV reconstruction	7	25 (12.6–43.3)	0	-	0.03
Ascending aorta prosthetic repair	4	14.2 (5.7–31.4)	3	10.7 (3.7–27.2)	0.686
Mean gradient , mm Hg	7.5±3.2	(6.2–8.7)	9±3.5	(7.6–10.3)	0.096
Maximal gradient, mm Hg	16.3±6.04	(13.9–18.6)	17.5±5.1	(15.5–19.4)	0.404
Area of the opening, cm^2	1.9±0.2	(1.8–1.9)	2.04±0.5	(1.8–2.2)	0.222
AI up to grade I after surgery	28	100 (87.9–100)	23	82.1 (64.4–92.1)	0.02
ICU length of stay (days)	3.5±4.6	(1.7–5.2)	3.3±4.6	(1.5–5.08)	0.97
Total length of hospital stay after surgery (days)	11.2±10.2	(7.2–15.1)	14.5±10.1	(10.5–18.4)	0.81

Note: ECC – duration of extracorporeal circulation; MI – myocardial ischaemia; CABG – coronary artery bypass grafting; MV – mitral valve; TV – tricuspid valve; LV – left ventricle; AI – aortic insufficiency; ICU – intensive care unit.

STATISTICAL ANALYSIS

The obtained findings were processed using the program IBM® SPSS® Statistics Version 21 (21.0.0.0). The data are presented as M±SD. Significance of differences between the continuous variables was determined using the Mann-Whitney test. Significance of differences between the categorical variables was determined using the Chi-squared test. The critical level of significance was 0.05. The control group was selected using the propensity score matching (PSM) technique.

RESULTS

There were no lethal outcomes in the Study Group. Hospital mortality in the Comparison Group amounted to 3.57% (1 patient), with the cause of death being acute cardiac failure on POD 5 (p=0.013). The duration of surgery was less in the "MedLab-KT" group, amounting to 121.5±51.2 min, than in the AVR group amounting to 274.2±55.3 (p=0.04). The time of aortic cross-clamping was significantly less in the "MedLab-KT' group patients – 38.4±17.1 min, compared with AVR group – 96.7±20.8 (p=0.03). There was a statistically significant difference in the AC duration: in the Study Group amounting to 56.1±19.5 min and in the comparison group to 119.9±23.4 min (p=0.04). The average gradient on the AV in the "MedLab-KT' group was lower (7.5±3.2 mm Hg) than in the AVR group (9±3.5 mm Hg), however, there was no statistically significant difference in the parameters (p=0.096). Aortic insufficiency (AI) above grade I was not encountered in either group, with AI in all cases

Table 4

Complications associated with the procedure during hospitalization

Complications	MedLab-KT (n=28)	% (95% CI)	AVR (n=28)	% (95% CI)	P
Life-threatening haemorrhage	0	-	0	-	-
Acute renal failure	1	3.5 (0.6–17.7)	0	-	0.313
Myocardial infarction	0	-	0	-	-
Cardiogenic shock	0	-	0	-	-
Implantation of permanent pacemaker	5	17.8 (7.8–35.5)	5	17.8 (7.8–35.5)	1.000
New-onset atrial fibrillation	1	3.5 (0.6–17.7)	3	10.7 (3.7–27.2)	0.299
All cases of lethal outcomes	0	-	1	3.5 (0.6–17.7)	0.313
Death of cardiovascular complications	0	-	1	3.5 (0.6–17.7)	0.313
Neurological complications	0	-	2	7.14 (1.9–22.6)	0.150
Stroke	0	-	2	7.14 (1.9–22.6)	0.150
Infarction + stroke + mortality	0	-	3	10.7 (3.7–27.2)	0.07

of the "MedLab-KT" prosthesis being conditioned by paraprosthesis fistulas (not more than 2 mm) and for mechanical valves by trivial transport regurgitation. Besides AV replacement, the patients underwent correction of accompanying pathology of the heart: prosthetic repair of the mitral valve, ascending portion of the aorta, reconstruction of the left ventricle. No statistically significant differences in the length of stay at intensive care unit (p=0.97) and length of in-hospital (p=0.81) were observed. The characteristics of the perioperative period by the groups are shown in Table 3.

All patients of the "MedLab-KT' group were discharged in a satisfactory condition, with the haemodynamic result of the operation being considered as satisfactory. The postoperative mortality rate in the AVR group amounted to 3.6% (1 patient) Two patients with mechanical prostheses were found to have acute cerebral circulation impairment (17.4, p=0.150) at the prehospital stage. One patient of the Study Group required renal replacement therapy. The perioperative complications are shown in Table 4

DISCUSSION

Rapid development of transcatheter techniques in treatment of cardiovascular patients reaching during the past two decades also the sphere of valve pathology of the heart is an evident stage of the development having demonstrated efficiency. Hybrid and catheter techniques today make it possible to perform correction of the aortic defect in a cohort of patients previously considered inoperable due to high risk of open surgical intervention [11, 12]. However, the method of transcatheter replacement requires certain morphological parameters: for each model of the prosthesis there are limitations on the height of location of ostia of the coronary arteries relative to the fibrous ring, presence of large calcified conglomerates on the cusps of the native valve – these aspects significantly increase the risk of occlusion of the ostium of the coronary arteries in implantation. Besides, there is a group of patients with combined aortic stenosis and lesion of coronary arteries and/or other heart valves, requiring open surgical correction. This work demonstrates using a balloon-expandable stent-valve in open surgical approach. Advantages of this technique are considered to be as follows: no need of either total resection of native valve cusps or total decalcification of the aortic arch, as well as suture-free method of implantation, thus significantly decreasing the duration of EEC and MI in the Study group. Mention should also be made of a possibility of combined interventions on the heart (coronary artery bypass grafting, prosthetic repair of the mitral valve, tricuspid valve plasty, prosthetic repair of the ascending portion of the aorta, left ventricular reconstruction, myoseptectomy).

The uniqueness of the "MedLab-KT" system consists in the fact that the leaflets of the prosthesis of the valve are made of a 0.1-mm thick polytetrafluorethylene plate. Currently, this is the only prosthesis with synthetic leaflet cusps to be implanted into the position of the AV. This model has passed all stages of preclinical and clinical trials and currently there are data on safety and efficacy of the prosthesis in transcatheter implantation in the immediate and mid-term periods [5, 6]. The technique of open transaortic implantation requires further study of its results at both the in-hospital and remote stages.

CONCLUSIONS

We compared herein the immediate clinical and haemodynamic results of open implantation of the balloon-expandable aortic prosthesis "MedLab-KT", thus allowing us to draw the following conclusions:

1. The method of open implantation of the "MedLab-KT" prosthesis in conditions of ECC and MI does not lead to increased mortality and complications rates, length of hospital stay and ICU length of stay, making it possible to significantly reduce the time of MI, with

good haemodynamic echocardiographic parameters.

2. The presented method may become an alternative to standard surgical replacement of the AV in high-risk surgical patients who by morphological characteristics or the scope of the indicated surgical intervention are ineligible for transcatheter AV implantation.

Conflict of interest: none declared.

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