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TRANSCATHETER AORTIC VALVE IMPLANTATION VS. SURGICAL AORTIC VALVE REPLACEMENT: COMPARATIVE ASSESSMENT OF RESULTS

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SUMMARY

Aim. The aim of this study is to compare hospital and long-term outcomes in patients with low surgical risk after aortic stenosis correction in surgical aortic valve replacement (SAVR) and transcatheter aortic valve implantation (TAVI).

Materials and methods. Patients with aortic stenosis (AS) were included in the study. The main criterion for inclusion – the presence of indications for surgical correction of an isolated aortic valve defect. The first group included patients after TAVI (n = 11). As a control group, patients who underwent surgical correction aortic stenosis (n = 23). The TAVI group used non-repositories CoreValve (Medtronic) and repositioned Lotus (Boston Scientific) valves. Biological prosthesis Uniline (KemKor) was used in the group of surgical patients. The efficacy of the interventions was evaluated at the hospital and annual follow-up, based on the analysis of the combined endpoint, and major adverse cardiovascular events.

Results. The mean age of the patients was 66.9±5.7 years in the SAVR group and 75.3±4.1 years in the TAVI group (p=0,003). The average score for EuroSCORE II was 3.49±0.3 in the SAVR group and 3.93±1.2 in the TAVI group (p=0,31). Repositionable and non-repositionable valves were implanted in 2 and 9 cases, respectively. The combined endpoint was noted in one patient in the TAVI group and in four patients in the SAVR group according to the annual observation results. There are three (13%) fatal outcomes in the surgical prosthesis group.

Conclusion. The possibility of using TAVI in low-risk patients with aortic stenosis was demonstrated on the basis of comparable results of evaluating efficacy and safety with SAVR in 1-year follow-up.

Keywords: *aortic valve stenosis, transcatheter aortic valve implantation.*

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INTRODUCTION

Presently, aortic stenosis (AS) is the most common pathology of the cardiac valve apparatus [1]. Increasing of life expectancy in the population during last decades resulted in increasing number of patients having calcified AS. Among 60-80 year old patients, symptoms of sclerosis and calcinosis of aortal valve are diagnosed in 40% of cases, while among older than 80-years patients similar changes occur in 75% of cases [2].

Stenotic damage of an aortic valve (AV) is a life-threatening condition, accompanied by high risk of sudden cardiac death development. Traditional surgery aortic valve replacement (SAVR) is a golden standard for treatment patients having critical AS, which allows to extend length of and improve life quality. Nevertheless, up

Table 1. Clinical and Demographic Characteristics of Patients

Item		TAVI Group n = 11	%	SAVR Group n = 23	%	p
Age, years		75,3±4,1 (62-83)		66,91±5,73 (60 – 77)		0,003
Males		6	54,5	9	39,1	0,63
Rhythm disturbances	Complete AV block	1	9,1	0	0	0,7
	Atrial fibrillation	6	54,5	5	21,7	0,12
	Supraventricular tachycardia	1	9,1	3	13,04	0,81
	Ventricular extrasystole	4	36,4	9	39,1	0,82
	SSS	1	9,1	0	0	0,7
	Frederic's syndrome	1	9,1	0	0	0,7
Surgery	EPM implantation	2	18,2	0	0	0.18
	AV bioprosthesis	2	18,2	0	0	0,18
	PCI	3	27,3	1	4,3	0,17
Concomitant conditions	Stable angina ≥ 2 FC	1	9,1	5	21,7	0,67
	PICS	1	9,1	0	0	0,7
	CHF ≥ 3 FC (NYHA)	6	54,5	14	60,8	0,98
	Thrombosis of LAtr	2	18,2	0	0	0,18
	Ischemic heart disease	4	36,4	5	21,7	0,62
	Insignificant BCA stenoses	4	36,4	6	26,08	0,83
	CILE	1	9,1	3	13,04	0,81
	Diabetes mellitus	6	54,5	5	21,7	0,12
	Diabetic nephropathy	1	9,1	0	0	0,7
	CRD ≥ 2 Stage	2	18,2	1	4,34	0,49
	Stroke	2	18,2	1	4,34	0.49
	COPD	2	18,2	2	8,7	0,81
	Chronic cor pulmonale	1	9,1	0	0	0,7
	PATE	1	9,1	0	0	0,7
	Lung emphysema	1	9,1	1	4,3	0,81
	Hydrothorax	2	18,2	2	8,7	0,81
	Ascites	1	9,1	0	0	0,7
	EuroScore II	3,93±1,2 (2,8 – 6,1)		3,49±1,57 (1,23– 8,92)		0,31

Comments: AV – atrioventricular, SSS – sick sinus syndrome, EPM – electric pacemaker, PCI – percutaneous coronary intervention, AV – aortic valve, FC – functional class, PICS – postinfarction cardiosclerosis, CHF – congestive heart failure, LAtr – left atrium, BCA – brachiocephalic arteries, CILE – chronic ischemia of lower extremities, CRD – chronic renal disease, COPD – chronic obstructive pulmonary disease, PATE – pulmonary artery thromboembolism

Table 2. Echo-CG Dynamics

	Echo-CG before treatment TAVI n = 11	Echo-CG before treatment SAVR n = 23	p	Echo-CG after TAVI n = 11	Echo-CG after SAVR n = 23	p	Echo-CG 12 month after TAVI n = 11	Echo-CG 12 month after SAVR n = 23	p
FDS, cm	5,77±0,68	5,88±0,84	0,65	5,55±0,57	5,4±0,46	0,59	5,7±0,62	5,41±0,59	0,19
FSS, cm	3,9±1,14	3,82±0,79	0,94	3,67±0,7	3,79±0,58	0,71	3,67±0,47	3,58±0,44	0,25
EDV, ml	167,8±47,3	182,5±60,5	0,53	152,6±36,8	142,4±29,4	0,55	162,2±39,9	143,6±34,2	0,41
ESV, ml	73,5±56,3	72,2±39,3	0,78	60±26,9	64,9±23,2	0,57	58,4±16,8	54,8±21,5	0,27
EF, %	59,62±18,06	61,5±12,6	0,99	61,62±11,9	55,3±9,6	0,16	64,57±3,45	61,6±7,9	0,45
IVS, cm	1,48±0,23	1,52±0,42	0,97	1,43±0,19	1,44±0,3	0,11	1,3±0,12	1,29±0,4	0,16
LVBW, cm	1,48±0,23	1,49±0,37	0,96	1,44±0,2	1.38±0,26	0,12	1,27±0,09	1,26±0,18	0,38
AA, cm	3,65±0,44	3,96±0,68	0,3	3,51±0,42	3,78±0,49	0,1	3,25±0,36	3,78±0,52	0,63
SV, ml	94,37±22,5	109,6±40,6	0,49	92,62±22,6	77,15±19,02	0,09	103,85±23,84	88,7±19,6	0,59
LA, cm	4,83±0,67	4,9±0,8	0,64	4,55±0,61	4,25±0,74	0,29	4,42±0,4	4,88±053	0,24
RA, cm	5,2±1,03	4,5±0,81	0,27	4,4±0,56	3,95±0,49	0,31	4,2±0,33	4,16±0,62	0,63
RV, cm	1,88±0,41	1,83±0,3	0,32	1,83±0,37	1,71±0,34	0,47	1,75±0,26	1,85±0,31	0,35
MV: regurgi-tation, n	1 (3 Deg.)	5 (2 Deg.)	0.91	2 (2 Deg.)	1 (2 Deg.)	0.34	6 (2 Deg.)	1 (2 Deg.)	0.003
AV Regurgi-tation, n	3 (3-4 Deg.)	5 (3-4 Deg.)	0.75	3 (2 Deg.)	0	0.02	3 (1 Deg.)	0	0.04
AV Pmax., mm Hg	75.4±11.7	84.9±37.8	0.25	19.6±7.8	21.8±14.5	0.96	15.6±6.6	22.0±14.6	0.44
AV Calci-nosis	11	25	0.36	11	0	0.000	11	0	0.000
TV: regurgi-tation, n	2 (2 Deg.)	3 (2 Deg.)	0.78	0	1 (2 Deg.)	0.59	1	2 (2 Deg.)	0.54
Sys. PAP, mm Hg	43,7±9,6	38,2±12,5	0,12	36±9,2	30,1±7,5	0,43	28,8±9,5	27,8±8,1	0,37

Comments: FDS – final diastolic size, FSS – final systolic size, EDV – end diastolic volume, ESV – end systolic volume, EF – ejection fraction, IVS – interventricular septum, LVBW – back wall of left ventricle, AA – ascending aorta, SV – stroke volume, LA – left atrium, RA – right atrium, RV – right ventricle, MV – mitral valve, AV – aortic valve, TV – tricuspid valve, PAP – pulmonary artery pressure.

Table 3. Echo-CG Dynamics in TAVI Group

n=11	Echo-CG before Treatment	Echo-CG before Discharge	Echo-CG Checkpoint	p
FDS, cm	5,77± 0,68	5,55± 0,57	5,7± 0,62	Ptot = 0,16 P1-2 = 0,63 P1-3 = 0,23 P2-3 = 0,49
FSS, cm	3,9± 1,14	3,67± 0,7	3,67± 0,47	Ptot = 0,27 P1-2 = 0,53 P1-3: 0,001 P2-3 = 0,41
EDV, ml	167,8± 47,3	152,6± 36,8	162,2± 39,9	Ptot = 0,25 P1-2: 0,000 P1-3: 0,74 P2-3 = 0,15
ESV, ml	73,5± 56,3	60± 26,9	58,4± 16,8	Ptot = 0,83 P1-2: 0,32 P1-3: 0,73 P2-3 = 0,17
EF, %	59,62± 18,06	61,62± 11,9	64,57± 3,45	Ptot = 0,02 P1-2: 0,182 P1-3: 0,000 P2-3 = 0,075
IVS, cm	1,48± 0,23	1,43± 0,19	1,3± 0,12	Ptot = 0,72 P1-2: 0,16 P1-3: 0,000 P2-3 = 0,64
LVBW, cm	1,48± 0,23	1,44± 0,2	1,27± 0,09	Ptot = 0,62 P1-2: 0,84 P1-3: 0,000 P2-3 = 0,53
AA, cm	3,65± 0,44	3,51± 0,42	3,25± 0,36	Ptot = >0,9999 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
SV, ml	94,37± 22,5	92,62± 22,6	103,85± 23,84	Ptot = 0,04 P1-2 = >0,9999 P1-3: 0,013 P2-3: 0,004

n=11		Echo-CG before Treatment	Echo-CG before Discharge	Echo-CG Checkpoint	p
LA, cm		4,83± 0,67	4,55± 0,61	4,42± 0,4	Ptot = >0,9999 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
RA, cm		5,2± 1,03	4,4± 0,56	4,2± 0,33	Ptot = 0,09 P1-2: 0,000162 P1-3: 0,012 P2-3 = >0,9999
RV, cm		1,88± 0,41	1,83± 0,37	1,75± 0,26	Ptot = >0,9999 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
MV: regurgitation, n		1	3	6	Ptot = 0,07 P1-2 = >0,9999 P1-3: 0,003 P2-3 = 0,5
AV	Regurgitation, n	3 (3-4 Deg)	3 (I Deg)	3 (I Deg)	Ptot = >0,9999 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
AV	Pmax, mm Hg	75,4± 11,7	19,6± 7,8	15,6± 6,6	Ptot = 0,000 P1-2: 0,001 P1-3: 0,00001 P2-3 = 0,45
AV	Calcinosis	11	11	11	Ptot = >0,9999 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
TV: regurgitation, n		2	1	1	Ptot = 0,75 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
PAP, mm Hg		43,7± 9,6	36± 9,2	28,8± 9,5	Ptot = >0,9999 P1-2 = >0,9999 P1-3: 0,000 P2-3 = >0,9999

omments: Echo-CG – echocardiography, FDS – final diastolic size, FSS – final systolic size, EDV – end diastolic volume, ESV – end systolic volume, EF – ejection fraction, PAP – pulmonary artery pressure, IVS – interventricular septum, LVBW – back wall of left ventricle, SV – stroke volume, MW – myocardium weight, LA – left atrium, RA – right atrium, RV – right ventricle, MV – mitral valve, AV – aortic valve, TV – tricuspid valve, AA – ascending aorta.

Table 4. Echo-CG Dynamics in SAVR Group

n = 23	Echo-CG before Treatment	Echo-CG before Discharge	Echo-CG Checkpoint	p
FDS, cm	5,88±0,84	5,4±0,46	5,41±0,59	Ptot = 0,12 P1-2 = 0,15 P1-3 = 0,46 P2-3 = >0,9999
FSS, cm	3,82±0,79	3,79±0,58	3,58±0,44	Ptot = 0,86 P1-2 = 0,1 P1-3 = 0,47 P2-3 = >0,9999
EDV, ml	182,5±60,5	142,4± 29,4	143,6±34,2	Ptot = 0,09 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
ESV, ml	72,2±39,3	64,9±23,2	54,8±21,5	Ptot = 0,86 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
EF, %	61,5±12,6	55,3±9,6	61,6±7,9	Ptot = 0,045 P1-2 = 0,03 P1-3 = 0,94 P2-3 = 0,6
IVS, cm	1,52±0,42	1,44±0,3	1,29±0,4	Ptot = 0,003 P1-2 = >0,9999 P1-3 = 0,003 P2-3 = 0,18
LVBW, cm	1,49±0,37	1.38±0,26	1,26±0,18	Ptot = 0,0015 P1-2 = >0,9999 P1-3 = 0,001 P2-3 = 0,29
AA, cm	3,96±0,68	3,78±0,49	3,78±0,52	Ptot = 0,43 P1-2 = >0,9999 P1-3 = 0,63 P2-3 = >0,9999
SV, ml	109,6±40,6	77,15± 19,02	88,7±19,6	Ptot = 0,01 P1-2 = 0,01 P1-3 = 0,69 P2-3 = 0,41
LA, cm		4,9±0,8	4,25±0,74	4,88±053	Ptot = 0,01 P1-2 = 0,01 P1-3 = 0,57 P2-3 = 0,1
RA, cm		4,5±0,81	3,95±0,49	4,16±0,62	Ptot = 0,42 P1-2 = 0,78 P1-3 = 0,98 P2-3 = >0,9999
RV, cm		1,83±0,3	1,71±0,34	1,85±0,31	Ptot = 0,7 P1-2 = >0,9999 P1-3 = >0,9999 P2-3 = >0,9999
MV: regurgitation, n		5 (2 Deg)	1 (2 Deg)	1 (2 Deg)	Ptot = 0,08 P1-2 = 0,15 P1-3 = 0,15 P2-3 = >0,9999
AV	Regurgitation, n	5 (3-4 Deg)	0	0	Ptot = 0,004 P1-2 = 0,01 P1-3 = 0,01 P2-3 = >0,9999
	Pmax, mm Hg	84,9±37,8	21,8±14,5	22,0±14,6	Ptot = 0,000 P1-2 = 0,000 P1-3 = 0,000 P2-3 = >0,9999
	Calcinosis	23	0	0	Ptot = 0,000 P1-2 = 0,000 P1-3 = 0,000 P2-3 = >0,9999
TV: regurgitation, n		3 (2 Deg)	1 (2 Deg)	2 (2 Deg)	Ptot = 0,58 P1-2 = 0,89 P1-3 = >0,9999 P2-3 = >0,9999
PAP, mm Hg		38,2±12,5	30,1±7,5	27,8±8,1	Ptot = 0,004 P1-2 = 0,12 P1-3 = 0,005 P2-3 = >0,9999

Comments: Echo-CG – echocardiography, FDS – final diastolic size, FSS – final systolic size, EDV – end diastolic volume, ESV – end systolic volume, EF – ejection fraction, PAP – pulmonary artery pressure, IVS – interventricular septum, LVBW – back wall of left ventricle, SV – stroke volume, MW – myocardium weight, LA – left atrium, RA – right atrium, RV – right ventricle, MV – mitral valve, AV – aortic valve, TV – tricuspid valve, AA – ascending aorta

to 32% of patients do not undergone to the surgical treatment due to the serious co-morbidity background [3]. Transcatheter aortic valve implantation (TAVI) becomes more and more popular alternative to surgery AV replacement, since there is no need for thoracotomy and application of artificial circulation apparatus during the endovascular operation [4]. TAVI is the only radical treatment method in cases of inoperable patients with critical AS or patients of high surgical risk. As compared to medication therapy or valvuloplasty, TAVI has essentially better results in cases of inoperable patients with critical AS. Besides, outcomes after TAVI and surgery AV replacement in high-risk patients are comparable [4, 5].

According to Directives 2017 by European Cardiology Society on treatment of cardiac valve pathology surgical AV replacement in clinically significant AS cases can be recommended to medium surgical risk patients [6]. Recent studies have shown comparable results of endovascular and surgical methods of treatment for AS in patients of medium surgical risk [7, 8]. Results of these studies were reflected in the last directives, in which TAVI is proposed not only for patients with clinically significant AS who are ineligible for SAVR, i.e. for patients of high surgical risk or having contraindications to SAVR, but also for AS patients of medium surgical risk [6]. Presently, though, there are few comparative studies between TAVI and SAVR in AS patient groups of low surgical risk.

Objective of the present study is assessment of TAVI application possibility in low surgical risk patient group, based on comparative results evaluation in patients undergone TAVI or surgical AV replacement.

MATERIALS AND METHODS

In the present study, there were formed 2 groups of patients. Main criterion of inclusion was indications for surgical correction of isolated AV stenosis. At that, patients intended for endovascular treatment with TAVI were approved by multidisciplinary team while considering contraindications against surgical aortic valve replacement. Into the first group were included patients undergone TAVI (n = 11) during period from second half of 2014 to first half of 2017. Average follow-up period was 12.8±1.5 months. In the control group were included patients (n = 23) who underwent surgical AV replacement during period from 2015 to 2016. Average follow-up period was 11.9±1.8 months. In both patient groups before admission, before discharge, and one year after discharge was carried out echocardiographic examination (Echo-CG).

In the TAVI group two types of valves were implanted: non-repositionable CoreValve (Medtronic) (n = 9) and repositionable Lotus (Boston Scientific) valves (n = 2). Average duration of the procedure was 114.1±12.5 minutes. Among the SAVR group biological prosthesis UniLine (Kemcor) in all cases was applied.

Table 5. Hospital Complications

Показатель	TAVI Group n = 11	%	SAVR Group n = 23	%	p
Death	0	0	1	4,34	0,7
MI	0	0	0	0	-
Stroke / TIA	0	0	0	0	-
Haemorrhage 3b by BARC scale	1	9,1	1	4,34	0,81
Resternotomy due to haemorrhage	0	0	1	4,34	0,7
Progress of CHF FC (NYHA)	1	9,1	0	0	0,7
Contrast medium induced nephropathy	1	9,1	0	0	0,7
Renal dysfunction	0	0	1	4,34	0,7
Pneumonia	0	0	4	17,4	0,36
Hydrothorax	1	9,1	10	43,4	0,1
Hydropericardium with heart compression	0	0	1	4,34	0,7
Pericardium drainage	0	0	1	4,34	0,7
Rhythm and conduction disturbances	3	27,3	5	21,7%	0,93
Need in continuous pacing with EPM	2	18,2	0	0	0,18
Multiple organ failure syndrome	0	0	1	4,34	0,7
Wound complication	0	0	1	4,34	0,7
Diastasis of sternum as a result of wound complications	0	0	1	4,34	0,7
Composite safety endpoint	3	27,3	3	13	0,3

Comments: MI – myocardial infarction, TIA – transitory ischemic attack, CHF FC– functional class of congestive heart failure, EPM – electric pacemaker, DIC – disseminated intravascular clotting, BARC – Bleeding Academic Research Consortium

Table 6: Annual Follow-Up Period

Event	TAVI Group n = 11	%	SAVR Group n = 23	%	p
Death	0	0	3	13	0,1
MI	0	0	0	0	-
Stroke / TIA	0	0	0	0	-
Cardiac insufficiency FC III–IV	1	9,1	0	0	0,7
Emergency hospitalization	0	0	0	0	-
Composite efficacy endpoint	1	9,1	3	13,0	0,37
Administration of medications	11	100	20	86,9	0,54

Comments: MI – myocardial infarction, TIA – transitory ischemic attack, FC – functional class

Prosthesis sizes varied from 21 mm to 25 mm. In prevailing majority of cases was used cardioplegia with Custodiol. Average time of artificial circulation was 102.1±34.7 minutes, at that, clamping of aorta was limited by 50 to 130 minute period.

Stratification of surgical risk was carried out using EuroScore II scale. Composite safety endpoint included all-cause mortality, stroke, life-threatening bleeding, acute renal failure, serious complications at the access site, any repeated intervention during 30 days after the indicated intervention. Composite efficacy endpoint included all-cause mortality, stroke, and repeated admissions on account of cardiac insufficiency, expressed cardiac insufficiency (Functional Class III or IV) during one year after index procedure.

STATISTICAL ANALYSIS

Comparisons of quantitative features within groups were conducted using Mann-Whitney test. Qualitative features were evaluated using Pearson's 2 test with Yates' correction. Comparisons between groups were conducted using rank dispersion analysis by Kruskal-Wallis test by ranks. Study results were processed using Statistica Application Package for Windows 8.0 (StatSoft Inc., USA).

RESULTS

Patient groups proved to be comparable by all clinical and demographic features except for age (p = 0.003), because there were younger patients who underwent SAVR.

Half of patients had Type II diabetes mellitus. Comorbidity included CRD, chronic pulmonary diseases (COPD, emphysema, PATE) which significantly increased risks of complications and aggravated prognoses. Thus, average EuroScore II counts in these groups were comparable (TAVI group, 3.93±1.2 (2.8-6.1); surgery group, 3.49±1.57 (1.23-8.92) (p = 0.31)) (Table 1).

ANALYSIS OF ECHOCARDIOGRAPHY RESULTS

Echocardiographic examinations (Echo-CG) were carried out in all patients at different phases of observation. No significant

differences between groups were detected. Same dynamics of pressure gradients at AV was recorded both on the hospital phase and on annual phase of observation. At early postoperative period, pressure gradients at AV significantly, by 55 mm Hg on average, decreased from initial value in the patient cohort being studied. At annual observation phase steady tendency of decreasing the gradient went on. Significant difference of regurgitation degrees between groups at aortic valve and mitral valve 12 months after surgery is, probably, evidence of more precise technology of SAVR.

During analyzis of the volume indices dynamics of left ventricle decrease of the end diastolic volume (EDV) and end systolic volume (ESV) was detected already in early postoperative period; on the day of discharge from the hospital ESV decreased by 10 ml on average. At the checkpoint moment some (statistically insignificant) EDV increase, along with reduction of interventricular septum (IVS) thickness and back wall of left ventricle (BWLV) thickness, was observed, as well as increase of such feature as stroke volume. Besides, there was statistically significant increase of LV ejection fraction (EF), which was detected during dynamic observation. Such positive dynamics shows compensatory positive remodelling of the heart and restoring left ventricle geometry after correction of aortic defect. Carried out treatment of AS also provided significant reduction of the heart's right part and decrease of pressure in the pulmonary artery that can additionally confirm positive hemodynamics reformation resulted from elimination of critical gradient at AV (Table 2).

During evaluation of Echo-CG among TAVI patients in each group separately significant positive dynamic of the following parameters is: left ventricle ejection fraction, final systolic size, final diastolic size, pulmonary artery pressure (PAP), interventricular septum thickness (IVS) and back wall of left ventricle (LVBW) thickness, gradient at AV, stroke volume (Table 3).

In the SAVR group against TAVI patients positive dynamic was observed as reduction of IVS and LVBW, decrease of gradient at AV and decrease of PAP (Table 4).

Therefore, positive dynamics of Echo-CG values in TAVI Group was observed in more parameters than in SAVR.

During post-operative period at the hospital there were no significant differences in development of complications compared to the control group, in spite of the fact that study group included older patients. Among SAVR patients there was one lethal case as a result of complicated multiple organ failure syndrome in the post-operative period.

One patient had a haemorrhage that required execution of emergency resternotomy. Among most common complications in the surgery group were pneumonia and hydrothorax. SAVR also caused a number of wound complications. For example, one patient had total diastasis of the soft tissues and sternum (Table 5).

There were no statistically significant differences obtained, though the combined endpoint for treatment safety was twice as higher than in the control group.

During annual follow-up period no significant differences in complication occurrence were detected, too. However, in the surgery group two fatal outcomes were recorded additionally to the hospital period because of IM development (according to information from relatives). So, in spite of statistical insignificance, absolute values show obvious tendency for greater efficacy of TAVI procedure, based on both mortality (0% in TAVI group vs. 13% in SAVR group, p = 0.54) and combined endpoint analysis (9.1% vs. 17.4%, respectively, p = 0.9). Combined efficacy endpoints in both groups had no significant difference.

DISCUSSION

Numerous studies have shown that AV replacement surgery in patients of older age groups with expressed comorbid background is associated with rather high hospital mortality rate, which can achieve 11-15% [9, 10]. First TAVI procedure was performed in 2002 by A. Crieber in a patient having critical calcified AS, which was considered inoperable because of expressed condition gravity and high risk [11]. Recently more than 200,000 TAVI procedures in 65 countries of the world are carried out [12]. TAVI is quite often performed in inoperable patients, as well as patients having high or medium surgery risk, in which cases TAVI provides low mortality and low complication rate [13, 14]. Indications for TAVI in medium-risk patients, though, were included into international recommendations only in 2017 [15].

Results of four national European registers published in 2011, which include high-risk patients in accordance with EuroScore scale (18-30%) showed annual survival of patients in the range of 71.9 to 81.6%. These registers also stated that patients operated via transfemoral access had higher survivability [16, 17].

In their turn, M.J. Reardon et al. during two years observed 797 high-risk patients (average score by STS scale was 7.4±3.2%) from 45 states of the USA, randomized into two groups: TAVI and surgery AV replacement. Lower mortality rate (22.2%) was observed after TAVI, against surgery group (28.6%), $p<0.05$, as well as lower cerebrovascular accident incidence (24%, $p<0.01$) [18].

In 2016 results of a SURTAVI study (n = 1,746) were presented, which for the first time showed possibility of TAVI application in medium-risk patients. First endpoint (all-cause mortality or disabling cerebrovascular accident) occurred in 12.6% cases of TAVI group, and in 14.0% cases of surgical AV replacement group. At that, surgical replacement caused higher risk of a cerebrovascular accident (5.6% vs. 3.4%, $p<0.05$) and acute renal insufficiency (4.4% vs. 1.7%, $p<0.05$) during first 30 days after the index event. Authors stated that need in pacemaker implantation occurred more often after TAVI (25.9% vs. 6.6%, $p<0.05$), compared to surgical AV replacement group. In all appearances this was associated with particular features of the transcatheter valve model, CoreValve (Medtronic), which was implanted in 84% cases [7].

Our results of treatment for AS obtained in low surgical risk patients are comparable by endpoints in both groups under study. We did not revealed statistically significant differences of efficacy or safety between surgical and endovascular interventions, though apparent tendency to more acceptable results in the TAVI group was recorded. Positive dynamics of Echo-CG data was observed in a greater number of parameters in the TAVI group than in the SAVR group, and this may serve as an additional argument for the TAVI procedure efficiency. Main limitations of our study were small excerpts under study and relatively short observation period. Extensive multicentre randomized studies of longer observation period are needed in order to get a valid conclusion about two treatment methods being compared.

CONCLUSION

Possibility of TAVI applying in low-risk patients having AV stenosis was demonstrated period on the basis of efficacy and safety evaluation results, comparable to SAVR in one-year follow-up.

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