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RESEARCH

Simultaneous transfemoral endovascular procedures for aortic valve replacement (TAVI) and percutaneous coronary intervention (PCI) in old patients with aortic valve atherosclerotic stenosis (AVAS) and coronary artery disease (CAD)

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Aim: To evaluate the effectiveness of simultaneous TAVI and coronary stenting in elderly and old patients with AVAS and CAD at high surgical risk.
Methods: The study comprised 121 patients who underwent TAVI. They were assigned to two groups: I–patients who underwent TAVI with simultaneous coronary stenting (n = 30); II–patients with AVAS without severe stenotic changes in the coronary arteries. They underwent only TAVI (n = 91). The in-hospital period and the mid-term results have been studied.
Results: The success of simultaneous TAVI and PCI was 100%. There were no intra- or perioperative deaths, acute myocardial infarction, acute brain stroke, or acute renal failure requiring dialysis. During the 6-month follow-up, one patient died from cancer. There were no other serious complications. The left bundle branch block occurred in 23.3% of cases and regurgitation (leakage) on the aortic valve in 6.6% of cases.
Conclusion: Simultaneous TAVI and coronary stenting in elderly and old patients with severe aortic stenosis and CAD are feasible and safe. Within the first 30 days after the procedure, there were no significant differences in mortality and severe complication rates between the two groups.

Keywords: aortic stenosis, coronary artery disease, stenting, TAVI, simultaneous endovascular procedures, advanced-ageł

Introduction

Atherosclerotic stenosis is the most common aortic valve pathology (AVAS) in adults (1). This disease affects mainly aged people, so its incidence progressively increases with age. In patients aged more than 80 years, the rate of such alterations is up to 75% (2). AVAS is considered severe in cases with an orifice area of < 1 cm^2 and critical if the orifice area is < 0.7 cm^2 (3–6). Taking into account that the majority of advanced-age patients with AVAS are susceptible to atherosclerosis, over one-half of them have coronary artery disease. Up to now, open-heart surgery for aortic valve replacement and CABG has been considered the "gold standard" for the treatment of such patients. However, advanced-age patients with severe concomitant diseases are at great risk for surgical and post-surgical complications; besides, some of them have contraindications for operations with extracorporeal circulation (7). For this reason, the procedure of transcatheter aortic valve implantation (TAVI) has been elaborated and introduced into the clinical practice

of many countries worldwide (8). In cases with concomitant CAD, the patients also undergo PCI. This strategy is generally adopted and does not cause controversies. However, there is no common opinion concerning the order of performing the two above-mentioned endovascular procedures (9).

Up to now, the experts have not arrived at a common view concerning the order of priority in these procedures' performance. The majority of researchers believe that during the first stage, maybe immediately after diagnostic coronary angiography, one hasto perform stenting in order to correct coronary circulation disturbances. Such tactics permit us to avoid periprocedural myocardial ischemia at the time of the second stage, that is, during TAVI. Also, due to the time interval between the two procedures, such tactics contribute to a significant decrease in the risk of contrast-induced nephropathy. Some researchers even believe that if patients with severe AVAS and CAD do not undergo stenting at least 1 month prior to TAVI, it could be a formal contraindication for the performance of the next procedure (4). Meanwhile, one should bear in mind the negative aspects of such combined management of AVAS and CAD, namely, the increased probability of bleeding as the patients receive DAPT; the eventual risk of aortic valve disease decompensation, etc. All this can significantly complicate the procedure of TAVI and, in some cases, make it unfeasible.

The second option is to perform TAVI as the first stage, and then perform coronary stenting. In such a manner, we can avoid complications typical of severe aortic stenosis. TAVI performed during the first stage of treatment can by itself improve myocardial perfusion to such a degree, that in some cases, it would be possible to avoid the procedure on the coronary arteries, even in the presence of CAD. However, if the stenting is still necessary, one has to take into account that access to the coronary arteries will become more difficult. Hence, many questions related to the use of such tactics remain unsolved (10).

Finally, the third option is simultaneous TAVI and coronary stenting. For a long period of time, most clinical practitioners stood against such tactics, considering them dangerous and insufficiently valid. Meanwhile, simultaneous coronary stenting and TAVI seem attractive for several reasons, the most important of which is the minimization of the probability of periprocedural myocardial ischemia and also, which is crucial for the patient, the elimination of the necessity of re-admission for the second endovascular procedure. The reduction of the number of admissions and the number of drugs and consumables used has an important economic effect. Truly speaking, such a strategy also has several negative moments–namely, a certain increase in the probability of complications due to the length of the procedure; increased exposure and contrast volume. However, the literature on this issue is very scarce. To be fair, it should be noted that recently the attitude of clinical practitioners toward the tactics of simultaneous performance of both endovascular procedures has shifted in the favor of this manner of treatment. Nevertheless, the analysis of the literature shows that to date, the number of such procedures performed worldwide is lower in comparison with the other options (10–14). Some authors have demonstrated the feasibility of safe simultaneous combined treatment of high-risk patients with severe aortic stenosis and CAD. According to their data, there were no differences in 30-day mortality and severe complications rates between the patients who underwent simultaneous coronary arteries stenting and TAVI and the patients who underwent these procedures separately.

We were among the first to perform combined endovascular procedures of TAVI and coronary artery stenting in elderly and old patients with AVAS (15, 16). We presented one such case at PCR-2015 during the joint Russian–Israeli: "How should I treat" session: "TAVI and PCI in the treatment of aortic stenosis with concomitant coronary *artery disease–some controversial issues*." Most colleagues who took part in the discussion were supportive of the separate performance of these procedures. Nevertheless, we kept accumulating our experience with simultaneous procedures, and to date, we have performed 30 combined simultaneous procedures without in-hospital mortality, acute myocardial infarction, acute ischemic stroke, and acute renal failure.

In this paper, we present the results of our study aimed at the analysis of the feasibility, effectiveness, and safety of simultaneous combined TAVI and PCI in 30 advanced-age patients with AVAS and CAD who were at high surgical risk. These patients formed Group I. In the large majority of cases, the patients had discrete lesions of no more than three vessels and no more than one completely occluded coronary artery. Patients with a SYNTAX score of > 22 were not included in the study. For the comparative analysis, we have taken the data of 91 patients with AVAS who underwent only TAVI. These cases formed Group II. The severity of aortic valve lesions in both groups was not significantly different. Several patients from Group II also had stenotic atherosclerosis of the coronary arteries; however; 27 (29.7%) of them underwent stenting earlier, while in the remaining patients the stenotic alterations were not hemodynamically significant.

Abbreviations: AV, aortic valve; LBBB, left bundle branch block; CAD, coronary heart disease; CAG, coronary angiography; EDV, end-diastolic volume of the left ventricle; EDD, end-diastolic dimension of the left ventricle; ESV, end-systolic volume of the left ventricle; ESD, end-systolic dimension of the left ventricle; LCA, left coronary artery; AMI, acute myocardial infarction; CVA, acute cerebrovascular accident; PICS, postinfarction cardiosclerosis; RCA, right coronary artery; LAD LCA, left anterior descending branch of the left coronary artery; MSCT, multispiral computer tomography; TIA, transitory ischemic attack; LV EF, left ventricular ejection fraction; PCI, percutaneous interventions; ECG, electrocardiography; EchoCG, echocardiography; TAVI, transcatheter aortic valve implantation.

Methods of diagnosis and treatment

In total, the study comprised 57 patients with AVAS. As noted above, depending on the type and volume of the endovascular procedures, the patients were assigned to 2 groups:

Group I: 30 patients with AVAS and CAD who underwent simultaneous TAVI and coronary artery stenting from May 2012 to October 2019. Three patients from this group (12.5%) had a history of CABG. At the moment of the endovascular procedure, all patients had clinical signs of angina pectoris, and 59.1% of them were in NYHA class III–IV. The study excluded the patients with non-valvular aortic stenosis; congenital aortic stenosis or anatomically bicuspid aortic valve; coronary arterial ostia adjacent (>1.0 nm) to the aortic valve ring; an angiographic picture of large calcifications at the base of the left or right coronary cusp (menace of calcification displacement with the compression of the coronary arterial ostium); intracardiac tumors, thrombi or vegetations; hypertrophic cardiomyopathy; history of mitral valve replacement with a biological prosthesis; marked atheromatosis or kinking of the iliac and femoral arteries; hypersensitivity or intolerance of the drugs and contrast media necessary for the performance of TAVI or coronary arteries stenting; septic condition, endocarditis, or aggravation of infective disease; marked left ventricular failure with left ventricular ejection fraction < 20%; recent CVA; erosive gastritis or active gastric ulcer; and hemorrhagic diathesis or coagulopathy.

Group II: In 27 patients, PCI had been performed on average 4.6 ± 0.9 months prior to TAVI. As a result, it is important to note that anyone of the patients from this group had non-corrected stenotic lesions of the coronary arteries. The criteria for non-inclusion in the group were the same as for Group I.

The diagnosis of AVAS and CAD was made on the basis of the clinical and instrumental examinations. Besides routine examination methods, all patients underwent mandatory transesophageal EchoCG, MSCT-aortography with 3D reconstruction, selective coronary angiography, aortography, and angiography of the lower limb.

In Group 1, prior to the initiation of anesthesia, the patients underwent coronary stenting from transfemoral access, contralateral to the access used for TAVI performance. Stenting was carried out in accordance with the generally adopted technique. The volume of the intervention was determined on the basis of selective coronary angiography data. Complete revascularization was achieved in all cases. After stenting, as noted above, TAVI was performed from the contralateral femoral artery. Another femoral access was used for the placement of a pigtail catheter for the guidance of the valve implantation procedure.

In the majority of cases, TAVI in both groups was performed under endotracheal anesthesia using surgical access with femoral artery exposure and the placement of an 18F introducer. In all cases, without exception, a temporary pacing lead was positioned in the right ventricle. An aortic valve prosthesis was implanted under fluoroscopic guidance with contrast enhancement as well as under transesophageal EchoCG guidance. After aortic valve implantation, the main access was sutured, while on the contralateral access site, passive hemostasis was achieved by manual compression. The patients were de-anesthetized in the operating room with control of their neurological status. In accordance with the protocol adopted in our institution after TAVI, the patients remained under mandatory 24-h follow-up in the intensive care unit.

Statistical analysis

A comparative analysis of the qualitative variables was carried out using Fischer's exact test and the chi-square method. The quantitative variables were presented as means (± SD) and compared using Student's *t*-test. The differences in the occurrence of various events in the groups were assessed using the log-rank test. All echocardiographic indices were assessed using either the two-sample Student's *t*-test or the Wilcoxon rank sum test for continuous variables. The two-tailed alpha level of 0.05 was used for the analysis. Statistical analysis was performed using SAS software (SAS Institute, Inc., Cary, NC, USA).

Study limitations

The small sample size and the low end-point detection frequency are the limitations of this retrospective study.

Results

As shown in **Table 1**, the main clinical, historical, and laboratory data did not differ significantly between the groups.

As one can see from the table, the average age of patients in Group I was 78.3 ± 3.6 years. A total of 63.3% of patients were females. The average patients' age in Group II was 78.5 ± 3.99 years, over one-half of them (70.4%) were also females. Thus, the groups did not differ by age or gender. There were 10% of smokers in Group I and 7.4% in Group II ($p > 0.05$). The number of patients with a history of myocardial infarction, arterial hypertension, and type 2 diabetes mellitus was significantly higher in Group I ($p > 0.05$). All patients in Group I and 2 patients in Group II had angina attacks. The average incidence of ST-T segment deviations revealed by 24-h monitoring in Group I was 5.4 ± 0.45. Similar deviations in Group II were seen only in two patients.

According to EchoCG, the indices of intracardiac hemodynamics, including mean and maximal systolic

TABLE 1 | Clinical and historical data in the groups of study.

Indices	Group I (n = 30)	Group II (n = 27)	P
Age (years)	78.3 ± 3.6	78.5 ± 3.99	0.081
Females	19 (63.3%)	19 (70.4%)	0.051
Postinfarction scar, n (%)	4 (13.3%)	1 (3.7%)	0.358
NYHA III/IV, n (%)	17 (56.7%)	7 (25.9%)	0.237
Arterial hypertension (%)	19 (63.3%)	12 (44.4%)	0.412
Diabetes mellitus (%)	7 (23.3%)	2 (7.4%)	0.225
COPD, n (%)	3 (10%)	2 (7.4%)	0.059
CRF, n (%)	3 (10%)	4 (14.8%)	0.078
Atherosclerosis of brachiocephalic arteries, n (%)	5 (16, 6%)	3 (11.1%)	0.051
History of CABG, n (%)	3 (10%)	0	0.067
History of PCI, n (%)	0	8 (29.6%)	0.234
Syntax score, %	18.6 ± 10.5	5.9 ± 9.7	0.354
Angina attacks	30 (100%)	2 (7.4%)	0.123
Smokers	3 (10%)	2 (7.4%)	0.052
Incidence of ST-T deviation (average, per day)	5.4 ± 0.45	0.04 ± 0.003 (?)	0.081

TABLE 2 | Preoperative EchoCG data in the studied groups.

Indices	Group I (n = 30)	Group II (n = 27)	P
LV EF,%	64.6 ± 8.9	62.3 ± 9.4	0.054
Mean gradient on the aortic valve, mm Hg	58.5 ± 15	58.5 ± 15.1	0.089
Maximal gradient on the aortic valve, mm Hg	98.3 ± 19.5	100.5 ± 23.1	0.061
AV orifice area, cm2	0.57 ± 0.13	100.5 ± 23.1	0.075
Flow velocity on the aortic valve, m/s	4.6 ± 1.3	4.8 ± 1.6	0.056

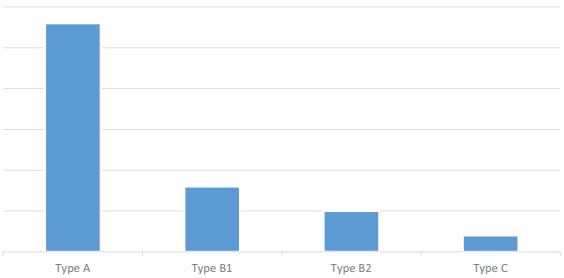

FIGURE 1 | Characteristics of stenotic lesions of the coronary arteries in Group I according to ACC/AHA classification.

pressure gradient on the aortic valve, as well as the aortic valve orifice area, were not significantly different between the groups (Table 2).

In Group I, while performing combined endovascular procedures, at the first stage we performed stenting of the coronary arteries in accordance with the generally accepted technique, using local anesthesia at the access site. Transfemoral access was used in most cases. Coronary angiography revealed 43 stenotic lesions of the coronary arteries > 75% in 30 patients. Type A stenosis (ACC/AHA classification) prevailed among all stenoses (Figure 1).

In Group II, 27 patients had a history of coronary arteries stenting on an average of 4.6 ± 0.9 months prior to TAVI.

In Group I, 64 drug-eluting stents (DES) were used for coronary artery stenting. The most commonly used were Xience Prime-25 (46.3%), Promus Element-10 (28.5%), and Resolute Integrity-9 (25.2%) stents. The average stent diameter was 2.82 ± 0.48 mm, and the average length was 18.6 ± 5.6 mm (Figure 2).

The second stage of the procedure, TAVI, was performed immediately after PCI. In the vast majority of cases (93.3%), general anesthesia and transesophageal EchoCG were used. In the remaining 8 cases (6.7%), deep sedation and transthoracic EchoCG guidance were used.

In Group II, in the vast majority of cases, TAVI was also performed under general anesthesia.

Surgical transfemoral access was used in 85.2% of cases (n = 23), subclavian access in 3.7% (n = 1), and in another 3.7% of cases (n = 1), retroperitoneal access through the iliac artery. Access through a transfemoral puncture was used in 33.3% of cases (n = 2).

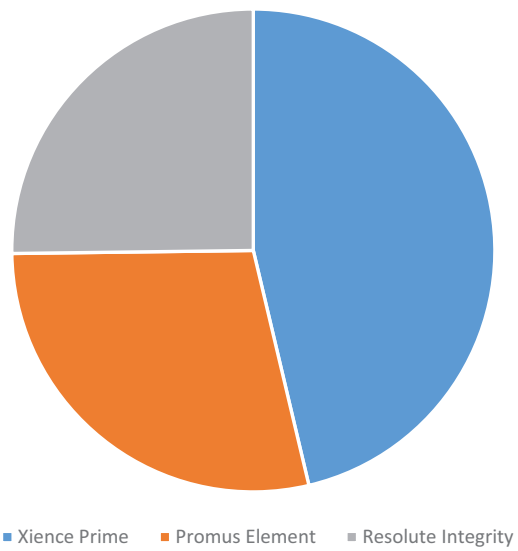

FIGURE 2 | Implanted stents in Group II.

A CoreValve (Medtronic) valve was implanted in 81.5% of cases (n = 22), 14.8% (n = 4) received a Sapien XT (Edwards) valve, and 3.7% (n = 1) a Lotus (Boston Scientific Limited). The types and sizes of the implanted valves are shown in Table 3.

As one can see from Table 3, in Group I, the self-expandable CoreValve prostheses were used in 83.3% of cases, while the remaining patients received the balloon-expandable Sapien XT valve. The most commonly used diameter was 26 mm (50%). The CoreValve prosthesis was also the most commonly used in Group II (82.4%), 26 mm in

TABLE 3 | The types and the sizes of the implanted valves in the studied groups.

Valve type	Group I (n = 30)	Group II (n = 27)	P
CoreValve	25 (83.3%)	22 (81.5%)	0.089
26 mm	13	32	
29 mm	9	36	
31 mm	3	7	
Sapien XT	5 (16.7%)	4 (14.8%)	0.051
23 mm	3	10	
26 mm	2	4	
Lotus	0	1 (3.7%)	0.064
23 mm		2	

TABLE 4 | Some data pertaining to the performed endovascular procedures in the studied groups.

Indices	Group I (n = 30)	Group II (n = 27)	P
Procedure duration (min)	132.6 ± 26.7	104.1 ± 24.3	0.125
FluoroScopy duration (min)	34.8 ± 103	23.3 ± 8.95	0.214
Contrast volume, ml	399.2 ± 96.5	286.5 ± 102.6	0.342
Transfemoral access	27 (90%)	23 (85.2%)	0.056
General anesthesia	28 (93.3%)	26 (96.3%)	0.093

39.6% of cases and 29 mm in 39.6% of cases. The evaluation of the early results is based on intraoperative and postoperative data as well as on the information obtained within 30 days after endovascular procedures.

As one can see from **Table 4**, the procedure duration and the volume of contrast were significantly higher in Group I in comparison with Group II. The average duration of the procedure in Group I was 132.6 ± 26.7 min, the contrast volume was 399.2 ± 96.5 ml, and the duration of scopy was 34.8 ± 10.3 min, while in Group II, these indices were 104.1 ± 24.3 min, 286.5 ± 102.6 ml, and 23.3 ± 8.95 min, respectively.

The following complications were taken into consideration: perioperative, hospital, and 30-day mortality; cardiac tamponade; the changeover to the "open" procedure; prosthesis dysfunction; vascular complications; CVA/TIA; AMI; the necessity of temporal pacing or implantation of a permanent pacemaker; bleeding; moderate or severe paraprosthetic regurgitation; thrombosis of the aortic valve prosthesis; and acute renal failure, requiring renal replacement therapy (RRT).

In Group I, the first stage of the procedure consisted of the stenting of the coronary arteries. As previously noted, all patients received DES. The average number of implanted stents per patient was 2.1 ± 0.8. Multiple stenting was performed in 57.8% of patients. The average diameter of the implanted stents was 2.85 ± 0.48 mm, and the average length was 18.6 ± 5.6 mm. The most commonly stented artery was the LAD, followed by the RCA. In two cases, we performed bifurcation stenting of the left main coronary artery with passage to the LAD and the CxB of the LCA. In two patients, the stenting was performed after successful recanalization of the chronically occluded coronary artery: in one case, the middle segment of LDA was affected, and in another, the proximal segment of the diagonal branch.

The success rate of simultaneous TAVI and coronary arteries stenting in Group I was 100%. However, in one case (3.3%), due to prosthesis dislocation, we had to perform valve-in-valve implantation: initially, the female patient received a self-expandable 26 mm CoreValve prosthesis. After its dislocation toward the aorta and the resulting development of marked aortic regurgitation, the similar 26 mm CoreValve prosthesis was implanted with good results. In Group I, with the exception of one abovementioned case, all procedures were performed without significant intra- or postoperative complications. However, the complete left bundle branch block (LBBB) occurred after the procedure in 7 patients (23%). In our opinion, this complication can be related to balloon valvuloplasty performed before prosthesis implantation. Intra- and perioperative mortality in Group I was 0%. Onehas to note that transfemoral access for TAVI was used in all patients from this group.

In Group II, in 1 case, it was necessary to perform "valve-in-valve" implantation. During the implantation of the balloon-expandable 23 mm Sapien XT valve (Edwards), the prosthesis migrated to the aorta, which led to the development of total aortic regurgitation. An emergency open-heart surgery was performed, the prosthesis was removed, and then aortic valve replacement with a mechanical prosthesis was carried out. The patient was discharged on day 13 in satisfactory condition.

The intraoperative right ventricular wall perforation with the pacing catheter tip occurred in 2 (7.4%) cases during valvuloplasty and pacing, leading to hemotamponade. In all cases, the patients were referred to open-heart surgery, the defects were sutured, and both of them were successfully discharged. In Group II, the LBBB was seen in 8 (29.6%) patients. Intra- and perioperative and hospital mortality was 0%. In both groups, due to open surgical access, there were no cases of massive bleeding from the access site. The rate and character of complications are shown in **Table 5**.

The rate of paraprosthetic regurgitation was slightly higher in Group II. Heart rhythm disturbances were significantly more common in Group II. The rate of permanent pacemaker implantation was significantly higher in Group II.

The duration of stay in the intensive care unit was similar in both groups–an average of 1.5 ± 1.3 days; the same is true for the hospital stay–an average of 7.8 ± 3 days.

In Group I, practically all patients had an uncomplicated in-hospital course. There were no angina attacks or other signs of CAD aggravation, including acute myocardial infarction (AMI). In Group II, one female patient had a

TABLE 5 | Post-TAVI complications rate (in-hospital and 30-day).

Indices	Group I (n = 30)	Group II (n = 27)	P
Intra- and perioperative mortality	0	0	0.053
In-hospital mortality	0	0	0.089
30-day mortality	0	0	0.061
Myocardial infarction	0	1 (3.7%)	0.078
Stroke/TIA	1 (3.3%)	0	0.059
Major bleedings	0	0	0.063
«Valve-invalve»implantation	1 (3.3%)	1 (3.7%)	0.091
Hemotamponade	1 (3.3%)	2 (7.4%)	0.057
Changeover to "open" surgery	0	0	0.076
Stent-grafting of the femoral artery (dissection)	1 (3.3%)	1 (3.7%)	0.081
LBBB	7 (23.3%)	8 (29.6%)	0.063
Heart rhythm disturbances	1 (3.3%)	2 (7.4%)	0.212
Permanent pacemaker implantation	1 (3.3%)	9 (9.9%)	0.413
Moderate-to-severe paraprosthetic regurgitation		5 (5.5%)	0.053
Hemodialysis required	0	0	

TABLE 6 | The mid-term results in studied groups.

Indices	Group I (n = 30)	Group II (n = 27)	P
Survival	96.7%	100%	
Angina attacks	6.3%	7.6%	0.073
Brain stroke	0	1 (3.7%)	0.178
NYHA 1–2	23.3%	30.8%	0.061
In-stent stenosis or stent occlusion	0	–	
Progressive stenotic atherosclerosis of native coronary arteries revealed by selective coronary angiography (number of arteries)	1 (3.4%)	1 (3.7%)	0.083

TABLE 7 | Data of ultrasound heart investigation in the studied groups within 6 months after the procedures.

Indices	Group I (n = 29)	Group II (n = 27)	P
Mean gradient on the aortic valve (mmHg)	9.6 ± 4.1	11.5 ± 4.6	0.081
Maximal gradient on the aortic valve (mmHg)	17.9 ± 9.3	21.3 ± 8.3	0.068
LVEF,%			
Before the procedure	64.6 ± 8.9	63.9 ± 8.4	0.053
In 6 months	66.5 ± 9.1	64.5 ± 9.6	0.078
EDD (cm)			
Before the procedure	4.7 ± 0.5	4.7 ± 0.6	0.062
In 6 months	4.8 ± 0.5	5 ± 0.44	0.095
ESD (cm)			
Before the procedure	3 ± 0.6	2.9 ± 0.5	2.9 ± 0.5
In 6 months	3.1 ± 0.6	3.1 ± 0.4	0.061
EDV (ml)			
Before the procedure	107.1 ± 26.5	105.3 ± 30.8	0.059
In 6 months	114.6 ± 30.6	120.1 ± 24.1	0.087
ESV (ml)			
Before the procedure	34.7 ± 12.4	38.3 ± 13.1	0.065
In 6 months	41.2 ± 23.0	43.1 ± 13.2	0.079
Aortic regurgitation (degrees 2 and 2.5)			
In 6 months	2 (6.8%)	7 (25.9%)	$p < 0.001$

posterior wall AMI within 1 day after valve implantation, probably as a result of calcium mass dislocation during the implantation procedure. After the conducted therapy, the patient was transferred to the rehabilitation department.

Thus, the total hospital survival in both groups was 97.5%. The patients were discharged with the prescription for double antiplatelet therapy (Aspirin + P2Y12 platelets receptor inhibitors). During a 30-day follow-up at the rehabilitation stage, the patients felt well. There were no deaths or serious complications, including AMI or stroke. During this period, one patient from Group II required pacemaker implantation for intermittent rhythm migration episodes and over 2-s pauses revealed by 24-h ECG monitoring (**Table 5**).

The mid-term follow-up was 6 months (visit to the hospital or telephone questionnaire). After 6 months, the majority of patients in both groups were clinically stable, the signs of moderate or severe heart failure were absent, and the angina attacks did not occur (**Table 6**).

The mid-term survival in Group I was 96.7%. One patient died from cancer. The survival rate in Group II was 100%. However, one patient had an acute cerebrovascular accident.

As seen in **Table 7**, **6** months after the procedures, the indices of the aortic valve function were satisfactory and comparable in both groups. The mean systolic pressure gradient on the aortic valve was 9.6 ± 4.1 mm Hg and 11.5 ± 4.6 mm Hg in Groups I and II, respectively ($p = 0.049$), and the maximal gradient was 17.9 ± 9.3 mm Hg and 21.3 ± 8.5 mm Hg ($p = 0.06$). The indices of LVEF, ESD, EDD, ESV, and EDV also were not significantly different between the groups.

Meanwhile, one has to note that the number of patients with paravalvular regurgitation on the aortic valve was significantly higher in Group II-25.9% in comparison with 6.8% in Group I, $p < 0.001$.

After 6 months, the heart function was not significantly different between the studied groups. In Group I, 76.7% of patients had no signs of heart function disturbances (NYHA class 0), another 20% had NYHA class I, and 3.3% had NYHA

class II. In Group II, these indices were distributed as follows: no signs of heart function disturbances in 69.2% (NYHA 0), NYHA class I in 25.3%, and NYHA class II in 5.5%.

In Group I, clinical signs of angina were absent in 93.3% of patients; the remaining 6.7% had angina of effort of functional class 1. In Group II, the signs of angina were absent in 92.3% of patients; the remaining 7.7% were in functional class 1.

Coronary angiography was performed in 18 (62%) patients from Group I. The remaining patients refused the investigation because of their sense of wellbeing. The stents were patent without visible alteration in all 18 examined patients from Group I. Progressive stenosis of the native coronary artery (the CxB of the LCA) was revealed in 1 patient from this group. This vessel was stented with DES. In Group II, coronary angiography was performed if the patients complained of angina or its equivalents only. There was only 1 such patient (3.7%); coronary angiography revealed progressive stenosis in the native LAD of the LCA. The LAD was stented with DES.

Discussion

First of all, the main goal of our study was to evaluate whether it is possible to perform combined simultaneous procedures of coronary artery stenting and TAVI in advanced-age patients with AVAS and CAD safely, effectively, without compromising the quality and without complications typical to long endovascular procedures requiring a higher amount of contrast.

Our study showed that the patients from the group of simultaneous TAVI and coronary stenting were free from such complications as death, acute myocardial infarction, acute stroke, or other severe hypoxic complications during the intraprocedural, periprocedural, and in-hospital periods. Despite the obviously longer duration of the procedure in Group I, the greater contrast expenditure, and the longer fluoroscopy in comparison with Group II, none of the studied patients had either severe clinical or laboratory signs of acute renal failure requiring dialysis in the early postoperative period, nor undesirable (negative) consequences of excessive exposure. One death occurred only in Group II–periprocedural and hospital mortality was 3.6%. However, one has to note that the lethal complications seen in 3 patients from this group could occur independently of the treatment option.

As for the serious complications seen in our study, it is worth noting one case of prosthesis dislocation with marked dysfunction of the aortic valve; for this reason, valve-in-valve implantation using a 26-mm CoreValve prosthesis was performed with good results. In Group II, a similar situation occurred in two patients. In one of them, it happened during the implantation of a self-expandable CoreValve prosthesis, and in another–of a balloon-expandable Edwards prosthesis. Paraprosthetic aortic regurgitation of 3–4 degrees developed in one case after the implantation of a 29-mm CoreValve prosthesis. Taking into consideration, the impossibility of prosthesis repositioning and basing ourselves on the guidelines of the manufacturer, we decided to implant the second 29 mm CoreValve prosthesis. The implantation was successful. In another case, during the implantation of the balloon-expandable 23-mm Sapien XT (Edwards) valve, there was a complete valve dislocation into the aorta with the development of total aortic regurgitation. The valve was fixed at the level of the descending aorta. At the next stage, the second Sapien XT (Edwards) valve (26 mm) was implanted. The implantation again was not optimal, as the prosthesis was partially dislocated to the aorta with the development of total aortic regurgitation. During the emergency open-heart surgery, the prosthesis was removed and then aortic valve replacement with a mechanical prosthesis was carried out. The patient was discharged in satisfactory condition on day 13. The remaining procedures were performed without any technical problems.

As noted above, in Group I, the first stage consisted of coronary artery stenting with DES. In the vast majority of cases, multiple stenting was performed. The most commonly stented was the LAD of the LCA and the RCA. In two cases, we performed complex bifurcation stenting of the left main coronary artery with the passage to the LAD and the CxB of the LCA. All procedures were performed without significant intra- and postoperative complications. However, the incidence of complete LBBB in Group I was somewhat higher than in Group II (23 vs. 17.6%).

One of the most severe complications of TAVI in our experience was the perforation of the right (and in one case, of the left) ventricular wall. The causes of these complications cannot be directly related to the tactics of TAVI performance–isolated or in combination with coronary arteries stenting. These complications are mainly related to ventricular wall trauma with either the pacing lead tip or the damaged rigid guidewire advanced to the left ventricle. In our opinion, the main cause of trauma of the right ventricle is related to the fact that during balloon valvuloplasty and heart pacing at a frequency of about 150 bpm, the right ventricle is almost empty, and its contractions in such a state create “favorable” conditions for ventricular wall injury with the lead’s tip, especially if the lead’s tip is located near the free ventricular wall and directed toward it. We believe that in order to avoid the trauma of the right ventricular wall, one has to try to position the lead’s tip in such a way that, first, it should not be located immediately near the free right ventricular wall and, second, it should be directed toward the interventricular septum. Also, we put high hopes on eventual intra-TAVI pacing using a guidewire advanced into the left ventricle. One can already find the descriptions of clinical cases using this technique (17). All complications related to the ventricular walls trauma (4.4%) were seen in Group II;

however, we do not consider this fact as a consistent pattern, but rather as a coincidence.

In another case, as we have already noted, the hemotamponade was caused by left ventricle perforation by a rigid guidewire damaged and laminated during the procedure. All resuscitation measures were ineffective, and heart surgery was not performed because of irreversible heart arrest. Yet another patient from Group 2 died on day 3 after TAVI from mesenteric thrombosis and peritonitis. Intra- and perioperative mortality rate was 2%. The in-hospital mortality rate was 3.3%.

The rate of paraprosthetic regurgitation in both groups did not exceed 7% and was insignificantly higher in Group II. Various heart rhythm disturbances were insignificantly more common in patients who underwent isolated TAVI. The permanent pacemakers were implanted slightly more often in the same group.

In total, the postoperative in-hospital period was eventless in both groups, with the exception of one female patient in Group II who had an acute posterior wall AMI within 1 day after TAVI, probably as a result of calcium mass dislocation during the procedure of valve implantation. After the conducted therapy, she was transferred to the rehabilitation department and later discharged.

There were no significant differences in the length of stay in the intensive care unit and the hospital between the studied groups.

The patients were discharged with the prescription for double antiplatelet therapy (Aspirin + P2Y12 platelet receptor inhibitor).

Within the first 30 days after discharge, the patients from both groups felt well. There were no deaths or other severe complications, including myocardial infarction or stroke. During this period, one patient from Group II required pacemaker implantation for episodes of intermittent rhythm migration and pauses longer than 2 s (revealed during 24-h ECG monitoring).

In 6 months, most patients from both groups remained clinically stable. They had no signs of marked heart failure or angina attacks. One patient from Group I died from cancer. The mid-term survival in this group was 96.7%. Significantly higher mortality (9%) was seen 1 year after simultaneous TAVI and PCI by H. Zhou et al. (18).

The mid-term survival in Group II was 100%; however, 1 patient suffered an acute cerebrovascular accident. As judged by hemodynamic data (EchoCG), the vast majority of patients had good indices with an average maximal systolic pressure gradient at the aortic valve of 18.7 ± 8.2 mm Hg. This value was not significantly different between the groups. Neither did the groups differ by such indices as LVEF, ESD, EDD, ESV, and EDV. Meanwhile, one has to note that the number of patients with paravalvular regurgitation in Group II was significantly higher (23.6 vs. 4.2%, $p < 0.001$).

It is of particular importance that the vast majority of patients in both groups (93.3 and 92.3%, respectively) had no clinical signs of angina, while the remaining patients had angina of effort of functional class 1. Coronary angiography performed in 60% of patients after simultaneous procedures demonstrated good results of stenting in all cases. Only one patient from this group had progressive stenosis of the native coronary artery (the CxB of the LCA), requiring stenting with DES. Angina attacks developed in one patient from Group II; coronary angiography revealed progressive stenosis of the LAD of the LCA. This patient also underwent stenting with DES. Hence, it can be said that at 6 months after simultaneous combined coronary stenting and TAVI in advanced-age patients who underwent control coronary angiography (18 patients); good results of stenting were almost completely preserved.

Thus, our study is in agreement with other authors' conclusions concerning the feasibility and safety of combined simultaneous treatment of high-risk patients with marked aortic stenosis and CAD (11–14, 19). According to these authors, as well as to our results, during the first 30 days after the procedure, there were no significant differences in mortality and severe complications between the patients who underwent simultaneous coronary artery stenting and TAVI and those who underwent these procedures separately. Our data also correlate with the conclusions of Tarus et al. (20), who did not find a significant difference in the rate of complications and mortality between the studied groups of patients in the early postoperative period. Our data are also consistent with the results of Abugroun et al. (21), who have performed a comparative analysis of the results of combined surgical treatment (aortic valve replacement and CABG) and of combined TAVI and coronary artery stenting in patients with atherosclerotic aortic valve stenosis and CAD. These authors came to the conclusion that combined TAVI and PCI were related to lower mortality, lower probability of acute renal failure, and bleeding. The in-hospital stay of these patients was also shorter than that of patients receiving surgical treatment (AVR and CABG). Furthermore, vascular complications and the necessity of pacemaker implantation were higher in the groups of TAVI and PCI than in any other group. As for vascular complications, as noted above, we mainly used surgical access, so we had no cases of vascular complications. Meanwhile, one has to remember that the authors who had performed such a comparative analysis had also noted a significantly higher cost of endovascular procedures in comparison with open-heart surgery (18).

Thus, our study comparing early and mid-term results in two groups of advanced-age patients with AVAS and CAD: (a) after combined simultaneous TAVI and coronary arteries stenting and (b) after isolated TAVI, has demonstrated the absence of significant differences of intra- and perioperative and early, as well as of mid-term results (6 months after the procedure). Despite the longer duration of the procedures in the group of combined simultaneous treatment, the higher contrast volume, and the longer duration of X-ray

fluoroscopy, most clinical, laboratory, and angiographic indices were not significantly different between the groups. It concerns, in particular, the complications that could develop due to the duration of the procedure, the use of higher contrast volume, and higher exposure. Also, one has to note that in the mid-term we did not see any particularities in the aortic valve prosthesis condition or the condition of stents in Group I. At 6 months, almost all stents functioned without any significant changes.

Meanwhile, in order to definitely answer the question about the place of simultaneous procedures of TAVI and coronary stenting in the treatment of advanced-age patients with severe aortic valve stenosis and CAD, it is necessary to further accumulate experience and to perform a meticulous comparative analysis of the results after various options of combined endovascular management of aortic valve disease and CAD. It is quite possible that even with a large experience we shall not receive a univocal and universal answer. One has to solve the problem of treatment tactics on a case-to-case basis, taking into consideration multiple factors pertinent to the patient as well as to his condition, the presence of serious concomitant diseases, etc.

Conclusion

Simultaneously combined procedures of TAVI and PCI in advanced-age patients with AVAS and CAD at high risk for "open heart" surgery can be performed without an increased rate of such severe complications as intraoperative and perioperative mortality, acute myocardial infarction, acute stroke, and acute renal failure. The effectiveness and safety do not significantly differ between the patients after simultaneous procedures and isolated TAVI. It is true for the in-hospital period as well as for the midterm results (6 months).

However, the small sample size of this retrospective study and the low frequency of end-points registration are the limitations of his work. In order to obtain more reliable results and conclusions, the study should be continued, and more accomplished cases are necessary.

Author contributions

DI, SS, EK, VK, AS, IC, DA, VF, and NT contributed to the writing and revising of the manuscript.

Informed consent statement

Informed consent was obtained from all the patients.

Conflict of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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