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Research Article

Outcomes of Complete Transcatheter versus Complete Surgical Treatment in Patients with Severe Aortic Valve Stenosis and Concomitant Coronary Artery Disease

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Abstract

Background: There are many studies comparing surgical (SAVR) and transcatheter (TAVR) aortic valve replacement, but in most cases patients with complex coronary artery disease (CAD) were excluded from the trials. **Aim:** To evaluate clinical outcomes and echocardiography parameters of TAVR and percutaneous coronary intervention (PCI) compared with SAVR and coronary arteries bypass grafting (CABG) procedures in patients with concomitant aortic stenosis (AS) and CAD. **Methods:** Retrospective study involved 200 patients with significant AS with CAD, requiring prosthetic valve implantation and interventional or surgical CAD treatment. Data collected were epidemiological data, comorbidities, and echocardiography parameters before the aortic valve replacement and within a month after the replacement, the type of prosthesis, and early complications of the procedure and mortality rate for four years. **Results:** A total of 200 patients who underwent TAVR + PCI (100 patients) or SAVR + CABG (100 patients) were included. After 30 days follow-up period, there was no significant difference between groups for all causes mortality (3% vs. 9%, p=0.134). A new onset atrial fibrillation (8% vs. 34 %, p<0.001), acute kidney injury (0% vs. 7%, p=0.014) and red blood cells transfusions (10% vs. 24%, p=0.008) were significantly lower in patients undergoing TAVR + PCI compared to SAVR + CABG. Postoperative peak aortic valve gradient was significantly higher in the SAVR group (25.77 ± 1.39 mmHg) compared to patients treated with TAVR (15.56 ± 0.66 mmHg, p=0.002). Mild or greater paravalvular leakage (PVL) was more frequent in the TAVR group (43%) than in the SAVR group (22%, p < 0.001). Mortality rate for four years was assessed – there was a tendency of higher mortality rates in TAVR + PCI group, but this difference was not statistically significant. **Conclusions:** Compared to SAVR + CABG surgery, TAVR + PCI procedure, had lower rates for acute kidney injury (AKI), new onset atrial fibrillation (NOAF) and red blood cells (RBC) transfusions following 30 days analysis. Postoperative valve performance data showed that the peak gradient was lower in TAVR + PCI group, while the rates of significant aortic regurgitation were higher in this group. Long-term mortality rates tend to be higher in TAVR + PCI group, but this difference was not statistically significant.

Keywords: Aortic Stenosis, Transcatheter Aortic Valve Replacement, Surgical Aortic Valve Replacement, Coronary Artery Disease.

Introduction

Aortic stenosis (AS) is the most common valvular heart disease [1,2]. As atherosclerosis and AS share similar pathophysiology and risk factors, concomitant coronary artery disease (CAD) is highly prevalent among patients with severe AS and is associated with poorer outcomes [3]. CAD has been reported in more than 50% of AS patients undergoing both surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR) [4,5].

The comparative efficacy of TAVR and SAVR has been evaluated in large randomized trials, but patients with CAD requiring coronary revascularization were excluded from the majority of trials [6-8].

Subjects and Methods

The purpose of this study was to compare outcomes of TAVR + percutaneous coronary artery intervention (PCI) compared with SAVR + coronary artery bypass grafting (CABG) procedures in adult patients with concomitant severe AS and CAD.

A retrospective study involved 200 patients with significant AS, requiring prosthetic valve implantation, admitted to our hospital between January 2017 – December 2019. All of these patients also had CAD with significant stenoses of coronary arteries, requiring interventional or surgical treatment. Patients were divided into two groups – the first group was patients, who underwent TAVR + PCI within four to five weeks between procedures. The second group consisted of patients, who underwent SAVR + CABG simultaneously.

The research was approved by the Bioethics committee of our university. Data collected were epidemiological data, comorbidities, echocardiography parameters before the aortic valve replacement and within a month after the replacement, the type of prosthesis, early complications of the procedure and mortality rate for four years.

Data was analysed using IBM SPSS Statistics v26.0. Data was assessed using Smirnov-Kolmogorov test. Non-parametrical quantitative data was presented as median with minimal and maximal values. Parametrical quantitative data was presented as mean with standart deviation. Non-parametrical comparative data was assessed using Mann-Whitney test. Parametrical comparative data was assessed using Student T-test. Numeric data was presented as numbers and percentages. Groups were compared using Wilcoxon signed-rank test. Categorical variables were expressed as absolute numbers (percentages) and compared using the $\chi 2$ test. A p value <0,05 was concerned as statistically significant data.

Results

Two hundred patients were included. Of them, one hundred patients underwent TAVR + PCI and one hundred patients underwent SAVR + CABG. The baseline characteristics of the patients are presented in (Table 1). Patients in TAVR + PCI group were older, had significantly more comorbidities (prior myocardial infarction, chronic kidney disease, atrial fibrillation). Also, there was a significantly higher number of interventions in TAVR + PCI group (permanent pacemaker implantation, prior PCI and CABG) performed prior to TAVR.

		TAVR + PCI (n=100)	**SAVR + CABG (n=100)**	**p - value**
Age (years)		82.0 ± 5.5	75.0 ± 6,3	**<0.001**
Gender	**Female**	55 (45 %)	38 (38 %)	**0.016**
	Male	45 (55 %)	62 (62 %)	
BMI (kg/m²)		27.1 ± 4.3	28.07 ± 4.6	0.129
NYHA class III/IV		68 (68 %)	75 (75 %)	0.273
Coronary artery disease		100 (50 %)	100 (50 %)	0.121
Prior myocardial infarction		45 (45 %)	23 (23 %)	**0.001**
Prior CABG		20 (20 %)	1 (1 %)	**<0.001**
Prior PCI		48 (48 %)	18 (18 %)	<0.001
Prior stroke		15 (15 %)	8 (8 %)	0.121

Hypertension	100 (100 %)	95 (95 %)	0.059
Peripheral artery disease	3 (3 %)	0 (0 %)	0.246
Diabetes mellitus	12 (12 %)	21 (21%)	0.086
COPD	6 (6 %)	3 (3 %)	0.498
Chronic kidney disease	53 (53 %)	4 (4 %)	**<0.001**
Atrial fibrillation	43 (43 %)	21 (21 %)	**<0.001**
Permanent pacemaker	14 (14 %)	3 (3 %)	**0.009**
Hemoglobin (g/l)	121.0 ± 16.3	119.0 ± 18.1	0.259
Creatinine clearance (ml/min)	53.0 ± 22.23	69.5 ± 20.8	**<0.001**

Note: Values presented as number (percentage), mean (±standard deviation), or median (interquartile range). Bold represent statistically significant p-values. **Abbreviations: BMI,** body mass index; **COPD,** chronic obstructive pulmonary disease; **PCI,** percutaneous coronary intervention; **SAVR**, surgical aortic valve replacement; **TAVR,** transcatheter aortic valve implantation.

Table 1: Baseline clinical characteristics of study cohort.

SAVR + CABG group had significantly more patients with diabetes mellitus and better renal function. They were more likely to be in New York Heart Association (NYHA) class III or IV and had lower values of hemoglobin, but these differences were not statistically significant.

The early outcomes of the TAVR + PCI and SAVR + CABG groups were assessed and compared in the period of 30 days after the procedures. The results are shown in (Table 2).

	TAVR + PCI (n=100)	**SAVR + CABG (n=100)**	**p - value**
30-day all-cause mortality	3 (3 %)	9 (9 %)	0.134
Stroke	2 (2 %)	0 (0 %)	0.497
Aortic dissection	1 (1 %)	1 (1 %)	1.000
Myocardial infarction	0 (0 %)	1 (1 %)	1.000
New third-degree AV block	6 (6 %)	2 (2 %)	0.279
New-onset AF	8 (8 %)	34 (34 %)	**<0.001**
New permanent pacemaker	8 (8 %)	2 (2 %)	0.101
Infectious endocarditis	0 (0 %)	0 (0 %)	1.000
Cardiac tamponade	2 (2 %)	6 (6 %)	0.279
Sepsis	0 (0 %)	3 (3 %)	0.246
Acute kidney injury	0 (0 %)	7 (7 %)	**0.014**
Reintervention	0 (0 %)	0 (0 %)	1.000
Blood transfusion	10 (10 %)	24 (24 %)	**0.008**

Note: Values presented as number (percentage), mean (±standard deviation), or median (interquartile range). Bold represent statistically significant p-values. **Abbreviations: AV** - atrioventricular, **BMI,** body mass index; **COPD,** chronic obstructive pulmonary disease; **PCI,** percutaneous coronary intervention; **SAVR,** surgical aortic valve replacement; **TAVR,** transcatheter aortic valve implantation.

Table 2: The 30-day outcomes.

The 30-day mortality rate was higher in SAVR + CABG group, but this difference was not statistically significant. Complications as stroke, aortic dissection, myocardial infarction, third-degree atrioventricular block, infectious endocarditis, cardiac tamponade, sepsis were compared, but there were no significant differences between the groups. Complications as new onset atrial fibrillation (NOAF), acute kidney injury (AKI) and red blood cells (RBC) transfusions were significantly more prevalent in SAVR + CABG group.

The baseline echocardiographic characteristics between TAVR+PCI and SAVR+CABG patients are shown in (Table 3). Before valve implantation TAVR+PCI patients had a higher peak aortic valve gradient and a greater frequency of moderate or severe aortic regurgitation. Also, in TAVR + PCI group was significantly greater frequency of moderate and higher mitral and tricuspid regurgitation.

	TAVR + PCI (n=100)	**SAVR + CABG (n=100)**	**p-value**
Peak aortic valve gradient, mmHg	80.71 ± 28.22	67.37 ± 30.64	**0.002**
≥ Moderate aortic regurgitation	43 (43 %)	22 (22%)	**<0.001**
LV ejection fraction, %	46.30 ± 12.03	47.65 ± 9.52	0.826
LV mass index, g/m2	133.11 ± 33.01	132.43 ± 32.46	0.718
RV dysfunction (based by values of S')	24 (66.7 %)	12 (33.3 %)	0.09
mPAP	30.70 ± 9.37	25.84 ± 10.49	0.588
≥ Moderate mitral regurgitation	38 (38 %)	16 (16 %)	**<0.001**
≥ Moderate tricuspid regurgitation	32 (32 %)	11 (11 %)	**<0.001**

Note: Values presented as number (percentage), mean (±standard deviation) or median (interquartile range). Bold represent statistically significant p-values. **Abbreviations: LV,** left ventricle; **mPAP,** mean pulmonary artery pressure; **RV,** right ventricle, **SAVR,** surgical aortic valve replacement; **TAVR**, transcatheter aortic valve implantation.

Table 3: Baseline echocardiographic results: aortic valve hemodynamics.

Left ventricular ejection fraction (LVEF), aortic valve peak gradient and mean pulmonary artery pressure (mPAP) were compared in groups before and after the surgery. The results are shown in (Figures 1-3). Echocardiography parameters assessment after the surgery showed statistically significant differences in changes before and after the intervention between groups in mean pulmonary artery pressure ($p<0.001$) (Figure 2). Patients with an implanted transcatheter heart valve had a significantly lower peak aortic gradient at 30 days compared to patients treated with SAVR (15.56 ± 0.66 mmHg vs 25.77 ± 1.39 mmHg, accordingly, $p=0.002$). The percentage of ≥ moderate paravalvular aortic, total aortic regurgitation was significantly higher in TAVR+PCI group ($p <0.001$) (Table 4).

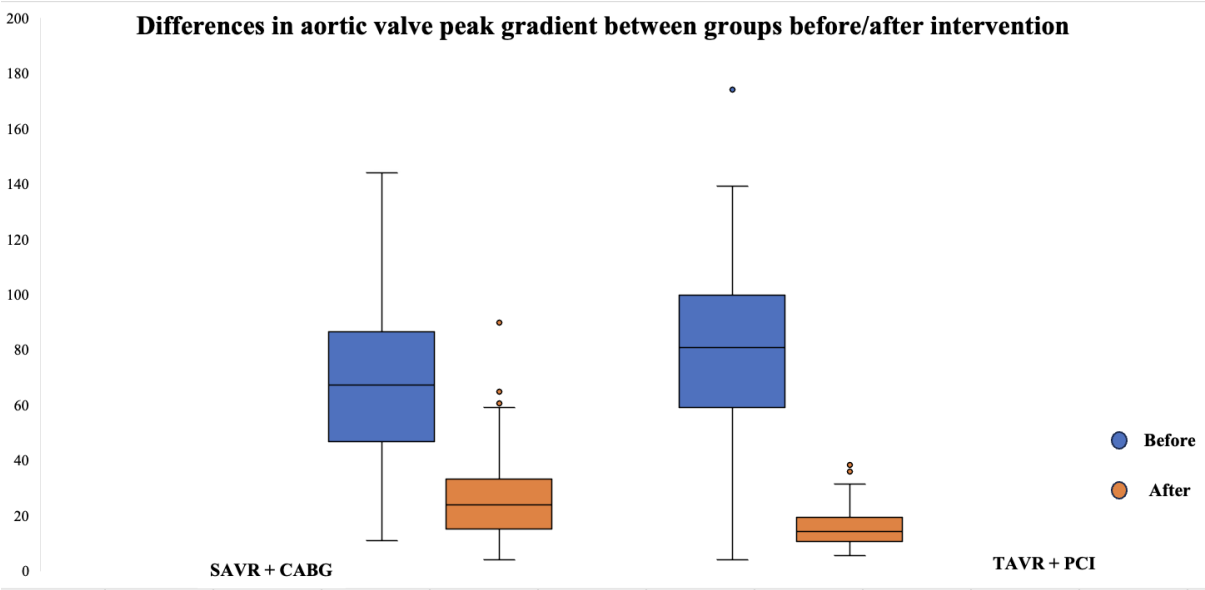

Figure 1: Differences in aortic valve peak gradient between groups before and after the intervention (p = 0.002). **Abbreviations: CABG** – coronary artery bypass grafting, **PCI** – percutaneous coronary intervention, **SAVR,** surgical aortic valve replacement; **TAVR**, transcatheter aortic valve replacement.

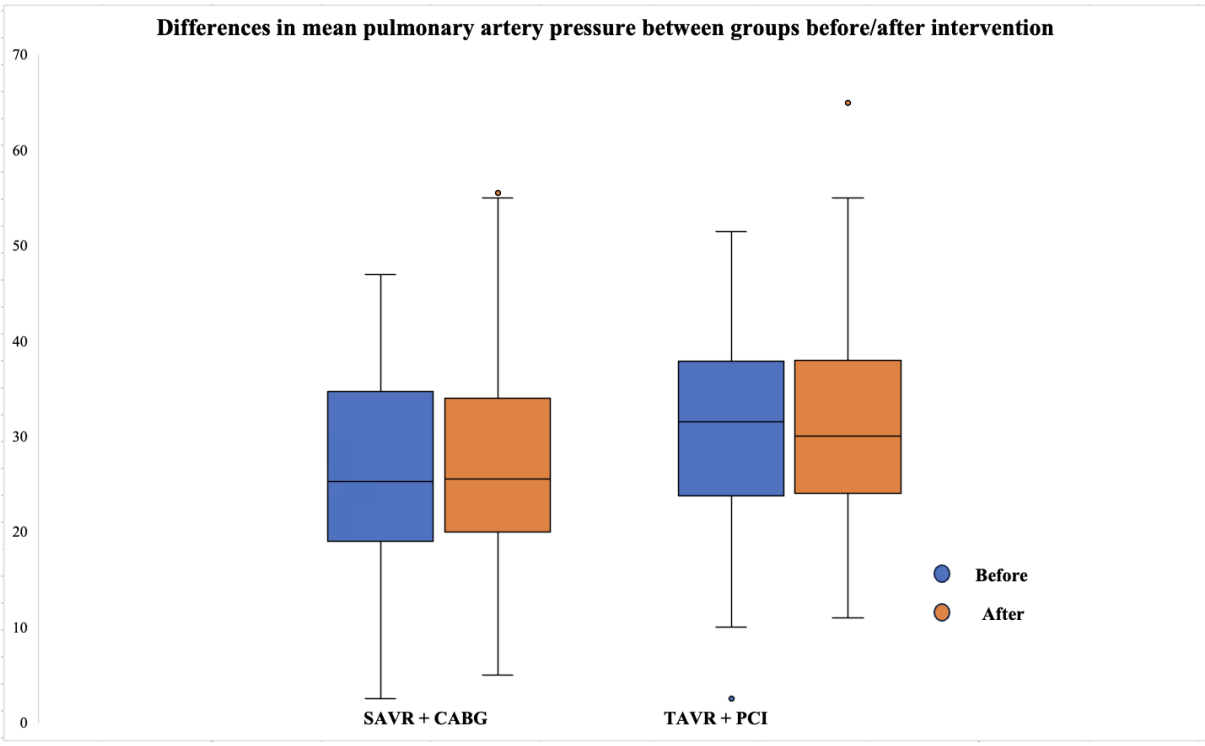

Figure 2: Differences in mean pulmonary artery pressure between groups after intervention (p<0.001). **Abbreviations: CABG** – coronary artery bypass grafting; **PCI** – percutaneous coronary intervention; **SAVR,** surgical aortic valve replacement; **TAVR,** transcatheter aortic valve replacement.

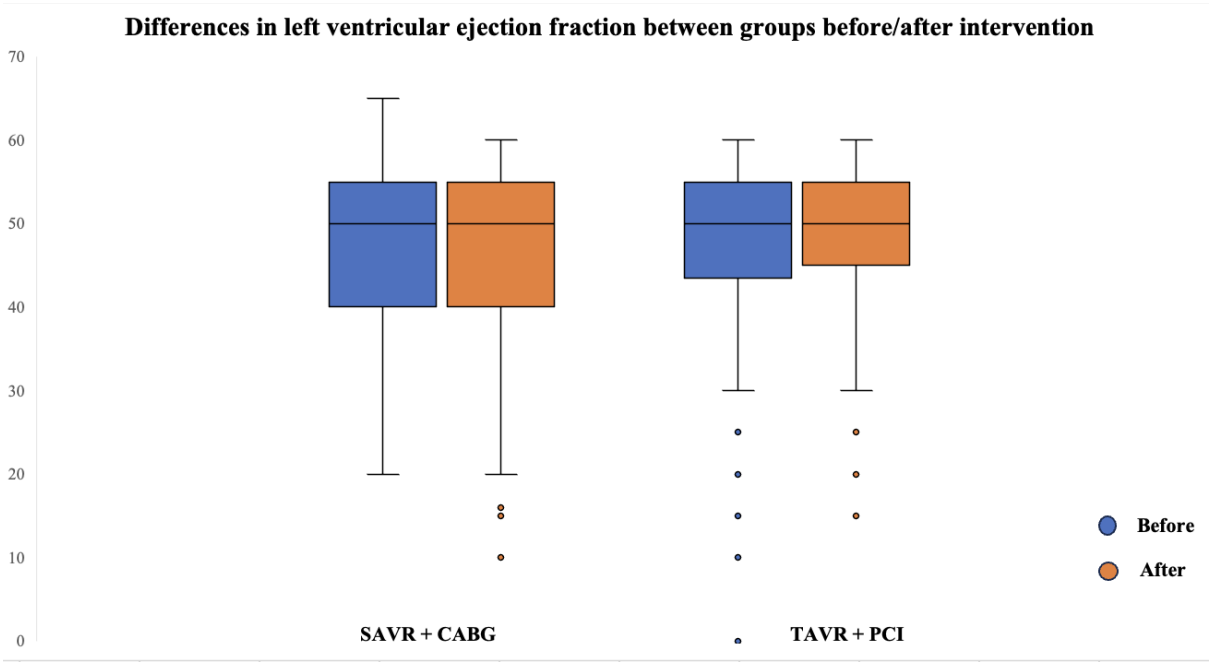

Figure 3: Differences in left ventricular ejection fraction between groups after intervention (p=0.002). **Abbreviations: CABG** – coronary artery bypass grafting, **LVEF** – left ventricular ejection fraction; **PCI** – percutaneous coronary intervention; **SAVR,** surgical aortic valve replacement; **TAVR,** transcatheter aortic valve replacement.

	TAVR + PCI (n=100)	***SAVR + CABG (n=100)***	***p - value***
LV ejection fraction, %	47.41±10.25	47.88 ± 9.85	*0.348*
LV mass index, g/m2	*133.27 ± 34.26*	*121.99 ± 33.08*	***0.029***
≥ II degree total aortic regurgitation (≥ II degree)	*18 (18 %)*	*2 (2 %)*	***<0.001***
≥ Moderate paravalvular aortic regurgitation	*18 (18 %)*	*0 (0 %)*	***<0.001***
Moderate/severe mitral regurgitation	*39 (39 %)*	*16 (16 %)*	***<0.001***
Moderate/severe tricuspid regurgitation	*32 (32 %)*	*12 (12 %)*	***<0.001***
Note: *Values presented as number (percentage), mean (±standard deviation) or median (interquartile range). Bold represent statistically significant p-values.* ***Abbreviations: LV,*** *left ventricular;* ***RV,*** *right ventricular;* ***SAVR,*** *surgical aortic valve replacement;* ***TAVR,*** *transcatheter aortic valve implantation.*			

Table 4: Echocardiographic results after aortic valve replacement

Also, there was a difference in change of LVEF – it improved from mean LVEF 46.98 ± 10.85 to 47.41±10.25 in TAVI+PCI group and from 46.30 ± 12.04 to 47.88 ± 9.85 in SAVR + CABG group (Figure 3) (p=0.002). There also were statistically significant differences between groups in the duration of hospitalization. Patients included to SAVR + CABG group had longer hospitalization than in TAVR + PCI group (p=0.002) (Figure 4).

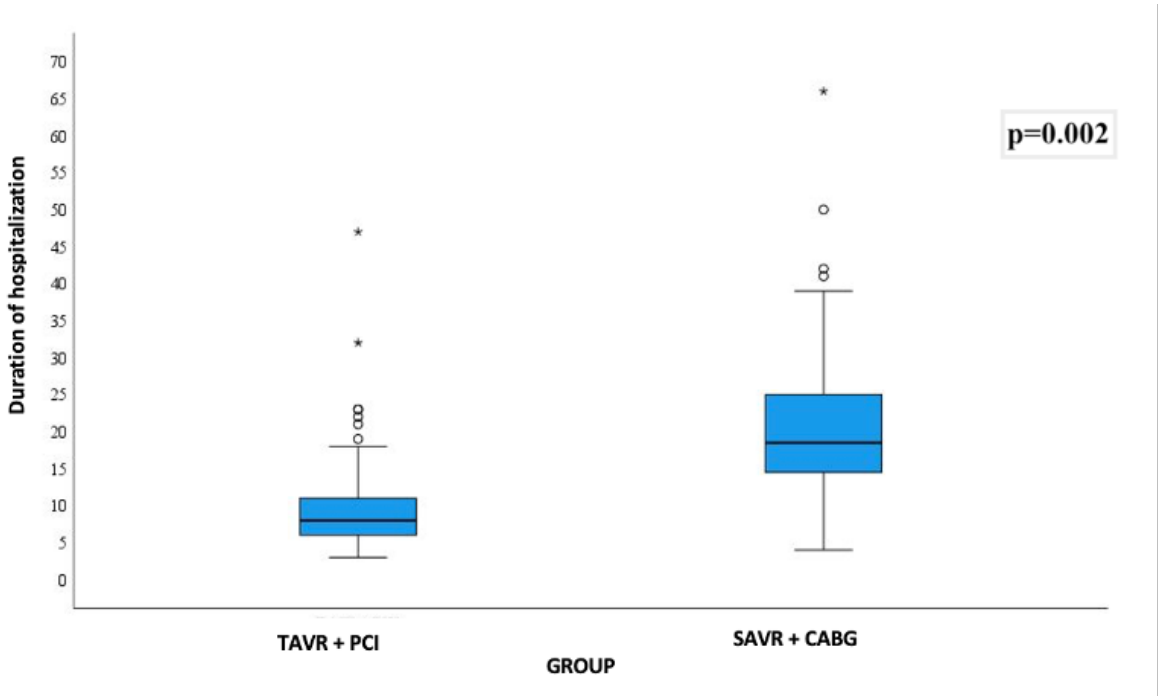

Figure 4. Differences in duration of hospitalization between groups after intervention. **Abbreviations: CABG** – coronary artery bypass grafting; **PCI** – percutaneous coronary intervention; **SAVR,** surgical aortic valve replacement; **TAVR,** transcatheter aortic valve replacement.

To evaluate long term outcomes – mortality rate yearly for four years was assessed. There was a tendency – short term mortality rate (at 30-days follow-up and at one year follow – up) was higher in SAVR + CABG group, long term (at 2 years, 3 years and four years follow – up) mortality rate was higher in TAVR + PCI group, but these differences were not significant (Figure 5).

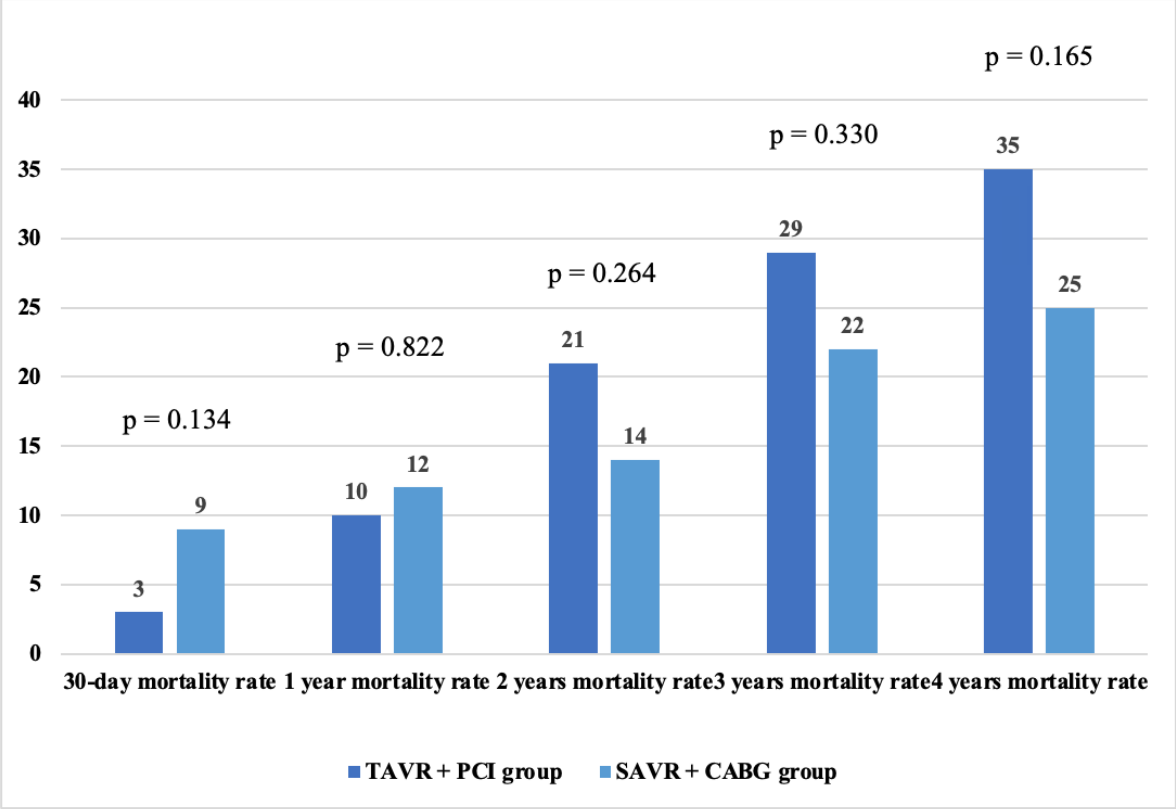

Figure 5: Mortality rate between groups in 30-day period and at follow-up for four years. **Abbreviations: CABG** – coronary artery bypass grafting; **PCI** – percutaneous coronary intervention; **SAVR,** surgical aortic valve replacement; **TAVR,** transcatheter aortic valve replacement.

Undergoing transcatheter aortic valve implantation there were implanted artificial aortic valves from different manufacturers: 82 of Medtronic CoreValve System (Medtronic, Minneapolis, Minnesota), 16 of "Acurate" (Boston Scientific, Marlborough, Massachusetts) and 2 of Myval™ (Meril Life Sciences Pvt. Ltd., Vapi, Gujarat, India) in TAVR + PCI group. In SAVR + CABG group, there were implanted 75 of "St. Jude Medical" (Abbott Laboratories, Abbott Park, Ill) and 25 "Sorin Group" (USA Inc, Arvada, CO, USA) artificial biological aortic valves.

Discussion

In this retrospective study, patients with AS and CAD who had TAVR + PCI were compared to those who had SAVR + CABG. Following 30 days analysis, those patients who had TAVR + PCI had shorter length of stay, lower odds for AKI, RBC transfusion and lower rate of NOAF.

According to literature, the reason for the postoperative development of NOAF after the replacement of the aortic valve may be related to electrolyte disbalance, systemic inflammatory reaction and local pericardial and myocardial inflammation after the surgery [9]. Nevertheless, despite that NOAF after surgical procedures in most cases is transient, but it is related to higher rate of stroke and mortality [10].

The higher rate of AKI in SAVR + CABG group may be due to relative renal ischemia associated with reduced cardiac output with cardiopulmonary bypass during the surgery [11]. Also, higher rate of RBC transfusions may be related to the scope of the intervention – SAVR + CABG are surgical procedures and due to that the hemorrhage during the surgery is higher and more prevalent than during the interventional procedure [12]. Also, the nature of a complex surgery may also had impact on higher rate on RBC transfusions comparing to isolated CABG.

Based by literature - new third-degree atrioventricular block (AVB) is more common in patients after TAVR than after SAVR – this may be due to the anatomical characteristics of the aortic root

- below the right coronary cusp and the noncoronary cusp is the septal membrane part, which contains the atrioventricular bundle branch, which is very superficially located under the endocardium, where the AVB will occur with slight compression or injury – this may happen if the prosthesis is placed too deeply into the left ventricular outflow tract [13]. The prevalence of pacemaker implantation following SAVR and TAVR ranges between 6.6% and 16.5% respectively [14-16]. In our study third-degree AVB was more prevalent in TAVR group, but this difference was not statistically significant. This data is consistent with isolated TAVR and SAVR procedures.

In our study, there was no significant difference in short and long-term mortality between patients who underwent TAVR + PCI or SAVR + CABG, although there was a trend toward TAVR + PCI group had lower short-term mortality but higher long-term mortality. It is associated with the fact that patients in the TAVR + PCI group were older and had higher surgical risk scores, comorbidities and frailty than patients in the SAVR group. Also, there was no significant difference in the vascular complications, infectious endocarditis, sepsis and rate of new permanent pacemaker implantation.

Postoperative valve performance data showed that the peak gradient was lower in TAVR+PCI group, while the rates of significant aortic regurgitation were higher in this group. As demonstrated in other trials, TAVR prostheses have superior forward hemodynamics compared to surgical stented prostheses with larger effective orifice area and lower transprosthetic pressure gradients, but more paraprosthetic aortic regurgitation [17,18]. The reported prevalence of paravalvular leak after TAVR varies from 7% to 40% [19]. Recent data suggest that the presence of paravalvular aortic regurgitation, regardless of degree, can negatively affect clinical outcomes and be associated with increased mortality [20].

These findings are similar to those of previous studies. 2019 published meta-analysis of aggregated data of seven randomized trials in 8020 patients with symptomatic, severe AS demonstrates that TAVR was linked to a higher risk of permanent pacemaker implantation and major vascular complications, but a reduced risk of major bleeding, NOAF, and AKI [21].

The limitations of the present study were mainly related to the retrospective nature, and the small sample size and non-randomized nature of the current study. Longer periods of follow-up and larger patients number are needed to appreciate the effect of either strategy on survival and rate of reintervention.

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