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Comparison of Balloon-Expandable and Self-Expandable Valves in Patients with Transcatater Aortic Valve Implantation in Terms of Demographic and Complications and Evaluation of the Predictors of Complications: A Retrospective Single Center Experience

Transkatater Aort Kapak İmplantasyonu Olan Hastalarda Balonla Genişleyebilir ve Kendinden Genişleyebilir Kapakların Demografik ve Komplikasyonlar Açısından Karşılaştırılması ve Komplikasyonların Öngördürücülerinin Değerlendirilmesi: Retrospektif Tek Merkez Deneyimi

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ABSTRACT Objective: Transcatheter aortic valve implantation (TAVI) offers an alternative to surgery for patients with symptomatic severe aortic stenosis. Currently, the most commonly used valves for clinical use are the Balloon-expandable Edwards SAPIEN and Self-expandable CoreValve Revalving valves. The aim of our study is to compare these valve types used in TAVI procedures performed in our center and to determine the predictors of complications. **Material and Methods:** 96 patients who underwent TAVI in our center were included in our study. Pre-procedural clinical, laboratory and echocardiographic data of patients who underwent TAVI were reviewed retrospectively. **Results:** Complications developed in 31 (32.3%) of the patients. Total complications were found to be higher in patients with balloon-expandable valve (18 vs. 13, p=0.036, respectively). In patients who developed complications, hemoglobin and hematocrit values at the time of admission to the hospital were found to be significantly lower, and C-reactive protein was found to be high. Among the echocardiographic findings at admission, the aortic valve area was found to be narrower and the maximum and mean gradient was higher in patients with complications. **Conclusion:** In our study, a lower complication rate was observed in self-expandable valves. Some independent markers of TAVI-specific complications and mortality were identified. Examination of new predictors and development of a TAVI-specific scoring system may be considered in future prospective controlled studies.

Keywords: Aortic valve diseases; aortic valve stenosis; transcatheter aortic valve replacement; postoperative complications

ÖZET Amaç: Transkateter aort kapak implantasyonu [transcatheter aortic valve implantation (TAVI)], semptomatik ciddi aort darlığı olan hastalarda cerrahiye bir alternatif sunar. Şu anda klinik kullanım için en yaygın kullanılan valfler, Balonla genişletilebilir Edwards SAPIEN ve Kendiliğinden genişletilebilir CoreValve Revalving valfleridir. Çalışmamızın amacı, merkezimizde uygulanan TAVI işlemlerinde kullanılan bu kapak tiplerini karşılaştırmak ve komplikasyonların öngörücülerini belirlemektir. **Gereç ve Yöntemler:** Çalışmamıza, merkezimizde TAVI uygulanan 96 hasta dâhil edildi. TAVI uygulanan hastaların işlem öncesi klinik, laboratuvar ve ekokardiyografik verileri retrospektif olarak incelendi. **Bulgular:** Hastaların 31'inde (%32,3) komplikasyon gelişti. Balonla genişleyebilir kapaklı hastalarda toplam komplikasyon daha yüksek bulundu (sırasıyla 18'e karşı 13, p=0,036). Komplikasyon gelişen hastalarda hastaneye başvuru anındaki hemoglobin ve hematokrit değerleri anlamlı olarak düşük, C-reaktif protein ise yüksek bulundu. Başvuru anındaki ekokardiyografik bulgular arasında komplikasyon gelişen hastalarda aort kapak alanı daha dar, maksimum ve ortalama gradiyent daha yüksek bulundu. **Sonuç:** Çalışmamızda kendiliğinden genişleyen kapaklarda daha düşük komplikasyon oranı gözlendi. TAVI'ya özgü komplikasyonların ve mortalitenin bazı bağımsız belirteçleri belirlendi. Gelecekteki prospektif kontrollü çalışmalarda, yeni öngörücülerin incelenmesi ve TAVI'ya özgü bir skorlama sisteminin geliştirilmesi düşünülebilir.

Anahtar Kelimeler: Aort kapak hastalığı; aort kapak stenozu; transkateter aort kapağının değiştirilmesi; postoperatif komplikasyonlar

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Transcatheter aortic valve implantation (TAVI) is a treatment modality that can be applied in patients with severe aortic valve stenosis. It appears as an alternative to surgical treatment.[1] It has made significant strides since it was first implemented in 2002 by Cribier et al.[2] Although this treatment method was initially developed for patients at high risk of surgery, it has also been applied to patients at moderate risk in recent years.[3] Two valves in especially are widely used in TAVI (Figure 1); these are self-expandable (SE) Medtronic CoreValve (Medtronic CoreValve family, Medtronic Inc., Minneapolis, MN, USA) and balloon-expandable (BE) Edwards SAPIEN (Edwards SAPIEN family, Edwards Lifesciences, Irvine, CA USA) valve.

Edwards SAPIEN valves were constructed by placing three bovine pericardial leaflets on a cobalt chrome frame. During rapid pacing, these valves are expanded by inflating the balloon contained within. Medtronic CoreValve valves, on the other hand, are formed by inserting three porcine pericardial leaflets into a self-expanding nitinol framework. In spite of advances, TAVI devices have limitations, such as the inability to restore or reposition after full expansion, hemodynamic deterioration during implantation or wide access sheath dimension. The requirement for permanent pacemaker (PPM) implantation is another significant restriction, especially for SE valves, but the effect on outcome is uncertain.[4] In addition, paravalvular leak (PVL) may occur, whose moderate or severe form is associated with higher mortality.[5] Advances in valve technology reduce mortality, bleeding, stroke, PVL and other complications.

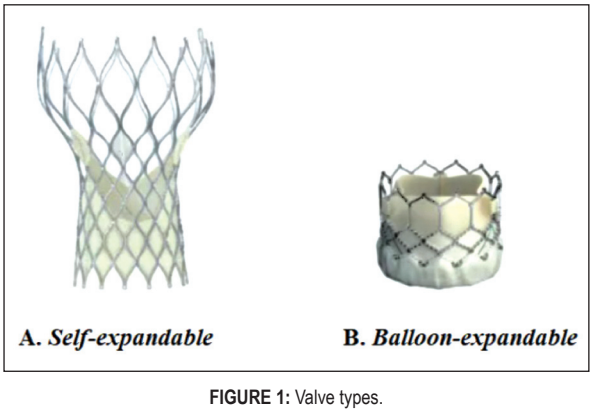

FIGURE 1: Valve types.

In our country, TAVI operations started in 2009 and has been tried to be performed and developed successfully.[6] Our aim in this study is to compare BE and SE valves in terms of demographic characteristics and complications, and to evaluate predictors of in-hospital complications in our 96 TAVI patients that we have operated and followed up in our clinic since the beginning of 2013.

MATERIAL AND METHODS

SELECTION OF PATIENTS

Our study was approved by the local ethics committee (Dicle University Faculty of Medicine Ethics Committee, date February 15, 2018 and file number 89). A consent forms required for participation in the study were obtained from all patients. Patient data were reviewed retrospectively. Our study complies with the Declaration of Helsinki (2013). This study enrolled 96 patients who had symptomatic severe aortic stenosis (AS) with high surgical risk and undergone a TAVI procedure in our center. Transfemoral sheath access was used to implant BE and SE devices.

Patients with symptoms, mean aortic valve gradient >40 mmHg, aortic valve area (AVA) <1 cm^2, EuroSCORE II ≥8, Society of Thoracic Surgeons (STS) score ≥8 (patients before 2017 were taken to TAVI procedure according to STS>10, Logistic Euroscore >20 according to ESC 2012 guideline, functional capacity ≥II, and surgical contraindications were included in the study.[7] The exclusion criteria included basically a narrow or very wide aortic valve annulus (≤18 mm or ≥30 mm) in patients' transthoracic echocardiography, narrowing of the aortic outflow tract with advanced sigmoid septum hypertrophy, a distance of <8 mm between the aortic calcific nodule and the main coronary artery, acute myocardial infarction, severe stenosis in the left main coronary artery, life expectancy of less than 12 months due to non-cardiac diseases, active infection, hemiplegia, inability to maintain hemodynamic stability before operation, and previous aortic root and valve surgery. The reasons for exclusion of our patients from aortic valve replacement were generally advanced age, chronic obstructive pulmonary disease (COPD), left heart failure, renal failure, malignancy, hemodynamic disorder and additional valve pathologies.

PRE-INTERVENTIONAL EVALUATION

In order to evaluate the aortic valve and root anatomy in detail, patients were evaluated with transthoracic echocardiography, transesophageal echocardiography and multi-detector computed tomography. Echocardiographic examinations were performed with the GE Vivid 5 (5-1 MHz multi-frequency probe, GE Medical Systems, Milwaukee, USA) device. Left ventricular ejection fraction (LVEF) was measured by Modified Simpson's method in apical four-chamber imaging. Aortic valve evaluation was performed by similar operators before and after the procedure. Coronary angiography was performed to evaluate the coronary anatomy. Dobutamine stress echo test was performed on 10 patients with serious low-flow low-gradient AS combined with low EF who had LVEF of 50% and mean gradient below 40 and 2 patients with low-flow low-gradient AS combined with preserved EF who had mean gradient below 40 and LVEF of ≥50% to examine whether valve stenosis is serious. A multidisciplinary team consisting of 2 cardiologists, 2 cardiac surgeons and 1 anesthesiologist decided whether to perform TAVI.

STATISTICAL ANALYSIS

"SPSS 18.0 software (SPSS Inc, Chicago, Illinois, USA)" statistical program was used. Using the Kolmogorov-Smirnov test, it was determined whether the continuous variables were normally distributed. Normally distributed variables were defined as mean±standard deviation, and non-normally distributed variables were defined as median (interquartile range) values. Normally distributed continuous variables were evaluated with the Student's t-test, and non-normally distributed continuous variables were evaluated using the Mann-Whitney U test. Categorical variables were compared using chi-square and Fisher exact tests. Binary logistic regression analysis was used to determine the independent predictors of complications. p value <0.05 was considered statistically significant.

RESULTS

TAVI was applied to 96 patients in our center between April 01, 2013 and January 01, 2018. Of these 96 patients, 60 (62.5%) were female and 36 (37.5%) were male. The mean age was 78.5±6.6 years. The demographic characteristics of the patients are summarized in Table 1. In the echocardiographic imaging before the procedure, the maximum gradient was 79.1±20.2 mmHG, the average gradient was 48.7±12.8 mmHG and the average AVA was 0.72±0.13 cm^2.

Of the implanted valves, 41 (42.8%) were Edwards SAPIEN and 55 (57.2%) were CoreValve Medtronic. Complications developed in 31 (32.3%) patients. Complication rates were not statistically significant in terms of gender [22 (36%)/9 (25%), p=0.237]. Death occurred in the periprocedural period in 12 (12.5%) of patients who underwent the procedure. Patients who developed death were older than the other patients (84.08±3.60 vs. 77.68±6.18, p=0.001, respectively) and had more comorbidities. Of the 12 patients who developed mortality, 4 had cardiac tamponade, 3 had malignant arrhythmia, 2 had complete atrioventricular (AV) block, 1 had coronary embolism, 1 had iliac artery injury and 1 had infection. The length of hospitalization of the patients was minimum 1, maximum 22 and average 4.87 days.

We performed TAVI transfemorally in all our patients. A closure device was used in all patients.

TABLE 1: Basic patient demographics at the time of admission.

	Patients who underwent TAVI (n=96)
Age	78.5±6.6
Gender M/F, n (%)	36 (37.5)/60 (62.5)
Complaint at the time of admission, n (%)	
1. Dyspnea	74 (77.1)
2. Angina	16 (16.7)
3. Syncope	6 (6.3)
Hypertension, n (%)	51 (53.1)
Diabetes mellitus, n (%)	25 (26)
CAD, n (%)	41 (42.7)
HPL, n (%)	18 (18.8)
CABG, n (%)	12 (12.5)
COPD, n (%)	24 (25)
CKD, n (%)	27 (27)
AF, n (%)	14 (14.6)
EuroSCORE II	10.7 (7.1-20.3)*
STS	17.7 (13.0-23.3)*
Smoking, n (%)	23 (24)

*Interquartile range; TAVI: Transcatheter aortic valve implantation; CAD: Coronary artery disease; HPL: Hyperlipidemia; CABG: Coronary artery bypass graft; COPD: Chronic obstructive pulmonary disease; CKD: Chronic kidney disease; AF: Atrial fibrillation; STS: Society of Thoracic Surgeons.

77.1% of patients presented with dyspnea, 16.7% with angina and 6.3% with syncope. Comorbidities were observed with hypertension in 53% of patients, diabetes mellitus in 26%, coronary artery disease in 42.7%, hyperlipidemia in 18.8%, COPD in 25%, and chronic kidney disease in 28.1% of patients. In addition, 12.5% of the patients had a previous coronary artery bypass graft operation. 1 patient had mitral valve repair and 1 patient had a bicuspid aortic valve.

COMPARISON OF VALVES

BE valve was implanted to 41 of the patients and self-expanding valve was implanted to 55 of the patients. Pre-dilatation was significantly more performed in BE valves (28 vs. 25, p=0.026, respectively). We found a statistically higher rate of complications in the BE valve (18 vs. 13, p=0.036, respectively). These complications are cardiac tamponade (BE: 5, SE: 2), complete AV block (BE: 2, SE: 7), femoral artery injury (BE: 3, SE: 1), infection (BE: 2, SE: 0), malignant arrhythmia (BE: 2, SE: 2), coronary embolism (BE: 1, SE: 0), iliac artery injury (BE: 1, SE: 1) and stroke (BE: 2, SE: 0). PPM was implanted in all patients who developed block. Primary surgical repair was performed in patients with arterial injury. One patient who developed coronary embolism underwent coronary angiography with successful stent implantation. Pericardiocentesis was performed urgently in patients with tamponade. Patients who underwent TAVI had a high mean STS score, as they had many advanced-stage risk factors [BE: 20.0 (15-25.5), SE: 15.7 (11.3-22), p=0.193, respectively]. In the periprocedural period, 7 deaths occurred in patients with BE valve while 5 deaths occurred in patients with self-expanding valve. The general characteristics of both valves are summarized in Table 2.

ASSESSMENT OF COMPLICATION PREDICTORS

Complications occurred in 31 patients. Of those who developed complications, 9 were men and 22 were women. The length of hospitalization was observed to be longer in patients who developed complications (Table 3). In the laboratory parameters at admission, it was observed that hemoglobin (HGB) and hematocrit (HCT) were significantly lower and C-reactive protein (CRP) were higher in patients who developed complications (11.3±1.7 vs. 12.3±1.9, p=0.020, 34.8±4.3 vs 38.3±5.3, p=0.002, 3.4±5.4 vs 1.5±3.1,

TABLE 2: Characteristics of patients with balloon-expandable and self-expanding valves.

		Balloon-expandable (n=41)	Self-expandable (n=55)	p value
Age, years		79.4±7.9	77.6±5.4	0.224
Gender (male/female)		13/28	23/32	0.311
Maximum gradient (mmHG)		75±17.4	82.45±21.8	0.074
Mean gradient (mmHG)		46.2±10.9	50.8±13.9	0.079
STS		20.0 (15-25.5)**	15.7 (11.3-22.0)**	0.193*
EuroSCORE II		11.5 (8.2-21.7)**	9.8 (6.7-20.0)**	0.120*
HT, n (%)		23 (56)	28 (50)	0.614
DM, n (%)		13 (31)	12 (21)	0.275
CAD, n (%)		17 (41)	24 (43)	0.831
HPL, n (%)		10 (24)	8 (14)	0.222
Pre-dilatation, n (%)		28 (68)	25 (45)	**0.026**
Post-dilatation, n (%)		16 (39)	20 (36)	0.790
COPD, n (%)		11 (26)	13 (23)	0.721
CKD, n (%)		13 (31)	14 (25)	0.500
Hospitalization time, day		5.35±4.4	4.49±4.1	0.207
Complication, n (%)		18 (43)	13 (23)	**0.036**
Death, n (%)		7 (17)	5 (9)	0.242
Paravalvuler leak, n (%)	Mild	15 (36)	24 (43)	0.487
	Moderate-severe	1 (2)	3 (5)	0.465

*Mann-Whitney U test was used; **Interquartile range; STS: Society of Thoracic Surgeons; HT: Hypertension; DM: Diabetes mellitus; CAD: Coronary artery disease; HPL: Hyperlipidemia; COPD: Chronic obstructive pulmonary disease; CKD: Chronic kidney disease.

TABLE 3: Comparison of general characteristics of patients with and without complications.

	With complications (n=31)	Without complications (n=65)	p value
Gender (M/F) n (%)	9 (29)/22 (71)	27 (41)/38 (59)	0.237
Age, years	80.32	77.60	0.061
HT, n (%)	18 (58)	33 (50)	0.503
DM, n (%)	8 (25)	17 (26)	0.971
CAD, n (%)	12 (38)	29 (43)	0.584
HPL, n (%)	7 (22)	11 (16)	0.507
Pre-dilatation, n (%)	21 (67)	32 (49)	0.088
Post-dilatation, n (%)	14 (45)	22 (33)	0.284
COPD, n (%)	6 (19)	18 (27)	0.378
CKD, n (%)	10 (32)	17 (26)	0.534
CABG, n (%)	4 (12)	8 (12)	0.934
Valve type, BE/SE	18 (58)/13 (42)	23 (35)/42 (65)	**0.036**
AF, n (%)	2 (6)	12 (18)	0.119
Smoking, n (%)	6 (19)	17 (26)	0.466
STS	18.0 (15.0-25.0)**	16.4 (11.9-23.2)**	0.193*
EuroSCORE II	11.3 (8.1-23.0)**	10.4 (6.8-19.1)**	0.120*
Hospitalization time, day	6.39±5.8	4.15±3.3	**0.020**

*Mann-Whitney U test was used; **Interquartile range; HT: Hypertension; DM: Diabetes mellitus; CAD: Coronary artery disease; HPL: Hyperlipidemia; COPD: Chronic obstructive pulmonary disease; CKD: Chronic kidney disease; CABG: Coronary artery bypass graft; BE: Balloon-expandable; SE: Self-expandable; AF: Atrial fibrillation; STS: Society of Thoracic Surgeons.

p=0.034, respectively). No significant difference was observed in other laboratory findings at admission (Table 4). In Echo parameters at the time of admission, AVA was lower (0.67±0.17 vs. 0.75±0.10, respectively; p=0.007), while maximum and mean gradients were significantly higher in patients with complications (86.9±23.7 vs. 75.3±17.3, p=0.008 and 54.6±15.6 vs. 45.98±10.1, p=0.002, respectively) (Table 5). The average hospitalization length was 6.39±5.8 days in patients with complications and 4.15±3.3 days in patients without complications (p: 0.020).

TABLE 4: Laboratory findings at the of admission for patients with and without complications.

	With complications (n=31)	Without complications (n=65)	p value
WBC (x10^3/uL)	7.7±3.1	8.2±2.4	0.428
HGB (g/dL)	11.3±1.7	12.3±1.9	**0.020**
HCT (%)	34.8±4.3	38.3±5.3	**0.002**
RBC (M/uL)	4.2±0.6	4.4±0.6	0.071
PLT (10e^3/uL)	211±70	225±71	0.355
RDW (%)	13.1±1.6	13.3±2.2	0.714
Creatinine (mg/dL)	0.8 (0.7-1.1)**	0.8 (0.7-1.2)**	0.882*
BUN (mg/dL)	45 (36-69)**	45 (37-64)**	0.953*
GFR (mL/min)	54 (42-65)**	59 (42.5-74.5)**	0.422*
Albumin (g/dL)	3.1±0.53	3.3±0.4	0.240
Sodium (mmol/L)	136.3±3.6	136.9±4.0	0.446
Potassium (mmol/L) (mmol/L)	4.6±0.5	4.5±0.5	0.393
CRP (mg/dL)	3.4±5.4	1.5±3.1	**0.034**

*Mann-Whitney U test was used; **Interquartile range; WBC: White blood cell; HGB: Hemoglobin; HCT: Hematocrit; RBC: Red blood cell; PLT: Platelet; RDW: Red cell distribution width; BUN: Blood urea nitrogen; GFR: Glomerular filtration rate; CRP: C-reactive protein.

TABLE 5: Echocardiography findings at the time of admission for patients with and without complications.

	With complications (N=31)	Without complications (N=65)	p value
AVA (cm²)	0.67±0.17	0.75±0.10	**0.007**
EF (%)	60 (50.0-60.0)**	50 (42.5-60.0)**	0.130*
LA diameter (cm)	4.4±0.67	4.5±0.61	0.507
IVS diameter (cm)	1.38±0.16	1.37±0.16	0.785
PW diameter (cm)	1.30±0.15	1.31±0.15	0.752
LVEDD (cm)	4.78±0.64	4.96±0.70	0.224
LVESD (cm)	3.14±0.70	3.4±0.88	0.095
sPAP (mmHG)	45.3±12.8	47.2±16.1	0.579
Maximum gradient (mmHG)	86.9±23.7	75.3±17.3	**0.008**
Mean gradient (mmHG)	54.6±15.6	45.98±10.1	**0.002**

*Mann-Whitney U test was used; **Interquartile range; AVA: Aortic valve area; EF: Ejection fraction; LA: Left atrium; IVS: Interventricular septum; PW: Posterior wall; LVEDD: Left ventricular end-diastolic dimension; LVESD: Left ventricular end-systolic dimension; sPAP: Systolic pulmonary arterial pressure.

TABLE 6: Independent predictors of TAVI complications.

	β	SE	Wald	OR (95% CI)	p value
Valve type (BE)	-1.392	0.589	5.581	0.248 (0.078-0.789)	**0.018**
Hemoglobin	-0.998	0.492	4.106	0.369 (0.141-0.968)	**0.043**
Hematocrit	0.444	0.193	5.278	1.558 (1.067-2.275)	**0.022**
C-reactive protein	-0.186	0.073	6.386	0.831 (0.719-0.959)	**0.012**

TAVI: Transcatheter aortic valve implantation; ß: ß coefficient; SE: Standard error; OR: Odds ratio; CI: Confidence interval; BE: Balloon-expandable valve.

PREDICTORS AFFECTING COMPLICATIONS IN BINARY LOGISTIC REGRESSION ANALYSIS

The model included variables that may affect the complications according to the binary logistic regression analysis (valve type, HGB, HCT, CRP). According to the analysis, the risk of complications increases by 24% with BE valve implantation, by 36% with one-unit decrease in HGB, by 1.5 times with one-unit decrease in HCT, and by 83% with one-unit increase in CRP (Table 6).

DISCUSSION

While the mean age of the patients included in the study was similar to the PARTNER 2, SOLVE, CENTER studies, it was different that female patients were more than males.[3,8,9] Similar to previous studies, in our study, it was thought that female dominance was related to the fact that the female population was higher than the male population in the elderly population of the country.[10,11]

A periprocedural death occurred in 12 (12.5%) of our patients. This rate is higher than some studies in recent years.[12-14] A balloon-expanding valve was implanted in 7 of these patients, while a self-expanding valve was implanted in 5 of them. Patients who died were older and had more comorbidities than others. In addition, deaths in general can be attributed to the inexperience of our center in the first years and the use of old generation valves at that time. Periprocedural death was not observed in TAVI procedures performed at our center within the past 1 year. With the increasing experience of our center and the development of valve technology, lower mortality and complication rates are observed in TAVI procedures.

Complications developed in 31 (32.3%) of our patients. In our center, complication rates were statistically significantly higher in patients with Edwars SAPIEN valve implants (p=0.036). Only AV complete block (SE: 7, BE: 2) was high in patients with self-expanding valves and other complications were more common in those with BE valves. This may be

due to the use of more Edwards SAPIEN valves in our center in the first years. Because of the lack of experience at that time and the fact that valve technology was not yet fully developed, the complication rates were higher in those years.

PPM rate in various studies was found between 7-12% in BE valve, and over 20% in SE valve.[9,15-17] We have a lower PPM implant rate at our center, with 4% for Edwars SAPIEN valves and 12% for CoreValve Medtronic valves. The incidence of heart block after TAVI is likely related to the number of repositioning attempts and implant depth. Also, the need for additional balloon valvuloplasty, balloon-prosthesis size, and anatomical factors with more severe calcification are well-known factors for PPM implantation. A significant increase in mortality can be observed with new-onset left bundle branch block and high AV block in patients undergoing TAVI.[16] Therefore, heart rhythm should be monitored regularly after discharge.

In our current study, ischemic stroke was numerically higher with BE valve compared to SE valve (SE: 0, BE: 2). While the results we found were similar to the SOLVE study, a lower stroke rate was found with the BE valve in the CENTER study.[8,9] The CENTER study in a large patient population hypothesized that the SE valve implantation mechanism would cause more strokes. As a result, our findings with fewer patients may be coincidental. Periprocedural strokes can be reduced with cerebral embolic protection devices. It reduced stroke rates in a recent individual patient-based meta-analysis (1.9% vs. 5.4%, p=0.0028).[18] It will be necessary to conduct future studies to determine how cerebral embolism protection devices affect clinical outcomes during TAVI.

In our study, a total of 6 (6.3%) major artery injuries were detected, including 4 femoral artery injuries and 2 iliac artery injuries. In a recent study conducted in North America, 3.7% of major artery injuries were observed.[19] With careful patient selection, increasing experience, development of access techniques, and reduction of sheath sizes, major artery injuries are expected to decrease to even lower levels.

In the current literature, cardiac tamponade after TAVI can be seen at rates of up to 4%.[20] In our study, cardiac tamponade was observed in 7 (7.3%) patients. Causes of cardiac tamponade in TAVI patients; pericardial bleeding after annular or aortic root rupture during balloon valvuloplasty, perforation of the right ventricle by the temporary pacing lead and perforation of the left ventricle with a rigid guidewire during the procedure.[21] Therefore, cardiac tamponade can be observed at higher rates in BE valves.

Of those who developed complications, 9 were men and 22 were women. No statistically significant difference was found between women and men. As expected, hospital stays were longer for patients who had complications. We found that low HGB and HCT and high CRP among laboratory parameters increase the risk of complications. In addition, in patients who developed complications, the valve area was narrower, maximum and mean gradient higher, among the echo parameters at presentation. These findings need to be supported by multicenter prospective studies. Post-procedure mild and moderate-severe PVL rates were similar in both groups. Especially in the Core valve patient group, we found the moderate-to-severe PVL rate lower than in previous studies.[22-24] The ratios we find may be coincidental.

STUDY LIMITATIONS

The number of men and women was not close to each other. In some patients, the procedure was performed under general anesthesia and in others only by sedation, without intubation. Complications were assessed without distinguishing between these patients. TAVI operations were performed by several different operators. There was a difference in experience between these operators. Another limitation of this study is the decrease in homogeneous structure as a result of the placement of different generations and different brands of valves, since the time of the operation coincided with the development period of valve technology.

CONCLUSION

BE valves had a higher overall complication rate in our study. In patients with complications, narrower valve area, higher gradients, low HGB and HCT values, and increased CRP were found. In addition to the independent predictors identified in our study, it is necessary to examine new predictors in randomized prospective controlled studies and develop a scoring system that predicts TAVI-specific complications and mortality.

Source of Finance

During this study, no financial or spiritual support was received neither from any pharmaceutical company that has a direct connection with the research subject, nor from a company that provides or produces medical instruments and materials which may negatively affect the evaluation process of this study.

Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Raif Kılıç, Faruk Ertaş;* ***Design:*** *Raif Kılıç, Tuncay Güzel;* ***Control/Supervision:*** *Raif Kılıç, Faruk Ertaş;* ***Data Collection and/or Processing:*** *Raif Kılıç, Adem Aktan;* ***Analysis and/or Interpretation:*** *Raif Kılıç, Bayram Arslan;* ***Literature Review:*** *Raif Kılıç, Tuncay Güzel;* ***Writing the Article:*** *Raif Kılıç, Adem Aktan;* ***Critical Review:*** *Raif Kılıç, Bayram Arslan.*

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