Acta Medica Alanya

RESEARCH ARTICLE

ARAŞTIRMA

Acta Medica Alanya

2022;6(3): 285-292

DOI: 10.30565/medalanya.1177186

Gender differences in patients undergoing transcatheter aortic valve replacement: a cross-sectional study

Transkateter Aort Kapak Replasmanı Uygulanan Hastalarda Cinsiyet Farklılıkları: Kesitsel Bir Çalışma

Adem Aktan[1*], Faruk Ertaş[2]

1. Mardin Training and Research Hospital, Department of Cardiology, Mardin, Turkey
2. Dicle University, Faculty of Medicine, Department of Cardiology, Diyarbakir, Turkey

ABSTRACT

Aim: Transcatheter aortic valve replacement (TAVR) is an effective treatment modality for patients with high-risk symptomatic severe aortic stenosis (AS) who are not suitable for surgery. Gender-related differences in TAVR are still deliberated, thus in this study we aimed to investigate the effect of gender on clinical outcomes in patients who underwent TAVR in our clinic.
Methods: 270 consecutive patients who underwent TAVR between January 2015 and January 2022 were included in the study. In addition to the patient's medical history, transthoracic or transesophageal echocardiography and computed tomography findings were examined to evaluate AS. Patients with symptomatic, high-risk severe aortic stenosis were treated with self-expanding Evolute-R devices. The patients were followed up for the first year after discharge. Follow-up was done by clinical visits and phone calls.
Results: In-hospital mortality (5.4% vs. 7.4%; p=0.507), death at one-year follow-up (14.9% vs. 13.1%, p=0.681), and major adverse cardiovascular and cerebrovascular events (MACCE) at one-year follow-up (26.4% versus 23.8%, p =0.627) rates, there was no statistically significant difference between male and female genders. Kaplan Meier curves were used for survival analysis, including one-year mortality and MACCE rates. Accordingly, no statistically significant difference was found between the two genders in terms of mortality and MACCE (respectively; p= 0.910; p=0.889).
Conclusion: In our patient group who underwent TAVR, we could not detect a significant difference in clinical outcomes between both genders. In recent years, the effect of gender on clinical outcomes may decrease with device and procedural developments.

Key words: Aortic stenosis, gender, mortality, transcatheter aortic valve replacement

ÖZ

Amaç: Transkateter aort kapak replasmanının (TAVR) cerrahiye uygun olmayan, yüksek riskli semptomatik şiddetli aort darlığı (AS) olan hastalar için etkili bir tedavi yöntemidir. TAVR'da cinsiyete bağlı farklılıklar hala tartışılmaktadır. Bu çalışma ile kliniğimizde TAVR uygulanan hastalarda cinsiyetin klinik sonuçlar üzerine etkisini araştırmayı amaçladık.
Yöntemler: Ocak 2015 ile Ocak 2022 tarihleri arasında TAVR yapılan ardışık 270 hasta çalışmaya dahil edildi. AS'yi değerlendirmek için hastanın tıbbi öyküsünün yanı sıra transtorasik veya transözofageal ekokardiyografi ve bilgisayarlı toraks tomografisi bulguları incelendi. Semptomatik, yüksek riskli şiddetli aort darlığı tespit edilen hastalara kendiliğinden genişleyebilen Evolute-R cihazlarıyla işlem yapıldı. Hastalar taburculuk sonrası ilk bir yıl takip edildi. Takipler klinik ziyaretler ve telefon görüşmeleriyle gerçekleşti.
Bulgular: Hastane içi mortalite (%5.4'e karşı %7.4 ; p=0.507), bir yıllık takipte ölüm (%14.9'e karşı %.13.1, p=0.681) ve bir yıllık takipte majör advers kardiyovasküler ve serebrovasküler olaylar (MACCE) (%26.4'e karşı %23.8, p=0.627) oranları açısından kadın ve erkek cinsiyetleri arasında istatistiksel olarak anlamlı farklılık saptanmadı. Bir yıllık mortalite ve MACCE oranlarını içeren sağkalım analizi Kaplan-Meier eğrileri kullanıldı. Buna göre her iki cinsiyet arasında mortalite ve MACCE açısından istatistiksel olarak anlamlı farklılık saptanmadı (sırasıyla; p= 0.910; p =0.889).
Sonuç: TAVR yapılan hasta grubumuzda her iki cinsiyet arasında klinik sonlanımlar açısından önemli bir farklılık saptayamadık. Son yıllarda cihaz ve prosedürle ilişkili gelişmelerle cinsiyetin klinik sonuçlar üzerine etkisi azaltılmıştır.

Anahtar Kelimeler: Aort darlığı, cinsiyet, mortalite, transkateter aort kapak replasmanı

Received: 19.09.2022 Accepted: 13.11.2022 Published (Online): 31,12,2022

*Corresponding Author: Adem Aktan, Mardin Training and Research Hospital, Department of Cardiology, Mardin, Turkey, +905445412951, dradem21@hotmail.com

ORCID : 0000-0003-0505-9784

To cited: Aktan A, Ertaş F. Gender Differences in Patients Undergoing Transcatheter Aortic Valve Replacement: A Cross-sectional Study Acta Med. Alanya 2022;6(3):285-292 doi: 10.30565/medalanya.1177186

INTRODUCTION

Degenerative aortic stenosis (AS) is the most common heart valve disease in developed countries [1]. The incidence is similar in men and women, and it constitutes nearly half of the valve diseases [2]. The effect of gender differences on clinical outcomes has recently become the focus of attention in cardiology. In that context, the effect of gender differences on clinical outcomes was investigated in cardiac procedures, such as percutaneous coronary intervention (PCI), coronary artery bypass operations (CABGO), catheter ablation in atrial fibrillation and cardiac implantable electronic devices [3 6].

Transcatheter aortic valve replacement (TAVR) has proven to be an effective treatment for patients with high-risk symptomatic severe AS who are not suitable for surgery [7-9]. Degenerative diseases are more common in women than in men, compared to atherosclerotic diseases, therefore the rate of female patients is relatively high in studies of aortic valve diseases in which degeneration is prominent and related to TAVR [10]. Studies have shown that female patients with severe AS undergo fewer aortic valve replacement (AVR) and their prognosis is worse than men [11]. Women do not favour surgery because of their small body structure, co-morbidities, greater avoidance of aggressive treatment and worse AVR results, compared to men [11]. Based on these studies, female gender has been included in The Society of Thoracic Surgeons (STS) risk score used for postoperative mortality, and has become an independent risk factor for surgery [12].

Although many studies have been reported on complications and mortality by gender after TAVR, the results are quite inconsistent [13]. Studies have shown that there is no clear consensus on the differences according to gender before and after TAVR and the situations related to protection from cardiovascular events that may develop as a result [14]. In this retrospective observational study, we aimed to investigate the effect of gender on clinical outcomes, in patients who underwent TAVR in our clinic.

MATERIALS AND METHODS

Study design

This was a retrospective study conducted with patients who underwent TAVR between January 2015 and January 2022. Some 270 consecutive patients who underwent elective or emergency transfemoral TAVR were included in the study. Patients undergoing TAVR were evaluated with a multidisciplinary approach before the procedure. A team of experienced interventional cardiologists performed the procedure. The study was conducted in accordance with the Declaration of Helsinki.

Eligibility Criteria

Inclusion criteria for the study were determined as follows: a) The patients with symptomatic severe AS who were considered as high-risk for valve surgery b) Patients evaluated as suitable for TAVR by a multidisciplinary team (a special cardiac team consisting of invasive and non-invasive cardiologists, cardiac surgeons and anesthesiologists), c) Criteria for severe AS: determined by echocardiography AV Doppler mean gradient was accepted as >40 mm Hg or peak jet velocity >4.0 m/s, and aortic valve area <1 cm2 or aortic valve index <0.5 cm2/m2.

Patients with a previous history of pacemaker implantation, TAVR or surgical AVR or bicuspid aortic valve, were excluded from the study. Furthermore, patients with a prior of infective endocarditis within the last six months, cardiogenic shock, life expectancy lower than one-year due to malignancy, were also excluded.

TAVR procedure and clinical follow-up

In addition to the patient's medical history, transthoracic or transesophageal echocardiography and computed tomography of the thorax were used to evaluate AS. Patients with symptomatic, high-risk severe AS were treated with self-expanding Evolute-R devices. TAVR procedures were performed by experienced invasive cardiologists, in a single center. Device selection and procedure was left to the discretion of the operator. The patients were followed up for the first year after discharge, which was ensure through clinical visits and phone calls.

Endpoints and definitions

In our study, the gender differences were compared in a heterogeneous patient population undergoing TAVR. The clinical endpoint was accepted as one-year rates of all-cause mortality and major adverse cardiovascular and cerebrovascular events (MACCE).

Statistical analysis

The SPSS (IBM, USA, version 25) was used for statistical analysis. Categorical variables were presented as percentages (%) and statistical analysis was done with the Chi-square test or Fisher's exact test. The distribution of continuous variables was evaluated by the Kolmogorov-Smirnov and Shapiro-Wilk tests. Normally distributed continuous variables were expressed as mean [standard deviation (SD)] or as median (interquartile range) in case of skewed distribution. Continuous variables between two independent groups were analyzed by the Student's t-test or Mann-Whitney U test, as appropriate. Log rank test and the Kaplan-Meier curve were used to determine the difference in event-free survival rates between the two groups. A p value of < 0.05 was considered statistically significant.

RESULTS

Baseline characteristics

A total of 270 patients were included in the study: 148 patients (54.8%) were in the female gender group and 122 patients (45.2%) were in the male gender group. Key characteristics of the study population are summarized in Table 1. The mean age of women was 80.1 (6.2) years, and the mean age of men was 77.8 (6.3) years. There was a significant difference between the groups (p=0.003). The New York Heart Association (NYHA) was used to measure the functional capacity of the patients before the procedure, and most of the patients were in the NYHA 3-4 (96.3%) group: there was no significant difference between the two groups (98% vs. 94.3%, p=0.108).

The most common comorbid disease in the study population was hypertension (55.9%), followed by anemia (53%), heart failure (38.5%), chronic renal failure (28.5%), dyslipidemia (25.2%), diabetes mellitus (24.4%) and atrial fibrillation (23.3%). There was no significant difference between the two groups in terms of body mass index, hypertension, diabetes mellitus, dyslipidemia, chronic obstructive pulmonary disease (COPD), history of cerebrovascular disease (CVD), chronic renal failure, anemia or atrial fibrillation. Other demographic and clinical characteristics of the patients are summarized in Table 1.

The proportion of men was higher in patients with prior PCI (28.4% vs. 35.2%, p=0.227) or a history of CABGO (6.1% vs. 20.5%, p<0.001). Likewise, heart failure was significantly higher in males across groups (25.7% vs. 54.1%, p<0.001, respectively). Smoking was significantly higher in males (14.9% vs. 37.7%, respectively, p<0.001). Although the rate of peripheral arterial disease was low in both populations, it was more common in males (1.4% vs. 4.9%, respectively, p=0.146). The size of the implanted valve was significantly higher in males (27.32(2.86) mm vs. 30.45(3.27) mm, p<0.001) (Table 1). There was no significant difference between the groups in terms of balloon predilatation and postdilatation rates (predilatation p=0.982, postdilatation p=0.774). Left ventricular ejection fraction (LVEF) was significantly lower in males [54.38(9.61) vs 46.81(12.62), p<0.001, respectively]. From left ventricular parameters: LVEDD (p<0.001), LVESD (p<0.001), LAD (p=0.012) were found to be low in women, while IVSD (p<0.001) was found to be high in men. The ascending aortic diameter was lower in women than in men (3.59(0.54) vs. 3.77(0.53), p=0.025, respectively). The rate of moderate-to-severe aortic regurgitation (AR) was significantly higher in women (16.8% vs. 7%, p=0.014). Moderate-severe mitral regurgitation (MR) (p=0.961) and tricuspid regurgitation (TR) (p=0.314) were not statistically significant between the two groups. Systolic pulmonary artery pressure (SPAP) values were not significant between the groups [42 (20) vs 40 (20), respectively, p=0.801] (Table 2). Echocardiographic and multislice computed tomography data of the patients before and after TAVR are summarized in Table 2.

Study outcomes and clinical endpoints

Although a permanent pacemaker, arrhythmia, acute renal failure, major bleeding and major vascular complications were more common in

Table-1. Baseline characteristics and procedural demographics

Characteristics	Overall n=270 (100%)	Female n=148 (54.8%)	Male n=122 (45.2%)	p value
Age, years	79.08(6.37)	80.13(6.25)	77.80(6.33)	0.003
Body mass index, kg/m²	23.0(2.52)	23.23(3.04)	22.73(1.66)	0.112
STS risk score, %	8.55(2.70)	8.83(3.02)	8.36(2.42)	0.161
NYHA III-IV, n%	260(96.3)	145(98.0)	115(94.3)	0.108
Hypertension, n%	151(55.9)	89(60.1)	62(50.8)	0.125
Diabetes mellitus, n%	66(24.4)	42(28.4)	24(19.7)	0.098
Dyslipidemia, n%	68(25.2)	41(27.7)	27(22.1)	0.294
Previous PCI, n%	85(31.5)	42(28.4)	43(35.2)	0.227
Previous CABGO, n%	34(12.6)	9(6.1)	25(20.5)	<0.001
Prosthesis valve, n%	3(1.1)	2(1.4)	1(0.8)	N/A*
Peripheral artery disease, n%	8(3.0)	2(1.4)	6(4.9)	0.146*
COPD, n%	29(10.7)	11(7.4)	18(14.8)	0.053
Atrium Fibrillation, n%	63(23.3)	40(27.0)	23(18.9)	0.114
Previous CVD, n%	4(1.5)	2(1.4)	2(1.6)	N/A*
Chronic renal failure, n%	77(28.5)	38(25.7)	39(32.0)	0.254
Heart failure, n%	104(38.5)	38(25.7)	66(54.1)	<0.001
Anemia, n%	143(53.0)	82(55.4)	61(50.0)	0.375
Smoking, n%	68(25.2)	22(14.9)	46(37.7)	<0.001
Implanted valve size, mm	28.74(3.42)	27.32(2.86)	30.45(3.27)	<0.001
Balloon Predilatation, n%	73(27.3)	40(27.4)	33(27.3)	0.982
Balloon Postdilatation, n%	64(24.0)	34(23.3)	30(24.8)	0.774

*Data are expressed as mean [standard deviation(SD)] or frequencies (percentages) as appropriate. STS; society of thoracic surgeons, NYHA; New York heart association, PCI; percutaneous coronary intervention, CABGO; coronary artery bypass graft operation, COPD; chronic obstructive pulmonary disease, CVD; cerebrovascular disease. N/A; not applicable. *Fisher Exact test was used

women in terms of procedural complications, no statistically significant difference was found. There was no significant difference between the two groups in terms of the frequency of early hospital readmission after TAVR (4.7% vs. 9.0%, respectively; p=0.160). Additionally, in-hospital mortality (5.4% vs. 7.4%; p=0.507), death at one-year follow-up (14.9% versus 13.1%, p=0.681), and MACCE at one-year follow-up (26.4% versus 23.8%), p=0.627), no statistically significant difference was found between male and female genders (Table 3). Other procedural complications and clinical endpoints are summarized in Table 3.

Accordingly, no statistically significant difference was found between both genders in terms of mortality and MACCE (p= 0.910, Log-rank: 0.013; p=0.889, Log-rank: 0.019, respectively) (Figure 1).

DISCUSSION

In our study, we examined the effects of pre- and post-procedure gender differences on clinical outcomes in patients who underwent the TAVR procedure. When we look at the results of TAVR, we found similar rates of successful implantation of the valve, peri-procedural complications, mortality and MACCE, although men and women have similar demographic characteristics.

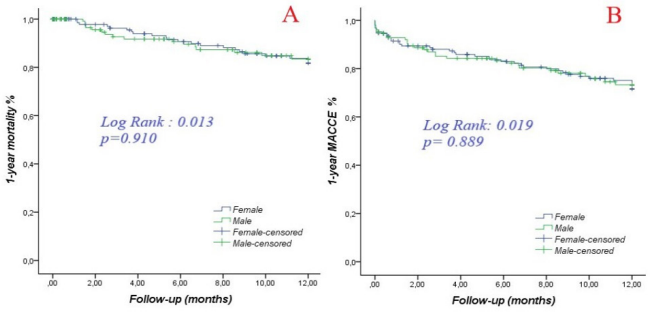

Figure 1. Comparison of men and women with Kaplan-Meier analysis for one-year mortality and one-year composite endpoint (MACCE)

The mean age and functional capacities of the patients participating in our study were higher in women than in women, and women presented with more advanced age and more severe symptoms compared to men. This result is consistent with previously reported study results [11]. In the PARTNER A study, it has been reported that mortality rates in patients who underwent TAVR

Table-2. Baseline Echocardiographic and Multislice Computed Tomography Parameters

Echocardiographic parameters		Overall n=270 (100%)	Female n=148 (54.8%)	Male n=122 (45.2%)	p value
AV doppler mean gradient, mmHg		48.64(9.50)	49.13(10.31)	48.05(8.42)	0.351
AV doppler max gradient, mmHg		79.10(15.01)	79.32(16.12)	78.83(13.60)	0.787
AV opening area, cm2		0.67(0.18)	0.67(0.17)	0.68(0.19)	0.925
LVEF, %		50.95(11.68)	54.38(9.61)	46.81(12.62)	<0.001
LVEDD, mm		4.87(0.61)	4.69(0.57)	5.10(0.60)	<0.001
LVESD, mm		3.52(0.81)	3.29(0.70)	3.90(0.84)	<0.001
LAD, mm		4.46(0.57)	4.38(0.56)	4.55(0.57)	0.012
IVSD, mm		1.39(0.17)	1.41(0.18)	1.35(0.20)	<0.001
Ascending aorta diameter, mm		3.67(0.54)	3.59(0.54)	3.77(0.53)	0.025
Moderate-severe MR, n%		81(30.7)	44(30.6)	37(30.8)	0.961
Moderate-severe AR, n%		30(11.5)	10(7.0)	20(16.8)	0.014
Moderate-severe TR, n%		63(23.8)	31(21.4)	32(26.7)	0.314
SPAP, IQR, mmHg		41(20)	42(20)	40(20)	0.801
Baseline Multislice Computed Tomography Measurements					
Aort-RCA distance, mm		16.88(3.79)	15.70(3.04)	18.05(4.10)	<0.001
Aort-LMCA distance, mm		13.27(3.77)	12.32(2.88)	14.26(4.31)	0.001
Ascending aorta, mm		34.60(4.10)	33.92(4.0)	35.31(4.11)	0.036
Aortic anulus diameter, mm		24.08(2.81)	22.65(2.07)	25.44(2.75)	<0.001
NCC-sinus valsalva diameter, mm		30.20(5.69)	27.97(5.34)	32.56(5.10)	<0.001
RCC-sinus valsalva diameter, mm		28.33(4.89)	26.58(4.23)	30.13(4.89)	<0.001
LCC-sinus valsalva diameter, mm		29.65(6.82)	27.24(6.37)	32.12(6.40)	<0.001
Aortic annulus perimeter, mm		77.59(8.21)	73.39(6.38)	81.74(7.72)	<0.001
Aortic annular area, mm2		457.02(99.36)	406.5(73.3)	505.7(97.1)	<0.001
Angular angle, IQR		48.21(8.93)	48.14(8.06)	48.28(9.77)	0.923
Echocardiographic parameters after TAVR					
LVEF, (%)		52.71(10.33)	54.73(10.24)	50.29 (9.96)	0.003
AV doppler mean gradient, mmHg		8.91(4.85)	9.34(4.88)	8.39(4.79)	0.216
SPAP, IQR, mmHg		35.98(14.22)	34.85(13.44)	37.38(15.12)	0.294
Paravalvular leak, n%	Mild	107(39.6)	53(35.8)	54(44.3)	0.158
	Moderate-severe	7(3.1)	4(3.1)	3(3.0)	N/A*

*Data are expressed as mean(SD), frequencies (percentages) or as median (interquartile range) as appropriate. AV; aortic valve, LVEF; left ventricle ejection fraction, LVEDD; left ventricle end diastolic diameter, LVESD; left ventricle end systolic diameter, LAD; left atrium diameter, IVSDD; interventricular septum diastolic diameter, MR; mitral regurgitation, AR; aortic regurgitation, TR; tricuspid regurgitation, SPAP; systolic pulmonary artery pressure, IQR; interquartile range, RCA; right coronary artery, LMCA; left mean coronary artery, NCC; non-coronary cusp, RCC; right-coronary cusp, LCC-left coronary cusp. N/A; not applicable. *Fisher Exact test was used.

were similar in men in the two-year follow-up compared to those who underwent AVR, while mortality rates were lower in women [15]. This causes TAVR rates to be higher in women than in men and similarly, the rate for women was higher in our study.

In a study conducted by O'Connor et al., it was reported that there were significant differences between the genders when the clinical and demographic characteristics of patients who underwent TAVR were compared [16]. Diabetes mellitus, high body mass index (BMI), previous myocardial infarction, prior percutaneous coronary intervention and low ejection fraction (EF), have been shown to be more common in male patients [17]. It has been shown that female patients have more advanced age, higher transvalvular gradient, higher pulmonary artery pressure, higher EF and smaller annulus values. Thus, although female patients are initially healthier in terms of baseline comorbidities compared to men, they become older and fragile. The findings of our study were also compatible with this, and we found the comorbidity rates to be similar for both genders.

In another study, pre-procedure multislice computed tomography was found to have smaller body surface areas, aortic annulus diameters, shorter coronary exit-annulus distances and less

Table-3.Procedural Complications and Clinical Endpoints of the Patients

Complications	Overall n=270 (100%)	Female n=148 (54.8%)	Male n=122 (45.2%)	p value
Technical success, n%	264(97.8)	144(97.3)	120(98.4)	0.555
Permanent pacemaker, n%	23(8.5)	14(9.5)	9(7.4)	0.542
New-onset stroke, n%	9(3.3)	5(3.4)	4(3.3)	N/A*
Pericardial tamponade, n%	7(2.6)	6(4.1)	1(0.8)	0.132*
Arrhythmia, n%	50(18.5)	30(20.3)	20(16.4)	0.414
Acute renal insufficiency, n%	14(5.2)	11(7.4)	3(2.5)	0.067
Major bleedings, n%	15(5.6)	10(6.8)	5(4.1)	0.343
Major vascular complications, n%	18(6.7)	10(6.8)	8(6.6)	0.948
Coronary obstruction, n%	1(0.4)	1(0.7)	0	N/A*
New-onset LBBB, n%	95(35.4)	51(34.5)	44(36.7)	0.707
Peri-procedural MI, n%	3(1.1)	1(0.7)	2(1.6)	0.593
Hospitalization day, IQR	3(4)	3(4)	3(5)	0.439
Early hospitalization postoperative, n%	18(6.7)	7(4.7)	11(9.0)	0.160
In-hospital mortality, n%	17(6.3)	8(5.4)	9(7.4)	0.507
First month death, n%	24(8.9)	13(8.8)	11(9.0)	0.947
First year death, n%	38(14.1)	22(14.9)	16(13.1)	0.681
In-hospital MACCE, n%	27(10)	14(9.5)	13(10.7)	0.744
First month MACCE, n%	34(12.6)	19(12.8)	15(12.3)	0.894
1-year MACCE, n%	68(25.2)	39(26.4)	29(23.8)	0.627

*Data are expressed as mean(SD), frequencies (percentages) or as median (interquartile range) as appropriate. LBBB; left bundle branch block, MI; myocardial infarction, IQR; interquartile range, MACCE; major adverse cardiac and cerebrovascular events. N/A; not applicable. *Fisher Exact test was used.

amount of valve calcification in women [16,18]. This situation is quite similar to the results of our study, and by considering these parameters in valve preference in women, smaller volumes of valves were preferred. Myocardial response to left ventricular pressure overload due to AS is different in men and women. While more concentric hypertrophy develops in female patients, inappropriate remodelling and related left ventricular dilatation are more prominent in males [18]. Therefore, myocardial fibrosis is lower in women and irreversible myocardial damage is less common, while systolic functions are more impaired in men. Similarly, in our study, while changes in diastolic parameters were observed less in women in echocardiographic examination, left ventricular hypertrophy was more often observed.

In previous studies, vascular complications after TAVR were found to be significantly higher in women, but this is thought to be due to more advanced age, smaller body surface area and smaller diameter vessels. In addition, vascular complications increase as a result of smaller mean diameters of the common femoral artery and greater vascular tortuosity [16]. However, in our study, although peripheral arterial disease was lower in women at the beginning, vascular complications increased significantly after TAVR, but no statistically significant difference was found between the two groups. When we look at the results of another study in which subgroup analyses of randomized studies were performed, it was observed that women were indeed older, had less comorbidity, and had higher rates of procedure-related vascular complications and bleeding. On the other hand, it has been shown that early and long-term survival rates in women are better than in men [19]. Similarly, in a meta-analysis including 47 188 patients, it was found that although periprocedural complication rates were higher in women, their one-year all-cause mortality rates were lower than those of men [20]. In the recent PARTNER-2 study, it was reported that women were more fragile, had higher STS scores and higher rates of vascular complications [21]. Accordingly, gender differences were not shown in terms of 30-day mortality, one-year mortality, stroke and other clinical outcomes [21]. Previous studies have shown that female gender is a risk factor for coronary obstruction after TAVR [22], however coronary obstruction was observed in only one patient in our study, but it was statistically insignificant. Likewise, we did not find a significant difference between the two genders in terms of permanent pacemaker implantation. Data

on the effect of gender in terms of periprocedural stroke rate are unclear. It is thought that the risk of stroke is higher in women due to the effect of the materials used during TAVR on atheroma plaques in the ascending aorta, due to the smaller aortic diameter [23]. In some studies, stroke rates were higher in women, while in others they were similar [16].

In the WIN-TAVR study conducted with 1 019 patients, it was shown that survival in women was better than in men [24]. On the other hand, the fact that fragility, osteoporosis and vertebral fractures are more common in women may cause intrathoracic rotation of the heart, making device implantation difficult [24]. Contrary to previous studies, this situation was thought to increase complications, but in our study, complication rates were not different between the two genders.

In another study, the rates of moderate and severe paravalvular AR were found to be similar between both genders [21]. Researchers attributed these results to increased experience, use of larger valves, and less paravalvular AR as a result of advances in valve technology [21]. In addition, some studies have found that the rates of paravalvular aortic failure and permanent pacemaker after TAVR are higher in men. The reason for this is thought to be larger valves, more osteoarthritis in men and complications related to the use of older technology valves, especially in the older studies [25]. Long-term rates of paravalvular AR may be lower in women and it is suggested that the reason for this may be patient valve incompatibility and left ventricular remodelling. Consistent with these findings, we did not find a significant difference between the two groups in our study, although the rate of mild paravalvular leak was less in women. In addition, there was no difference between the two groups in terms of moderate and severe paravalvular leak.

Limitations

There are some limitations of our study. One-to-one operator experience could not be evaluated and basic characteristics and comorbid conditions may have affected the results, as they were not homogeneously distributed between the genders. In addition, complications such as minor bleeding that did not require intervention, mild pleural effusion, wound infections and treatable arrhythmias were not considered.

Conclusion

We could not find a significant difference in clinical outcomes between both genders in our patient group who underwent TAVR. In recent years, with device and procedural developments, the effect of gender on clinical outcomes has decreased. In order to generalize the results of the study, multicenter studies with larger participation are needed.

Conflict of Interest: The authors declare no conflict of interest related to this article.

Funding sources: The authors declare that this study has received no financial support

Ethics Committee Approval: The trial was approved by Diyarbakır Gazi Yaşargil Training and Research Hospital ethics committee (Date and number: 09/09/2022-157).

ORCID and Author contribution: **A.A. (0000-0003-0505-9784):** Concept and Design, Data collection, Literature search, **F.E.(0000-0003-1860-6513):** Statistical Analysis, Manuscript Writing, Critical Review.

Peer-review: Externally peer reviewed.

Acknowledgement: None

REFERENCES

1. Lung B, Delgado V, Rosenhek R, Price S, Prendergast B, Wendler O, et al. EORP VHD II Investigators. Contemporary Presentation and Management of Valvular Heart Disease: The EURObservational Research Programme Valvular Heart Disease II Survey. Circulation. 2019;140(14):1156-69. doi: 10.1161/CIRCULATIONAHA.119.041080.
2. Panoulas VF, Francis DP, Ruparelia N, Malik IS, Chukwuemeka A, Sen S, et al. Female-specific survival advantage from transcatheter aortic valve implantation over surgical aortic valve replacement: Meta-analysis of the gender subgroups of randomised controlled trials including 3758 patients. Int J Cardiol. 2018;250:66-72. doi: 10.1016/j.ijcard.2017.05.047.
3. Pancholy SB, Shantha GP, Patel T, Cheskin LJ. Sex differences in short-term and long-term all-cause mortality among patients with ST-segment elevation myocardial infarction treated by primary percutaneous intervention: a meta-analysis. JAMA Intern Med. 2014;174(11):1822-30. doi: 10.1001/jamainternmed.2014.4762.
4. Swaminathan RV, Feldman DN, Pashun RA, Patil RK, Shah T, Geleris JD, et al. Gender Differences in In-Hospital Outcomes After Coronary Artery Bypass Grafting. Am J Cardiol. 2016;118(3):362-8. doi: 10.1016/j.amjcard.2016.05.004.
5. Kaiser DW, Fan J, Schmitt S, Than CT, Ullal AJ, Piccini JP, et al. Gender Differences in Clinical Outcomes after Catheter Ablation of Atrial Fibrillation. JACC Clin Electrophysiol. 2016;2(6):703-10. doi: 10.1016/j.jacep.2016.04.014.
6. Demir M, Özbek M, Polat N, Aktan A, Yıldırım B, Argun L, et al. Trend of Sex Differences and Predictors of Complications of Cardiac Electronic Device Implantations in the Southeast Anatolian Region of Turkey: An Observational Study. European Journal of Therapeutics. 2022;28:151-7. doi: 10.54614/eurjther.2022.0030.
7. Leon MB, Smith CR, Mack MJ, Makkar RR, Svensson LG, Kodali SK, et al. PARTNER 2 Investigators. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. N Engl J Med. 2016;374(17):1609-20. doi: 10.1056/NEJMoa1514616.
8. Mack MJ, Leon MB, Thourani VH, Makkar R, Kodali SK, Russo M, et al. PARTNER 3 Investigators. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. N Engl J Med. 2019;380(18):1695-1705. doi: 10.1056/

NEJMoa1814052.

9. Popma JJ, Deeb GM, Yakubov SJ, Mumtaz M, Gada H, O'Hair D, et al. Evolut Low Risk Trial Investigators. Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients. N Engl J Med. 2019;380(18):1706-15. doi: 10.1056/NEJMoa1816885.
10. Williams M, Kodali SK, Hahn RT, Humphries KH, Nkomo VT, Cohen DJ, et al. Sex-related differences in outcomes after transcatheter or surgical aortic valve replacement in patients with severe aortic stenosis: Insights from the PARTNER Trial (Placement of Aortic Transcatheter Valve). J Am Coll Cardiol. 2014;63(15):1522-8. doi: 10.1016/j.jacc.2014.01.036.
11. Itchhaporia D. Transcatheter aortic valve replacement in women. Clin Cardiol. 2018;41(2):228-31. doi: 10.1002/clc.22912.
12. O'Brien SM, Shahian DM, Filardo G, Ferraris VA, Haan CK, Rich JB, et al. Society of Thoracic Surgeons Quality Measurement Task Force. The Society of Thoracic Surgeons 2008 cardiac surgery risk models: part 2--isolated valve surgery. Ann Thorac Surg. 2009;88(1 Suppl):S23-42. doi: 10.1016/j.athoracsur.2009.05.056.
13. Al-Lamee R, Broyd C, Parker J, Davies JE, Mayet J, Sutaria N, et al. Influence of gender on clinical outcomes following transcatheter aortic valve implantation from the UK transcatheter aortic valve implantation registry and the National Institute for Cardiovascular Outcomes Research. Am J Cardiol. 2014;113(3):522-8. doi: 10.1016/j.amjcard.2013.10.024.
14. Kodali S, Williams MR, Doshi D, Hahn RT, Humphries KH, Nkomo VT, et al. Sex-Specific Differences at Presentation and Outcomes Among Patients Undergoing Transcatheter Aortic Valve Replacement: A Cohort Study. Ann Intern Med. 2016;164(6):377-84. doi: 10.7326/M15-0121.
15. Smith CR, Leon MB, Mack MJ, Miller DC, Moses JW, Svensson LG, et al. PARTNER Trial Investigators. Transcatheter versus surgical aortic-valve replacement in high-risk patients. N Engl J Med. 2011;364(23):2187-98. doi: 10.1056/NEJMoa1103510.
16. O'Connor SA, Morice MC, Gilard M, Leon MB, Webb JG, Dvir D, et al. Revisiting Sex Equality With Transcatheter Aortic Valve Replacement Outcomes: A Collaborative, Patient-Level Meta-Analysis of 11,310 Patients. J Am Coll Cardiol. 2015;66(3):221-8. doi: 10.1016/j.jacc.2015.05.024.
17. Günlü S, Demir M. Comparison of tenecteplase versus alteplase in STEMI patients treated with ticagrelor: A cross-sectional study. Am J Emerg Med. 2022;58:52-6. doi: 10.1016/j.ajem.2022.05.021.
18. Laricchia A, Bellini B, Romano V, Khawaja S, Montorfano M, Chieffo A. Sex and Transcatheter Aortic Valve Implantation: Impact of Female Sex on Clinical Outcomes. Interv Cardiol. 2019;14(3):137-41. doi: 10.15420/icr.2019.07.R1.
19. Masiero G, Paradies V, Franzone A, Bellini B, Biase CD, Karam N et al. TAVI spesific sex consideration. Mini-invasive Surg. 2022;6(4):1-19. doi: 10.20517/2574-1225.2021.104
20. Saad M, Nairooz R, Pothineni NVK, Almomani A, Kovelamudi S, Sardar P, et al. Long-Term Outcomes With Transcatheter Aortic Valve Replacement in Women Compared With Men: Evidence From a Meta-Analysis. JACC Cardiovasc Interv. 2018;11(1):24-35. doi: 10.1016/j.jcin.2017.08.015.
21. Szerlip M, Gualano S, Holper E, Squiers JJ, White JM, Doshi D, et al. Sex-Specific Outcomes of Transcatheter Aortic Valve Replacement With the SAPIEN 3 Valve: Insights From the PARTNER II S3 High-Risk and Intermediate-Risk Cohorts. JACC Cardiovasc Interv. 2018;11(1):13-20. doi: 10.1016/j.jcin.2017.09.035.
22. Ribeiro HB, Webb JG, Makkar RR, Cohen MG, Kapadia SR, Kodali S, et al. Predictive factors, management, and clinical outcomes of coronary obstruction following transcatheter aortic valve implantation: insights from a large multicenter registry. J Am Coll Cardiol. 2013;62(17):1552-62. doi: 10.1016/j.jacc.2013.07.040.
23. Holmes DR Jr, Brennan JM, Rumsfeld JS, Dai D, O'Brien SM, Vemulapalli S, et al. STS/ACC TVT Registry. Clinical outcomes at 1 year following transcatheter aortic valve replacement. JAMA. 2015;313(10):1019-28. doi: 10.1001/jama.2015.1474.
24. Chieffo A, Petronio AS, Mehilli J, Chandrasekhar J, Sartori S, et al. WIN-TAVI Investigators. Acute and 30-Day Outcomes in Women After TAVR: Results From the WIN-TAVI (Women's INternational Transcatheter Aortic Valve Implantation) Real-World Registry. JACC Cardiovasc Interv. 2016;9(15):1589-600. doi: 10.1016/j.jcin.2016.05.015.
25. Ferrante G, Pagnotta P, Petronio AS, Bedogni F, Brambilla N, Fiorina C, et al. Sex differences in postprocedural aortic regurgitation and mid-term mortality after transcatheter aortic valve implantation. Catheter Cardiovasc Interv. 2014;84(2):264-71. doi: 10.1002/ccd.25377.