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Influence of sex after elective thoracic endovascular aortic repair

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ABSTRACT

Objectives: This study aims to evaluate the early and mid-term outcomes of sex influence after elective thoracic endovascular aortic repair (TEVAR).

Patients and methods: A total of 69 patients (46 males, 23 females; mean age: 61.2±16.0 years; range, 42 to 86 years) who underwent an elective TEVAR between January 2019 and January 2021 were retrospectively analyzed. The patients were divided into two groups according to sex. All procedures were performed by the same endovascular team. Mainly Medtronic's Valiant® and Lifetech's Ankura® thoracic endografts were used. Technical success, early (30-day) morbidity and mortality, mid-term mortality, and secondary intervention rates were evaluated.

Results: Early mortality was 4.35% for both sex (p=0.975). In the early postoperative period, no complications requiring any reintervention were encountered. Eighteen patients experienced intentional left subclavian artery coverage. Prophylactic carotid-subclavian bypass was performed in two males and one female before the TEVAR procedure. Delayed left subclavian artery revascularization was performed in one male patient due to left arm ischemia. There was no other neurovascular complication. In the follow-up period (13±6.9 months), reintervention was performed in one female and two male patients for type 1 endoleak and one Petticoat procedure two months after the first TEVAR. There was only one late mortality due to retrograde type A dissection at the postoperative third month.

Conclusion: Our findings suggest that TEVAR in female sex is safe and effective with successful early morbidity and mortality results. The sex difference does not affect the early and mid-term outcomes of elective TEVAR.

Keywords: Outcome, sex, TEVAR, thoracic aortic aneurysm, type B dissection.

For thoracic aortic aneurysms (TAAs) and type-B aortic dissections (TBADs), thoracic endovascular aortic aneurysm repair (TEVAR) is the first-line treatment, owing to its less invasive nature and successful early morbidity and mortality results.[1] Open conventional surgery still carries higher mortality and morbidity with regard to thoracotomy, extensive surgical resection, aortic cross-clamp, hypothermia, ischemia, blood loss.[2] As patient population is overaged, even masterpiece operations may be complicated by coexisting cardiopulmonary comorbidities. The TEVAR may potentially offer significant reductions in the mortality and morbidity.

Sex differences in outcomes after vascular surgery exist and have been well studied.[3-13] There are differences between sexes at every stage of the disease, from epidemiology to pathophysiology and from morbidity to mortality.[1,8,11] Females usually present with smaller aneurysms along with greater growth rates and rupture risk. In spite of these facts,

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the current guidelines indicate earlier intervention for females.[1,11] The rational approach to aneurysm management in females must balance the hazards of repair with the probability of mortality from aneurysm rupture. For abdominal aortic aneurysms, female sex has worse outcomes after both open and endovascular repair.[5,6]

Different from abdominal aortic cases, for thoracic aortic pathologies, the ratio of men-to-women is between 1:1 and 3:1.[1,3,8-11] Women have a smaller normal diameter for aortas, smaller caliber access vessels and more complex aortic pathologies complicating not only open surgery, but endovascular procedures as well. As the patient population is not sufficient for women in cross-sectional or single-center studies, meta-analyses or reviews take place for comment.[7,11-13]

Considering all these reasons, there is currently little information concerning the outcomes of female patients following TEVAR. One recent large-scale, retrospective study of TEVAR using the National Surgical Quality Improvement Program data showed female sex to be associated with the increased 30-day mortality.[7] However, after adjusting for intraoperative variables, they suggested that the mortality difference might be, in part, explained by varying aortoiliac and femoral arterial disease burden between sexes. In the present study, we aimed to investigate sex differences on mortality and secondary interventions in our TEVAR experience and to present our mid-term follow-up results.

PATIENTS AND METHODS

This retrospective study was conducted at Ankara State Hospital, Department of Cardiovascular Surgery between January 2019 and January 2021. A total of 69 patients (46 males, 23 females; mean age: 61.2±16.0 years; range, 42 to 86 years) who underwent isolated elective TEVAR were included. The patients were divided into two groups according to sex and demographics and pre-, peri-, and postoperative findings were recorded. Urgent or hybrid procedures, complicated acute type B aortic dissections, aortic transections, procedures such as simultaneous TEVAR and endovascular aortic repair (EVAR) were excluded. All procedures were performed by the same endovascular surgical team. A written informed consent was obtained from each patient. The study protocol was approved by the Ankara State Hospital Ethics Committee (No: E1-20-603). The study was conducted in accordance with the principles of the Declaration of Helsinki.

Data including age, preoperative comorbidities, electrocardiogram (ECG), transthoracic echocardiography (TTE), and tomographic findings such as TAA diameter were evaluated. Perioperatively, amount of contrast agent, fluoroscopy time, cerebrospinal fluid (CSF) drainage, length of intensive care unit (ICU) stay and length of hospital stay (LOS) were noted.

Computed tomography angiography (CTA) was the first-line preoperative imaging modality to determine individual aortic anatomy and obtain measurements for strategy and sizing. Almost all procedures were performed under general anesthesia, except for one female patient with penetrating aortic ulcer who refused to experience general anesthesia and, instead, local anesthesia with limited sedation was performed to allow holding breath while taking angiogram shots. The ECG and TTE were performed for all patients. Coronary angiography was used for only symptomatic patients.

A follow-up imaging with CTA was routinely obtained for all patients at the first three months according to the patient's status and complication risks after hospital discharge and annually, thereafter.

Operative technique

All TEVAR procedures were performed in the hybrid operating room. A radial artery catheterization was inserted to monitor systemic blood pressure. Anticoagulation was ensured during the operation by heparin bolus (5,000 IU) at the beginning of the femoral catheterization, with additional heparin as needed to maintain an activating clotting time (ACT) of >250 sec. The CSF drainage was selectively performed and the drainage set was routinely inserted by an anesthesiologist before the procedure and heparin to minimize the risk of intrathecal or epidural bleeding with perioperative anticoagulation. The CSF was monitored for 24 to 72 h after the procedure. The CSF pressure was kept at a level of 8 to 10 cmH_2O and drainage was performed up to 48 to 72 h, if necessary. Balloon angioplasty was not applied to the patients in the presence of type B dissection.

For providing adequate landing zone, the left subclavian artery (LSA) or celiac artery may be sacrificed. Prior to coverage of the celiac artery, the anatomy and collaterals of the mesenteric vascular beds were carefully evaluated using preoperative CTA and digital subtraction angiography (DSA) intraoperatively. For LSA, similar approach was taken as preoperative studies for supra-aortic vessels,

Table 1. Demographic and clinical characteristics of male and female patients

	Female (n=23)				Male (n=46)				Total (n=69)				
Comorbidity	n	%	Mean±SD	Min-Max	n	%	Mean±SD	Min-Max	n	%	Mean±SD	Min-Max	*p*
Age (year)			59.8±16.8	43-83			62.6±15.1	42-86			61.2±16.0	42-86	0.387
Diabetes mellitus	6	26.1			7	15.2			13	18.8			0.111
Hypertension	14	60.9			32	69.5			46	66.6			0.530
Hyperlipidemia	8	34.8			14	30.4			22	31.9			0.284
Chronic obstructive pulmonary disease	9	39.1			20	43.5			29	42			0.862
Coronary artery disease	2	8.7			15	32.6			17	24.6			0.095
Coronary artery bypass grafting	0	0			5	10.9			5	7.2			0.157
Chronic renal failure	2	8.7			8	17.4			10	14.5			0.441
Cerebrovascular event	2	8.7			3	6.5			5	7.2			0.565
Peripheral arterial disease	0	0			5	10.9			5	7.2			0.586
Symptomatic	12	52.2			19	41.3			31	44.9			0.776

TEVAR: Thoracic endovascular aortic repair.

vertebral dominancy, cerebral blood supply from CTA and colored Doppler ultrasonography (CDUS) and, in the absence of contraindications including anatomical variations and/or stenosis, we covered the LSA with concern of the aortic extension without prophylactic or simultaneous revascularization. Delayed revascularization was performed, if necessary. While deployment, arterial blood pressure was always kept around 70 to 80 mmHg. After stent graft deployment, angiographic control for endoleaks was routinely performed as a completion angiogram. An endovascular balloon catheter (Reliant® balloon, Medtronic Inc., Santa Rosa, CA, USA or Tri-Lobe® balloon, W.L., Gore & Associates, Inc., Newark, DE, USA) was not liberally used to all landing or connection zones. The endografts used in this study was mainly the Medtronic's Valiant® (Medtronic Inc., Minneapolis, MN, USA) and LifeTech's Ankura® (LifeTech Scientific, Shenzhen, Guangzhou, China) thoracic endografts.

The primary outcome measures of the study were technical success, early (30-day) morbidity and mortality. Late mortality and secondary interventions after TEVAR were the secondary endpoints at the mid-term follow-up period. Early mortality was defined as any postoperative death within 30 days or death occurring during the hospital stay.

Statistical analysis

Statistical analysis was performed using the SPSS for Windows version 15.0 software (SPSS Inc., Chicago, IL, USA). Descriptive data were expressed in mean ± standard deviation (SD), median (interquartile range [IQR]) or number and frequency. Continuous variables were analyzed using the independent samples t-test or Mann-Whitney U-test, while categorical variables were analyzed using the chi-square test or Fisher's exact test. A p value of <0.05 was considered statistically significant.

RESULTS

Demographic data of both sexes are shown in Table 1. Although the male group was older than the female group, it was not statistically significant (p=0.387). Also, there was no statistically significant difference in the baseline demographic and clinical characteristics of the patients. Chronic obstructive pulmonary disease (p=0.862), chronic renal failure (CRF) (p=0.441), and coronary artery disease (CAD) (p=0.095) were more common in males, although it did not reach statistical significance. Besides, peripheral arterial disease (PAD) and prior coronary artery bypass graft (CABG) were only seen in the male group, probably due to the advanced age with a high rate of atherosclerosis in this group.

Etiological classification of aortic pathologies based on sex is shown in Table 2. For both sexes, atherosclerotic fusiform TAA was the most seen etiological and anatomical pathology. Both females and males had similar etiological structures.

Table 2. Etiological classification of aortic pathologies regarding to sex

	Female		Male		
	n	%	n	%	*p*
Type-B aortic dissection	8	34.7	15	32.6	
Fusiform aneurysm	9	39.1	22	47.8	0.748
Saccular aneurysm	6	26.1	9	19.6	

Table 3. Operative data

	Female		Male		
	Mean±SD	Min-Max	Mean±SD	Min-Max	*p*
Fluoroscopy time	11±5.6	6-25	10.9±6.5	4-32	0.685
Contrast (mL)	66.8±19.5	40-70	71.0±26.4	40-110	0.970
ICU time (h)	16.6±14.8	4-72	14.2±13.0	1-160	0.193
LOS (day)	4.4±4.0	1-20	5.8±5.5	1-22	0.343

ICU: Intensive care unit; LOS: Length of hospital stay.

Table 4. Postoperative data

	Female (n=23)		Male (n=46)		
	n	%	n	%	*p*
Proximal landing zones					0.322
Zone 2	4	17.4	20	43.5	
Zone 3	3	13.05	3	6.5	
Zone 4	13	56.5	20	43.5	
Zone 5	3	13.05	3	6.5	
LSA revascularization					0.273
Prophylactic	1	4.3	2	3.2	
Delayed	0	0	1	1.6	
SMFSG	0	0	6	13	
CSF drainage	2	8.7	13	28.2	0.063
LSA closure	4	17.4	14	30.4	0.245
Celiac closure	0	0	1	1.6	0.476
Early mortality	1	4.35	2	4.35	0.975

LSA: Left subclavian artery; SMFSG: Surgeon Modified Fenestrated Stent Graft; CSF: Cerebrospinal fluid.

Early mortality was identical for both sexes (4.35%) (p=0.975). In the early period, no complications requiring any reintervention were encountered. In the mean follow-up of 13±6.9 months, reintervention was performed in one female and two male patients for type 1 endoleaks and one Petticoat procedure to one male patient two months after the first TEVAR procedure. There was only one mortality in the follow-up period due to retrograde type A dissection at the postoperative third month who had TEVAR procedure for type B aortic dissection in the subacute phase.

Operative data of the patients are shown in Table 3. The mean aneurysm diameter was larger in males compared to females; however, there was no statistically significant difference (59.8±15.2 mm *vs.* 55.7±9.3 mm, respectively) (p=0.297). Procedural duration was longer and amount of contrast material that was used during the procedure was higher in the female group which could be due to anatomical obstacles, although it did not reach statistical significance (p=0.685 and p=0.970, respectively). Also, there was no statistically significant difference in the mean length of ICU stay (16.6±14.8 h for females *vs.* 14.2±13 h for males) (p=0.193) and mean LOS between the groups (4.4±4 days for females *vs.* 5.8±5.5 days for males; p=0.343). There was one celiac closure, 18 LSA closure three of whom had prophylactic carotid-subclavian bypass (CSB), one had delayed CSB due to left arm ischemia. The patients were discharged without any complication. After July 2020, back-table fenestration was initiated in our clinic and, in anatomically suitable patients, the surgeon-modified fenestrated stent graft (SMFSG) technique was performed for zone 2 landing to provide patency of LSA.[14,15] Six fenestrated stent grafts were successfully oriented in that period and they were all patent in the early follow-up. The CSF drainage was selectively used and 15 patients (21.74%) experienced CSF drainage. Proximal landing zones, CSF drainage, LSA and celiac closures, and their distribution between the groups are summarized in Table 4.

DISCUSSION

Our TEVAR experience showed satisfactory early and mid-term morbidity and mortality outcomes for both sexes. The early mortality rate was 4.35% for both sexes (p=0.975). After surviving TEVAR procedure, the mid-term follow-up period was uneventful and satisfactory. Czerny et al.[5] conducted a retrospective review of their TEVAR experience in 286 patients and observed no mortality difference based on sexes. A sub-study of the evaluation of the Medtronic Vascular Talent Thoracic Stent Graft system for the treatment of TAAs (VALOR trial) examined outcomes according to sexes in 195 patients.[9] They found worse early outcomes for females; however, once recovered from the initial TEVAR, women had satisfactory long-term outcomes. They concluded the sex difference on early outcomes solely be related to peri-procedural-related complications. The anatomical difficulties and peri-procedural complications due to smaller diameters and aortic tortuosity seems to be responsible for these results. Another suggestion for better results may be the earlier repair in females, as it is recommended in the current guidelines. Low-profile devices for broadening the treatment spectrum is also an important issue.

The previous sex-specific studies comparing males and females in TEVAR has shown that female patients are associated with numerically higher early mortality and outcomes.[5,7,9,12,13] Indeed, the inconsistent results obtained in these

studies can be attributed to a number of factors including the population size, etiological structures, symptomatology of the patients at presentation, evolving technology, practices, and the use of different stents and their sizing. The lower early mortality is possible with suitable anatomy, team experience, and device improvements over time.[13,16] Complicated aortic or vessel anatomy, worse baseline health and more symptomatic aneurysms may be possible reasons. In our study, symptomatic patients were numerically higher in female group than the male group (52.2% *vs.* 41.3%, respectively); however, there were no significant differences in the baseline demographics. Male patients had more CAD, CABG, CRF, and PAD, although it did not reach statistical significance, but showed a higher burden of cardiovascular atherosclerotic disease in males. These results suggest that TEVAR is safe and effective for both sexes with regard to early mortality and morbidity. After surviving the procedure, the early follow-up period was uneventful in this study and, therefore, the key issue should be anatomical specialties or peri-procedural complications and older-generation devices regarding profiles.

A proper proximal landing zone requires coverage of the LSA in 26 to 40% of patients undergoing TEVAR.[18-20] In 2009, the Society for Vascular Surgery (SVS) Guidelines on LSA revascularization were published; Nevertheless, controversy continues about this debate.[18] Some surgeons perform revascularization routinely, some selectively, and some only perform LSA revascularization, if symptoms occur after TEVAR.[18-20] The reason for prophylactic revascularization is to reduce neurovascular complications.[18-20] In our clinic, we used to perform selective LSA revascularization based on the individual anatomic features of each patient. In this study, prophylactic CSB was performed in only three patients. The LSA closure was applied to 18 patients (26.1%) (4 females, 17.4% and 14 males, 30.4%). Delayed LSA revascularization was performed in one male patient due to left arm ischemia. The patients were discharged without any complication. We decided to act independently for each patient according to the extension of the aortic pathology, the length of the aorta covered, condition of the supra-aortic arch vessels, the condition of the abdominal aorta and iliac arteries. To provide patency of the LSA endovascularly while landing at zone 2, since July 2020, the SMFSG technique and back-table fenestration were the treatment of choice and performed in anatomically suitable patients.[14,15] Six fenestrated stent grafts were successfully oriented up to January 2021 and they were all patent in the early follow-up period.

The exact mechanism of paraplegia and spinal ischemia after TEVAR has not been clearly elucidated, yet. After TEVAR, the foremost neurological complications are paraplegia and stroke.[21-24] The incidence of spinal cord ischemia following TEVAR varies considerably across studies between 0 and 10%.[21-24] After TEVAR, the presence of adequate collateral circulation can prevent cord ischemia. The CSF drainage have been the commonly used adjunct in reducing cord ischemia in open thoracoabdominal aneurysm repair.[21-24] We performed CSF drainage during and up to 48 to 72 h following TEVAR. We selectively applied CSF drainage in 15 patients (21.7%) (2 females, 8.7% and 13 males, 28.2%, respectively). In addition, we did not encounter any cerebrovascular events in the perioperative period in both sex groups.

The longer LOS for females was also evident in previous studies.[5-7,11,12] This condition may be related to the increased rate of complications, psychosocial factors such as anxiety or availability of home care. In our study, the ICU period was slightly longer in females; however, the LOS was slightly longer in male patients with no statistically significant difference.

Limited number of studies are available on sex-specific reintervention rates after TEVAR. More importantly, some studies have reported higher reintervention rates in males.[25,26] Endoleak is the most common indication for secondary interventions.[25,26] In the present study, reintervention was performed in one female and two male patients for type 1 endoleaks in the follow-up period. The reason why these results could not be compared with other series may be explained by the relatively low number of patients.

The main limitations of this study are the limited female patient population as other cross-sectional, single-center studies and the lack of a comparison with open surgery patients for the same period. The decision to repair an aortic aneurysm weighs the rupture risk, life expectancy and morbidity and mortality risk associated with repair.

In conclusion, TEVAR in female patients seems to be safe and effective with successful early morbidity and mortality results without any sex difference. Further studies with larger patient cohorts would

enable us to determine the most appropriate threshold for female patients and to comment on the interaction between sex and TEVAR outcomes to improve overall management.

Declaration of conflicting interests

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