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Sex-Related Differences in Clinical Presentation and Outcome of Transcatheter Aortic Valve Implantation for Severe Aortic Stenosis

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Objectives The purpose of this study was to clarify the impact of sex-related differences in transcatheter aortic valve implantation (TAVI) for high-risk patients with severe aortic stenosis.

Background Although TAVI is becoming a mature technique, the impact of sex differences remains unclear.

Methods The TAVI patients were included prospectively in a dedicated database from October 2006. The proportion of women (n = 131) was similar to that of men (n = 129). The Edwards valve (85.4%) and CoreValve (14.6%) were used through the transfemoral (65.0%), subclavian (3.1%), or transapical (31.9%) approach. All events were defined according to Valve Academic Research Consortium criteria.

Results Age was similar (83.1 ± 6.3 years), but women had less coronary and peripheral disease, less previous cardiac surgery, higher ejection fraction, and lower EuroSCORE (European System for Cardiac Operative Risk Evaluation [22.3 ± 9.0% vs. 26.2 ± 13.0%, p = 0.005]). Minimal femoral size (7.74 ± 1.03 mm vs. 8.55 ± 1.34 mm, p < 0.001), annulus size (20.9 ± 1.4 vs. 22.9 ± 1.7 mm, p < 0.001), and valve size (23.9 ± 1.6 mm vs. 26.3 ± 1.5 mm, p < 0.001) were smaller in women. Device success was similar (90.8% vs. 88.4%, p = 0.516) despite more frequent iliac complications (9.0% vs. 2.5%, p = 0.030). Residual mean aortic pressure gradient (11.6 ± 4.9 vs. 10.9 ± 4.9, p = 0.279) was also similar. The 1-year survival rate was higher for women, 76% (95% confidence interval: 72% to 80%), than for men, 65% (95% confidence interval: 60% to 69%); and male sex (hazard ratio: 1.62, 95% confidence interval: 1.03 to 2.53, p = 0.037) was identified as a predictor of midterm mortality by Cox regression analysis.

Conclusions Female sex is associated with better baseline clinical characteristics and improved survival, and is identified as a predictor of midterm survival after TAVI. (J Am Coll Cardiol 2012;59:566–71) © 2012 by the American College of Cardiology Foundation

Although sex-related differences in cardiovascular disease have been explored for a long time, only a few studies have been conducted to clarify sex differences in patients with aortic stenosis (AS) and the impact of sex on clinical outcomes after surgical aortic valve replacement (SAVR) (1–4). Certain studies have shown an increased short-term mortality rate (1,5), and female sex has been identified by EuroSCORE (European System for Cardiac Operative Risk Evaluation) as a predictor of perioperative mortality after cardiac surgery. Other studies have shown either better long-term survival in females (2,4) or no sex differences (3).

Transcatheter aortic valve implantation (TAVI) has recently emerged as a promising therapeutic option for patients with severe symptomatic AS, who are ineligible for or at high risk with conventional SAVR (6). However, there is a paucity of data describing sex-related differences in TAVI.

In contrast with percutaneous coronary intervention studies in which women only account for 15% to 20% of patients, women constitute 50% of patients eligible for TAVI, which guarantees the statistical relevance of analyses carried out in this context. Moreover, the cost effectiveness

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of TAVI procedures in women may be further enhanced by their longer life expectancy.

The purpose of this study was to highlight sex differences in clinical presentation and to identify predictors of midterm mortality in a large cohort of TAVI patients, based on the newly developed Valve Academic Research Consortium (VARC) criteria (7).

Methods

Study population and design. Between October 2006 and December 2010, consecutive high-risk patients with severe AS treated with TAVI at our institution were prospectively included in our database. Patients with symptomatic severe AS were considered candidates for TAVI if they had a logistic EuroSCORE >20%, or if surgery was deemed high risk, as previously described (8). The decision to proceed with TAVI was discussed by a dedicated heart team including experienced clinical and interventional cardiologists, cardiovascular surgeons, and anesthesiologists.

Valve and approach site selection strategy. Patients were selected to undergo TAVI by the transfemoral approach or alternative approaches depending on iliofemoral access (8). The valve prosthesis was selected according to the annulus size; the Edwards valve (Edwards Lifesciences, Irvine, California) was used in patients with an 18 to 24.5 mm annulus size, and the CoreValve (Medtronic, Santa Rosa, California) was used for 20 to 26.5 mm size (Fig. 1). The Edwards valve was predominantly used in patients with a 20 to 24.5 mm annulus amenable to treatment with either type of valve. The transapical and transsubclavian approaches were used as alternatives to unsuitable iliofemoral approach routes for the Edwards valve and CoreValve, respectively.

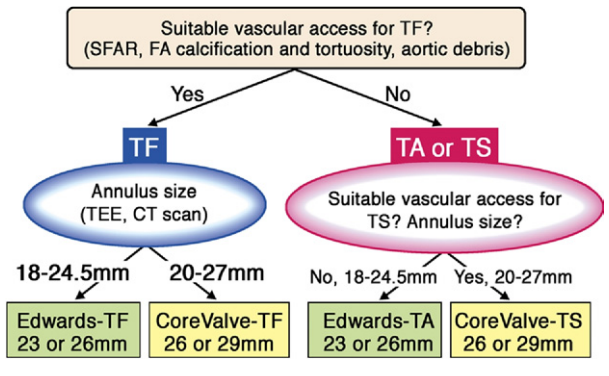

Figure 1 Valve Bioprosthesis Selection Strategy

Patients were selected to undergo transcatheter aortic valve implantation (TAVI) by the transfemoral (TF) approach or alternative approaches depending on the iliofemoral access. The valve prosthesis was selected according to the annulus size; the Edwards valve was used in patients with an 18 mm to 24.5 mm annulus size and the CoreValve for 20 mm to 26.5 mm. CT = computed tomography; FA = femoral artery; SFAR = sheath outer diameter/femoral artery ratio; TA = transapical; TEE = transesophageal echocardiography; TS = transsubclavian.

Procedures. The technical aspects of the TAVI procedures have been previously described (9,10). The majority of patients were pre-treated with aspirin 75 to 160 mg and clopidogrel 75 mg daily. Intravenous heparin was administered to keep a target activated clotting time (ACT) of 250 to 300 s. General anesthesia was used for all transapical and transsubclavian cases and for initial transfemoral procedures. Local anesthesia with mild sedation was introduced later for the transfemoral cases.

Post-procedural care. All patients were monitored in the intensive care unit for at least 24 h. Dual-antiplatelet therapy (aspirin 160 mg, clopidogrel 75 mg) was administered for 3 to 6 months, and thereafter aspirin was continued indefinitely.

Follow-up. After TAVI, all patients were assessed by a physician at 1, 3, 6, and 12 months post-operatively and thereafter annually. Additional follow-up data were collected through telephone interviews and contact with patients' family physicians, except for 1 case lost during follow-up.

Endpoint definitions. The primary endpoints of this study were device success, all-cause mortality (30-day and midterm) and combined 30-day safety endpoints as defined by the VARC (7). Device success was defined as successful vascular access, delivery, and deployment of 1 prosthesis, and correct position and performance of the prosthetic valve.

Statistical analysis. Quantitative variables are expressed as mean ± SD, and qualitative variables using numbers and percentages. Comparison of quantitative variables was performed with an unpaired Student *t* test or Wilcoxon rank-sum test. The chi-square test or Fisher's exact test was used to compare qualitative variables. A Cox regression analysis was performed to determine the predictors for midterm mortality. Statistical significance was defined as $p < 0.05$. The data were analyzed with PASW statistics version 17.0 (SPSS, Chicago, Illinois).

Abbreviations and Acronyms

AS = aortic stenosis
BMI = body mass index
BSA = body surface area
EuroSCORE = European System for Cardiac Operative Risk Evaluation
LVEF = left ventricular ejection fraction
NYHA = New York Heart Association
SAVR = surgical aortic valve replacement
TAVI = transcatheter aortic valve implantation
VARC = Valve Academic Research Consortium

Results

A total of 260 patients underwent TAVI using both commercially available bioprostheses: the Edwards valve in 222 cases (Cribier-Edwards [n = 13], Edwards-SAPIEN [n = 107], or SAPIEN-XT [n = 102], Edwards Lifesciences), and the third-generation CoreValve revalving system in 38 (Medtronic).

Patient and procedural characteristics. Of 260 patients, 131 were women (Table 1). Female patients tended to be older than male patients (83.8 ± 5.9 years vs. 82.4 ± 6.5 years, p = 0.080), with less coronary artery disease (48.9%

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Table 1 Baseline Characteristics of the Study Population

	Total (N = 260)	Female (n = 131)	Male (n = 129)	p Value
Age, yrs	83.1 ± 6.3	83.8 ± 5.9	82.4 ± 6.5	0.080
BSA, m^2	1.75 ± 0.19	1.65 ± 0.17	1.85 ± 0.16	<0.001
BMI, kg/m^2	25.7 ± 4.5	25.6 ± 4.8	25.9 ± 4.1	0.539
Diabetes mellitus	61 (23.5%)	24 (18.3%)	37 (28.7%)	0.049
Hyperlipidemia	126 (48.5%)	53 (40.5%)	73 (56.6%)	0.009
Hypertension	184 (70.8%)	93 (71.0%)	91 (70.5%)	0.937
Current smoker	17 (6.5%)	5 (3.8%)	12 (9.3%)	0.075
NYHA functional class III or IV	220 (84.6%)	113 (86.3%)	107 (82.9%)	0.461
Coronary artery disease	166 (63.8%)	64 (48.9%)	102 (79.1%)	<0.001
Previous MI	38 (14.6%)	10 (7.6%)	28 (21.7%)	0.003
Previous PCI	79 (30.4%)	33 (25.2%)	46 (35.6%)	0.050
Previous cardiac surgery	52 (20.0%)	18 (13.7%)	34 (26.4%)	0.011
Peripheral artery disease	87 (33.5%)	35 (26.7%)	52 (40.3%)	0.020
Cerebrovascular disease	33 (12.7%)	13 (9.9%)	20 (15.5%)	0.179
COPD	97 (37.3%)	50 (38.2%)	47 (36.4%)	0.774
eGFR, ml/min	52.0 ± 25.2	50.3 ± 23.5	53.6 ± 26.8	0.318
eGFR <60 ml/min	174 (67.7%)	90 (69.2%)	84 (66.1%)	0.598
Logistic EuroSCORE, %	24.3 ± 11.4	22.3 ± 9.1	26.2 ± 13.0	0.005
Aortic valve area, cm^2	0.60 ± 0.15	0.59 ± 0.17	0.61 ± 0.13	0.248
Aortic valve area index, cm^2/mm^2	0.34 ± 0.09	0.35 ± 0.10	0.33 ± 0.07	0.037
Mean pressure gradient, mm Hg	47.6 ± 18.1	49.7 ± 19.9	45.5 ± 15.8	0.069
LVEF, %	50.4 ± 14.1	53.5 ± 12.9	47.2 ± 14.6	<0.001
LVEF <40%	77 (29.6%)	26 (19.8%)	51 (39.5%)	<0.001
Aortic annulus size, mm	21.9 ± 1.8	20.9 ± 1.4	22.9 ± 1.7	<0.001
Ascending aorta size, mm	34.7 ± 4.3	33.8 ± 4.1	35.7 ± 4.3	0.002
Pulmonary hypertension	75 (28.8%)	35 (26.7%)	40 (31.0%)	0.447
Aortic regurgitation (0–4)	0.83 ± 0.71	0.85 ± 0.73	0.80 ± 0.67	0.532
Mitral regurgitation (0–4)	0.98 ± 0.72	1.00 ± 0.75	0.95 ± 0.70	0.629

Values are mean ± SD or n (%).

BMI = body mass index; BSA = body surface area; COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; EuroSCORE = European System for Cardiac Operative Risk Evaluation; LVEF = left ventricular ejection fraction; MI = myocardial infarction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention.

vs. 79.1%, $p < 0.001$), less previous cardiac surgery (13.7% vs. 26.4%, $p = 0.011$), and less peripheral artery disease (26.7% vs. 40.3%, $p = 0.020$), whereas left ventricular ejection fraction (LVEF) was higher in women compared to men (53.5 ± 12.9% vs. 47.1 ± 14.6%, $p < 0.001$). Finally, logistic EuroSCORE was lower in women than in men (22.3 ± 9.1% vs. 26.2 ± 13.0%, $p = 0.005$).

Echocardiography showed a similar aortic valve area (0.59 ± 0.17 cm^2 vs. 0.61 ± 0.13 cm^2, $p = 0.248$) but a larger valve area index (0.35 ± 0.10 cm^2/m^2 vs. 0.33 ± 0.07 cm^2/m^2, $p = 0.037$) in women who had a smaller body surface area (BSA [1.65 ± 0.17 vs. 1.85 ± 0.16 m^2, $p < 0.001$]) compared to women with a larger BSA. The annulus size was also smaller (20.9 ± 1.4 mm vs. 22.9 ± 1.7 mm, $p < 0.001$) as was the bioprosthesis size (23.9 ± 1.6 mm vs. 26.3 ± 1.5 mm, $p < 0.001$).

The Edwards valve was used in the majority (85.4%) of the whole cohort, and more frequently in women compared to men (91.6% vs. 79.1%, $p = 0.005$) (Table 2). The minimal femoral artery diameter (7.74 ± 1.03 mm vs. 8.55 ± 1.34 mm, $p < 0.001$) and femoral calcification score (0.37 ± 0.57 vs. 0.77 ± 0.75, $p < 0.001$) were smaller in women compared to men.

Device success, periprocedural complications, and outcome. Device success was achieved in 89.6% of the whole cohort, without significant sex-related differences (90.8% vs. 88.4%, $p = 0.516$). Although there was no significant difference in the rate of major vascular complications between sexes (11.5% vs. 9.3%, $p = 0.570$), iliac complications were more frequent in women compared to men (9.0% vs. 2.5%, $p = 0.030$) (Table 3). Conversion to open-heart surgery was required in 7 cases, 4 in female patients (2 valve migration, 1 annulus rupture, and 1 failed subclavian access) and 3 in male patients (1 valve migration, 1 annulus rupture, and 1 post-procedural severe AR [3.1% vs. 2.3%, $p = 0.718$]).

At discharge, the mean aortic pressure gradient was similar in both groups (11.6 ± 4.9 vs. 10.9 ± 4.9, $p = 0.279$) whereas post-procedural LVEF was higher in women than in men (56.8 ± 12.1 vs. 51.0 ± 12.7, $p < 0.001$), as it was before TAVI. No significant difference was observed in post-procedural aortic regurgitation ≥2 (34.4% vs. 27.1%, $p = 0.228$). The 30-day mortality was comparable between women and men (12.2% vs. 17.8%, $p = 0.207$) as was as the 30-day combined safety point (14.5% vs. 20.2%, $p = 0.231$).

Table 2 Procedural Characteristics of the Study Population

	Total (N = 260)	Female (n = 131)	Male (n = 129)	p Value
Edwards	222 (85.4%)	120 (91.6%)	102 (79.1%)	0.005
Transfemoral	138 (53.1%)	80 (61.1%)	58 (45.0%)	0.125
Transapical	83 (31.9%)	39 (29.8%)	44 (34.1%)	
Transsubclavian	1 (0.4%)	1 (0.8%)	0	
CoreValve	38 (14.6%)	11 (8.4%)	27 (20.9%)	0.005
Transfemoral	31 (11.9%)	10 (7.6%)	21 (16.3%)	0.346
Transsubclavian	7 (2.7%)	1 (0.8%)	6 (4.7%)	
Valve size, mm	25.1 ± 2.0	23.9 ± 1.6	26.3 ± 1.5	<0.001
Local anesthesia	102 (39.2%)	56 (42.7%)	46 (35.7%)	0.243
Sheath size, F	22.0 ± 3.4	21.6 ± 3.3	22.3 ± 3.5	0.090
Introducer sheath diameter, mm	7.72 ± 0.83	7.28 ± 0.55	8.15 ± 0.80	<0.001
Femoral artery MLD, mm	8.12 ± 1.25	7.74 ± 1.03	8.55 ± 1.34	<0.001
SFAR	0.99 ± 0.16	1.02 ± 0.14	0.96 ± 0.17	0.015
Femoral artery calcification score (0–3)	0.56 ± 0.69	0.37 ± 0.57	0.77 ± 0.75	<0.001
Femoral artery tortuosity score (0–3)	0.29 ± 0.55	0.26 ± 0.49	0.33 ± 0.61	0.442

Values are n (%) or mean ± SD.
MLD = minimal lumen diameter; SFAR = sheath outer diameter/femoral artery ratio.

Sex differences and predictors of midterm mortality. The median follow-up of this cohort was 217 days (interquartile range: 54 to 401 days). In total, 79 patients (32 female and 47 male) died during the follow-up period.

Although no significant sex differences were observed with respect to the 30-day mortality rate, women had a better midterm survival (Fig. 2). Male sex was also identified as a predictor of midterm mortality by Cox regression analysis (hazard ratio: 1.62, 95% confidence interval: 1.03 to 2.53, p = 0.037) (Table 4).

Discussion

This study provides the first precise description of sex-related differences in patients with severe AS undergoing TAVI using both the Edwards valve and the CoreValve. Female sex was associated with lower comorbidities and a lower EuroSCORE. Although no significant relationship with 30-day mortality was evidenced, female sex was associated with better midterm survival and also identified as a predictor of midterm survival.

Table 3 Post-Procedural Complications and Outcomes

	Total (N = 260)	Female (n = 131)	Male (n = 129)	p Value
Transfusion ≥4 U	19 (7.3%)	8 (6.1%)	11 (8.5%)	0.453
Local infection	9 (3.5%)	5 (3.8%)	4 (3.1%)	0.752
Major vascular complication	27 (10.4%)	15 (11.5%)	12 (9.3%)	0.570
In-hospital acute MI	2 (0.8%)	1 (0.8%)	1 (0.8%)	0.991
In-hospital cerebrovascular accident	4 (1.7%)	1 (0.8%)	3 (2.3%)	0.306
Cardiac tamponade	5 (1.9%)	3 (2.3%)	2 (1.6%)	0.664
Annulus rupture	3 (1.2%)	2 (1.5%)	1 (0.8)	0.509
Valve migration	8 (3.1%)	4 (3.1%)	4 (3.1%)	0.982
Conversion to open heart surgery	7 (2.7%)	4 (3.1%)	3 (2.3%)	0.718
Post-implantation				
Mean pressure gradient, mm Hg	11.2 ± 4.9	11.6 ± 4.9	10.9 ± 4.9	0.279
LVEF, %	53.9 ± 12.7	56.8 ± 12.1	51.0 ± 12.7	<0.001
LVEF change, %	3.7 ± 11.0	3.4 ± 10.6	4.0 ± 11.5	0.680
Aortic regurgitation (0–4)	1.15 ± 0.84	1.17 ± 0.85	1.12 ± 0.83	0.636
Aortic regurgitation ≥2	80 (30.8%)	45 (34.4%)	35 (27.1%)	0.228
Aortic regurgitation >3	11 (4.2%)	4 (3.1%)	7 (5.4%)	0.261
Mitral regurgitation (0–4)	1.01 ± 0.82	1.15 ± 0.85	0.89 ± 0.77	0.017
New pacemaker	17 (6.5%)	7 (5.9%)	10 (7.8%)	0.432
Device success	233 (89.6%)	119 (90.8%)	114 (88.4%)	0.516
30-day mortality	39 (15.0%)	16 (12.2%)	23 (17.8%)	0.207
30-day combined safety point	45 (17.3%)	19 (14.5%)	26 (20.2%)	0.231
Hospital stay, days	11.6 ± 8.6	11.6 ± 9.2	11.6 ± 8.0	0.980

Values are n (%) or mean ± SD.
LVEF = left ventricular ejection fraction; MI = myocardial infarction.

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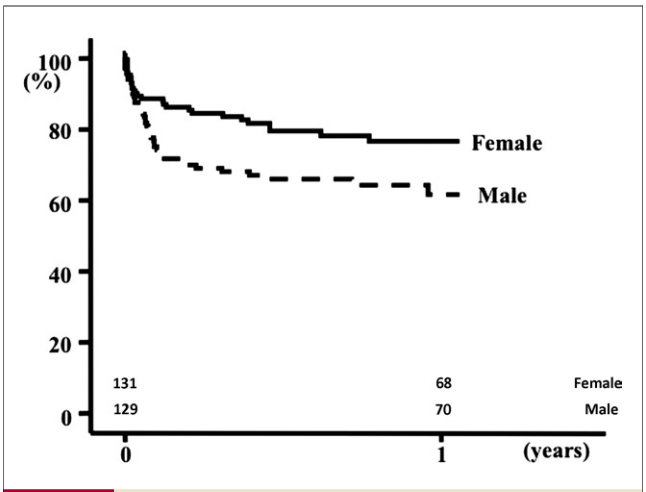

Figure 2 Impact of Sex on Midterm Survival

Although no significant sex differences were observed with respect to the 30-day mortality rate, female patients **(solid line)** had a better midterm survival compared to male patients **(broken line)** ($p = 0.037$).

In our study cohort, the mean age was higher (83.1 ± 6.3 years) compared with that of previously reported series of SAVR (1,4) because of the nature of the TAVI procedure implemented for inoperable or high-risk elderly patients. Women had a lower rate of comorbidity such as coronary artery disease and peripheral artery disease, and higher LVEF. These findings were comparable with previously published SAVR data (1,4). Smaller bioprosthesis sizes were selected for women than for men (23.9 ± 1.6 vs. 26.3 ± 1.5, $p < 0.001$) because of women's smaller aortic annulus size (20.9 ± 1.4 vs. 22.9 ± 1.7, $p < 0.001$). This is consistent with existing SAVR reports (4,5).

A clear difference between TAVI and SAVR was found in the logistic EuroSCORE. In general, female patients undergoing SAVR are of more advanced age and have a higher logistic EuroSCORE (1,4). However, this score was significantly lower in women than in men (22.3 ± 9.1 vs. 26.2 ± 13.0, $p = 0.005$), presumably due to less comorbidity.

Although there was no significant difference in the 30-day mortality rate, female sex was associated with better midterm survival, and Cox regression analysis identified male sex as a predictor of midterm mortality (hazard ratio: 1.62, 95% confidence interval: 1.03 to 2.53, $p = 0.037$).

Several contrasting reports on sex-related differences in SAVR have been published (4,5,11). In female patients, SAVR is technically demanding because of their smaller stature, BSA, and aortic root. These characteristics may partly explain their higher 30-day mortality rate with SAVR (5,11). In our study cohort, TAVI in female patients was successfully performed with a device success rate similar to that of male patients (90.8% vs. 88.4%, $p = 0.516$), because of the higher procedural feasibility inherent in this novel technique, despite the specific characteristics associated with being female.

Prosthesis-patient mismatch, resulting in a persistent abnormally high transvalvular gradient, also remains an important issue for SAVR in females because of their smaller aortic annulus, limiting the prosthesis size. It has also been reported as an independent predictor of operative mortality in several studies of SAVR (12,13).

In our TAVI cohort, excellent hemodynamic performance was achieved for both women and men, with a low mean aortic pressure gradient at discharge (11.6 ± 4.9 vs. 10.9 ± 4.9, $p = 0.279$), even with smaller prostheses in women. Furthermore, no significant differences were observed in post-procedural aortic regurgitation ≥2 (34.4% vs. 27.1%, $p = 0.228$). One study describing sex-related differences in SAVR showed a significantly higher survival rate for female patients, especially for those ≥79 years of age, whereas there was no significant difference among patients <79 years of age (4). Our TAVI study cohort had similar mean age, and its data were comparable with those of SAVR in patients of advanced age. The higher survival rate can be explained by women's longer life expectancy and is also influenced by a lower rate of comorbidity, as attested to by a lower EuroSCORE. Given the impact of confounding factors, the influence of sex on outcome may be of only borderline significance.

Study limitations. Our study reports results achieved in a single-center TAVI cohort consisting of a limited number of patients recruited in the initial phase of our experience with this new technology. Multivariate analysis was not performed because of the low endpoint count. Further studies of larger patient populations are required to confirm our results.

Table 4 Predictors for Midterm Mortality by Cox Regression Analysis

Variables	p Value	Hazard Ratio	95% CI
Male	0.037	1.62	1.03–2.53
Experience	0.023	1.73	1.08–2.78
Logistic EuroSCORE	0.027	1.02	1.00–1.04
Post-procedural aortic regurgitation ≥2	0.009	1.97	1.19–3.28
Transfusion ≥4 U	<0.001	4.66	2.39–9.09
Acute kidney injury	<0.001	4.88	2.49–9.56
Conversion to open heart surgery	<0.001	7.51	3.18–17.76
Periprocedural cerebrovascular accident	0.001	5.46	1.98–15.06
Major vascular complication	0.008	2.12	1.21–3.70
Age	0.67	1.01	0.97–1.05
Body surface area, m^2	0.68	0.78	0.24–2.50
Body mass index, kg/m^2	0.30	0.97	0.92–1.03
Coronary artery disease	0.19	1.38	0.85–2.23
COPD	0.12	1.42	0.91–2.21
LVEF <40%	0.40	1.22	0.77–1.95
Type of TAVI	0.88	1.05	0.56–1.99
Transapical approach	0.32	1.27	0.80–2.02
Transsubclavian approach	0.46	2.10	0.29–15.1
Valve migration	0.09	2.24	0.89–5.61

Univariate analysis was used to identify the predictors.

CI = confidence interval; TAVI = transcatheter aortic valve implantation; other abbreviations as in Table 1.

Conclusions

Female sex was associated with fewer comorbidities and a lower EuroSCORE. Despite women having smaller body, and femoral, aorta, and aortic annulus size, similar device success was achieved in women and men alike with an adequate reduction in the transprosthetic pressure gradient. Although no relation with the 30-day mortality rate was observed, female sex was associated with better midterm survival after TAVI.

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