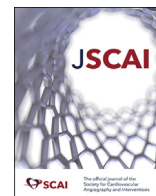




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Original Research

WIN Gulf TAVR Registry: Describing Sex Differences in Patient Characteristics, Prognosis, and Outcomes



Mirvat Alasnag, MD, FSCAI^{a,*}, Nouf Alanazi, MD^b, Shereen Al-Shaikh, MD^c, Khaled AlMerri, MD^d, Abdulrahman Almoghairi, MD^e, Abdullah Alenezi, MD^d, Waleed AlHarbi, MD^b, Haitham Amin, MD^c, Hussam Noor, MD^c, Fawaz Bardooli, MD^c, Hatim Al Lawati, MD^f, Khalid Al Faraidy, MD^g, Mohammed AlShehri, MD^h, Michael Thabane^{i,j,k}, Lehana Thabane, PhD^{i,j,k}, Khaled Al-Shaibi, MD^a

^a Cardiac Center, King Fahd Armed Forces Hospital, Jeddah, Saudi Arabia; ^b Department of Cardiac Sciences, College of Medicine, King Saud University, Riyadh, Saudi Arabia; ^c Mohammed bin Khalifa Cardiac Centre, Riffa, Bahrain; ^d Chest Disease Hospital, Al Shuwaikh, Kuwait City, Kuwait; ^e Prince Sultan Cardiac Center, Riyadh, Saudi Arabia; ^f Cardiac Center, Sultan Qaboos University Hospital, Muscat, Oman; ^g Cardiac Center, King Fahd Military Medical Complex, Dhahran, Saudi Arabia; ^h Prince Khaled Bin Sultan Cardiac Center, Khamis Mushait, Saudi Arabia; ⁱ Department of Health Research Methods, Evidence, and Impact (HEI), McMaster University, Hamilton, Ontario, Canada; ^j St. Joseph's Healthcare Hamilton, McMaster University, Hamilton, Ontario, Canada; ^k Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa

ABSTRACT

Background: Several international registries have examined outcomes in women undergoing transcatheter aortic valve replacement (TAVR). However, none of these studies included women from the Gulf region. The Women IN Gulf Transcatheter Aortic Valve Replacement (WIN Gulf TAVR) registry aimed to examine sex-based differences in patient characteristics and outcomes in patients undergoing TAVR in the region.

Methods: This registry is a prespecified subanalysis of the main Gulf TAVR registry. Baseline characteristics, procedural details and success, and 1-year outcomes were recorded. The primary outcome consisted of a composite of all causes of death, myocardial infarction (MI), and rehospitalizations at 1 year. The secondary outcomes were a composite of the individual components of the primary composite.

Results: A total of 347 women (44% of the Gulf TAVR registry) were included in the final analysis, with a mean age of 74.1 ± 9.1 years; mean ejection fraction of $56.20\% \pm 10.52\%$; and mean Society of Thoracic Surgeons score of 5.30 ± 4.35 . The composite primary end point occurred in 12.4% (95% CI, 9.3-16.2). The individual components of the primary end point were as follows: death, 4.3% (95% CI, 2.6-7.0); MI, 1.1% (95% CI, 0.4-2.9); and rehospitalization, 9.8% (95% CI, 7.1-13.3), with 7.2% (95% CI, 4.9-10.4) related to cardiac causes.

Conclusions: Women in the WIN Gulf TAVR registry had outcomes and baseline characteristics similar to men. Although higher rehospitalizations for cardiac causes and MI at 1 year in women were noted, the overall survival was better in women. These observations warrant a larger cohort to identify the drivers of events.

Introduction

The Women's INternational Transcatheter Aortic Valve Implantation registry was a prospective international registry that reported a 1-year Valve Academic Research Consortium (VARC)-2 composite efficacy end point of 16.5% in women undergoing transcatheter aortic valve replacement (TAVR) in Europe and the United States.¹ The investigators noted that baseline atrial fibrillation and previous percutaneous coronary intervention were independent predictors of the 1-year death or stroke. However, this did not include women from the Gulf region. The Women

IN Gulf Transcatheter Aortic Valve Replacement (WIN Gulf TAVR) registry is a prespecified subanalysis of the Gulf TAVR Registry.

The objectives of this analysis were to describe the risk profile, procedural success and complications, and 1-year composite outcome of death, myocardial infarction (MI), and rehospitalizations, as well as the individual components of the composite outcomes, in women who had undergone TAVR in the Gulf region. In addition, this analysis aimed to identify differences in the risk profile and drivers of events using contemporary transcatheter systems and practices in a Gulf cohort. It is imperative that regional data become available given the differences in

Abbreviations: BMI, body mass index; CKD, chronic kidney disease; MI, myocardial infarction; SAVR, surgical aortic valve replacement; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement; THV, transcatheter heart valve; VARC-2, Valve Academic Research Consortium 2; WIN, Women IN Gulf.

Keywords: aortic stenosis; cardiovascular outcomes; STS score; TAVR; women.

* Corresponding author: mirvat@jeddacath.com (M. Alasnag).

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Table 1. Characteristics with composite outcome (N = 795)

Demographics	Men (n = 448)	Women (n = 347)	P ^a
Age, y	74.91 ± 8.75	74.11 ± 9.10	.209
Age	–	–	.448
<65 y	56 (12.5)	48 (13.8)	–
65-74 y	146 (32.7)	125 (35.9)	–
≥75 y	245 (54.8)	175 (50.3)	–
Body mass index, kg/m ²	29.01 ± 5.68	32.96 ± 6.96	<.001
Body mass index	–	–	<.001
<25 kg/m ²	106 (23.7)	42 (12.1)	–
25-29.9 kg/m ²	167 (37.4)	66 (19.0)	–
≥30 kg/m ²	174 (38.9)	240 (69.0)	–
Diabetes mellitus	271 (60.6)	219 (62.9)	.507
Hypertension	365 (81.7)	299 (85.9)	.108
Atrial fibrillation	68 (15.2)	76 (21.8)	.016
Previous cerebrovascular accident	41 (9.2)	21 (6.0)	.102
Concomitant CAD	252 (56.4)	129 (37.1)	<.001
Previous PCI/CABG	158 (35.3)	88 (25.3)	.004
Peripheral arterial disease	39 (8.7)	22 (6.3)	.207
Bicuspid or tricuspid	422 (94.4)	330 (94.8)	.795
Native valve	436 (97.5)	340 (97.7)	.882
Aortic regurgitation	99 (22.1)	72 (20.7)	.620
Aortic stenosis mean gradient	45.15 ± 14.10	47.18 ± 14.40	.047
Aortic stenosis mean gradient	–	–	.178
<40	135 (30.2)	90 (25.9)	–
41-60	258 (57.7)	205 (58.9)	–
>60	54 (12.1)	53 (15.2)	–
Aortic stenosis area	0.73 ± 0.20	0.70 ± 0.21	.085
Ejection fraction, %	50.04 ± 13.54	56.20 ± 10.52	<.001
Ejection fraction	–	–	<.001
>55%	161 (36.0)	205 (58.9)	–
46%-55%	135 (30.2)	89 (25.6)	–
36%-45%	91 (20.4)	34 (9.8)	–
<35%	60 (13.4)	20 (5.7)	–
STS score mortality	4.59 ± 4.10	5.30 ± 4.35	.019
STS score mortality	–	–	.001
<4%	259 (57.9)	156 (44.8)	–
4%-9%	144 (32.2)	154 (44.3)	–
≥10%	44 (9.8)	38 (10.9)	–
Glomerular filtration rate, mL/min	66.99 ± 24.92	65.25 ± 27.94	.362
Glomerular filtration rate	–	–	.222
≥60 mL/min, stages 1 and 2	277 (62.0)	205 (58.9)	–
30-59 mL/min, stage 3	139 (31.1)	107 (30.7)	–
<30 mL/min, stages 4 and 5	31 (6.9)	36 (10.3)	–
Porcelain aorta	13 (2.9)	3 (0.9)	.042
Prohibitive surgical risk	270 (60.4)	220 (63.2)	.418

Values are mean ± SD or n (%).

CABG, coronary artery bypass grafting; CAD, coronary artery disease; PCI, percutaneous coronary intervention; STS, Society of Thoracic Surgeons

risk factors, socioeconomic determinants, anatomical variations, and life expectancy and frailty indices compared with other populations.

Methods

As part of the Gulf TAVR registry, this analysis consisted of multicenter retrospective observational data collected from 8 centers in the Gulf region between January 1, 2017, and December 31, 2019. A detailed description of the methodology was previously published.² All baseline characteristics, procedural details and success, and 1-year outcomes were recorded. The VARC-2 definitions were referenced for procedural complications and 1-year outcomes. The primary outcome consisted of a composite of all causes of death, MI, and rehospitalizations at 1 year. The secondary outcomes were the individual components of the primary composite.

Statistical analysis

All baseline characteristics were analyzed using descriptive statistics summarized as count (%) for categorical variables and mean (SD) or median (first quartile [Q1], the third quartile [Q3]) for continuous

Table 2. Procedural characteristics with composite outcome (N = 795)

Procedure variables	Men (n = 448)	Women (n = 347)
TAVR type: balloon expandable valve	163 (36.5)	140 (40.2)
TAVR size, mm	27.36 ± 2.99	25.10 ± 2.42
Access	–	–
Transfemoral	425 (95.1)	337 (96.8)
Transapical	17 (3.8)	10 (2.9)
Trans-subclavian	2 (0.4)	1 (0.3)
Transaortic	3 (0.7)	0 (0.0)
Acute procedural success	444 (99.3)	342 (98.3)
PCI, before and after	79 (17.7)	41 (11.8)
Bleeding	–	–
No	338 (75.6)	248 (71.3)
Minor	9 (2.0)	174 (50.0)
Major	20 (4.5)	13 (3.7)
Life threatening	80 (17.9)	12 (3.4)
Mean gradient after TAVR, mm Hg	9.61 ± 4.88	10.96 ± 5.98
Mean gradient after TAVR	–	–
<10 mm Hg	248 (57.0)	154 (45.7)
10-20 mm Hg	174 (40.0)	164 (48.7)
>20 mm Hg	13 (3.0)	19 (5.6)
Paravalvular leak	–	–
No	310 (69.4)	261 (75.0)
Mild	112 (25.1)	73 (21.0)
Moderate to severe	25 (5.6)	14 (4.0)
Balloon dilation, before or after	83 (18.6)	59 (17.05)
PPM	60 (13.4)	35 (10.1)
Post-TAVR CVA	7 (1.6)	4 (1.1)
Post-TAVR MI (clinically relevant)	2 (0.4)	3 (0.9)
Post-TAVR death	11 (2.5)	9 (2.6)
General Anesthesia	128 (28.6)	115 (33.0)
Complication	–	–
None	418 (93.5)	322 (92.5)
Coronary obstruction	4 (0.9)	5 (1.4)
Rupture	0 (0.0)	2 (0.6)
Embolization	4 (0.9)	4 (1.1)
Other	21 (4.7)	15 (4.3)
Emergency surgery	6 (1.3)	5 (1.4)

Values are mean ± SD or n (%).

CVA, cerebrovascular accident; MI, myocardial infarction; PCI, percutaneous coronary intervention; PPM, permanent pacemaker; TAVR, transcatheter aortic valve replacement.

variables depending on the distribution. The estimates of the outcomes were reported as estimates of the incidence of the composite outcome of death, MI and rehospitalizations, and individual components at 1 year as percentages (95% CI). All descriptive statistics and estimates of the incidence of outcomes are reported for both men and women separately. All analyses were performed using the R software.

Results

A total of 347 women (44% of the Gulf TAVR registry) were included in the final analysis, with a mean age of 74.1 ± 9.1 years; mean ejection fraction of 56.20% ± 10.52%; and mean Society of Thoracic Surgeons (STS) score of 5.30 ± 4.35 (Central Illustration). The transfemoral approach was used in 97% (337/348). Table 1

Table 3. Outcome frequencies censored at 1 year (N = 795)

Outcome of interest (N = 795)	Men (n = 448)	Women (n = 347)
Primary composite outcome	60 (13.4) [10.6, 16.9]	43 (12.4) [9.3, 16.2]
Secondary outcomes		
Death	28 (6.3) [4.3, 8.9]	15 (4.3) [2.6, 7.0]
Myocardial infarction	3 (0.7) [0.2, 2.0]	4 (1.1) [0.4, 2.9]
Rehospitalization	40 (8.9) [6.6, 12.0]	34 (9.8) [7.1, 13.3]
Cardiac	28 (6.3) [4.4, 8.9]	25 (7.2) [4.9, 10.4]
Heart failure	8 (1.8)	9 (2.6)
Pacemaker	2 (0.5)	0 (0.0)
Other	18 (4.0)	16 (4.6)
Noncardiac	12 (2.7) [1.5, 4.6]	9 (2.6) [1.4, 4.8]

Values are n (%) [95% CI] or n (%).

Table 4. TAVR valve types in men and women

Size (mm)	Total	Women	% Women	BEV	Men	Women	% Women	SEV	Men	Women	% Women
20	7	5	71.4	7	2	5	71.4	0	0	0	0
23	202	135	66.8	160	56	104	65	42	11	31	73.8
24.5	3	0	0	3	3	0	0	0	0	0	0
25	7	3	42.9	0	0	0	0	7	4	3	42.9
26	320	158	49.4	116	87	29	25	204	75	129	63.2
27.5	6	1	16.7	6	5	1	16.7	0	0	0	0
29	206	43	20.9	18	15	3	16.7	188	148	40	21.3
30.5	1	0	0	1	1	0	0	0	0	0	0
34	43	2	4.6	0	0	0	0	43	41	2	4.6
Total	795	347	43.6	311	169	142	45.7	484	279	205	42.3

BEV, balloon expandable valve; SEV, self-expanding valve; TAVR, transcatheter aortic valve replacement.

describes the baseline characteristics of men and women in the Gulf TAVR registry. A breakdown of the procedural outcomes in men and women is provided in Table 2. Baseline demographics were comparable with the male cohort of the main Gulf TAVR registry except for obesity, which was more commonly encountered in the female population (body mass index [BMI], 29.01 kg/m² in men vs 32.96 kg/m² in women; *P* = .001), and a higher STS mortality score in women (mean of 4.59 in men vs 5.3 in women; *P* = .019). On the contrary, concomitant coronary artery disease was more common in men (56.4% in men vs 37.1% in women; *P* ≤ .001). Furthermore, men had a significantly lower ejection fraction (50% in men vs 56% in women; *P* ≤ .001). The outcome rates included a composite primary end point of 12.4% (95% CI, 9.3-16.2); death, 4.3% (95% CI, 2.6-7.0); MI, 1.1% (95% CI, 0.4-2.9); and rehospitalization, 9.8% (95% CI, 7.1-13.3), with 7.2% (95% CI, 4.9-10.4) related to cardiac causes (Table 3).

Discussion

Overall, the baseline characteristics and immediate procedural outcomes for men and women in this Gulf cohort were comparable. The mean age was 74 years in both groups with similar comorbidities such as diabetes (271/448; 60% men and 219/347; 62% women) and peripheral vascular disease (39/448; 9.2% men and 22/347; 6% women). Women had a marginally higher rate of atrial fibrillation at baseline (68/448 in men and 76/347 in women); however, fewer women experienced a previous cerebrovascular event (41/448; 9% men vs 21/347; 6% women). Women tended to have a higher mean BMI (29.01 kg/m² in men and 32.96 kg/m² in women). A frailty index was not recorded in this cohort; therefore, the significance of BMI remains elusive. It is conceivable that frail women are not offered TAVR in the Gulf region.

Notably, the main Gulf TAVR registry reported that chronic kidney disease (CKD) of stage III and above was significantly associated with the primary composite end point (hazard ratio, 2.49; 95% CI, 1.31-4.73; *P* = .005).² The WIN Gulf TAVR substudy revealed that more women presented with stage III CKD compared with men (10.3% vs 6.9%). However, given the low overall event rate at 1 year, it is difficult to assign CKD as a driver of events in the subpopulation of women. Moreover, the published results from the Gulf TAVR registry reported a 3-fold increase

in the risk for the composite end point with severe left ventricular dysfunction. The baseline ejection fraction in women was 56%, compared with 50% in men. More men experienced concomitant coronary artery disease (56.4% men and 37.1% women) and reported previous revascularization (35.3% men and 25.3% women). Such differences did not reflect a worse baseline New York Heart Association class or a higher rate of heart failure readmissions in men. In fact, there was a trend toward a higher rate of MI in women (1.1%; 95% CI, 0.4-2.9) compared with that of men (0.6%; 95% CI, 0.2-2.0). Similarly, there was a trend toward higher rehospitalizations related to cardiac causes in women that did not reach statistical significance (9.8%; 95% CI, 7.1-13.3), of which cardiac causes occurred in 7.2% of women [95% CI, 4.9-10.4] vs 6.3% in men [95% CI, 4.4-8.9]. The 2 main cardiac causes for readmissions in the Gulf TAVR registry were pacemaker requirement and heart failure. The overall rate of permanent pacemaker implantation in women was lower than that in men (13.4% in men and 10.1% in women). Regarding readmissions, the need for a pacemaker accounted for 0.5% readmissions in men and 0.0% in women, making heart failure the leading cause of admissions in women, which warrants more intensive guideline-directed medical therapy on discharge (1.8% in men and 2.6% in women). Furthermore, the Gulf TAVR registry noted a 2-fold higher risk of the composite end point with a paravalvular leak. Women were less likely to develop any degree of paravalvular leak; 75% of women had no leak immediately post-TAVR compared with 69% of men, and moderate to severe leak was reported in 4% of women versus 5.6% of men. This is in fact consistent with international data denoting higher paravalvular leaks in men compared with those of women.³

Regarding acute procedural success, major and life-threatening bleeding were lower in women in the WIN Gulf TAVR registry (major, 4.5% men vs 3.7% women; life threatening, 17.9% men vs 3.4% women). Men did not have a higher baseline risk of bleeding in this cohort compared with women. For example, more women had atrial fibrillation and were on baseline anticoagulation compared with men. Furthermore, most patients were prescribed dual antiplatelet therapy on discharge. Any explanation would be speculative. Unlike other international registries, the Women's INternational Transcatheter Aortic Valve Implantation registry reported that women in the Gulf cohort had a lower rate of VARC-2 major bleeding (3.4% vs 4.4%).⁴ The most obvious differences between the Gulf population undergoing TAVR and European/American population were

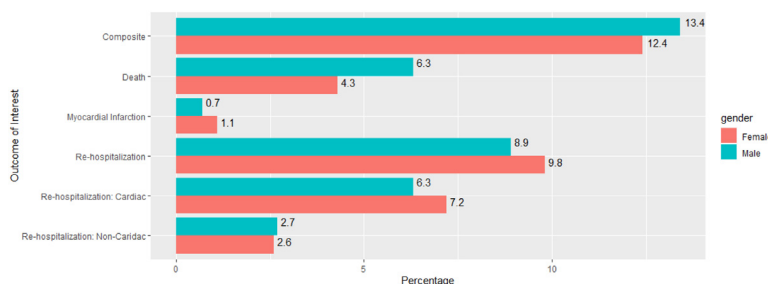


Figure 1. Bar chart depicting the primary and secondary outcomes by sex.

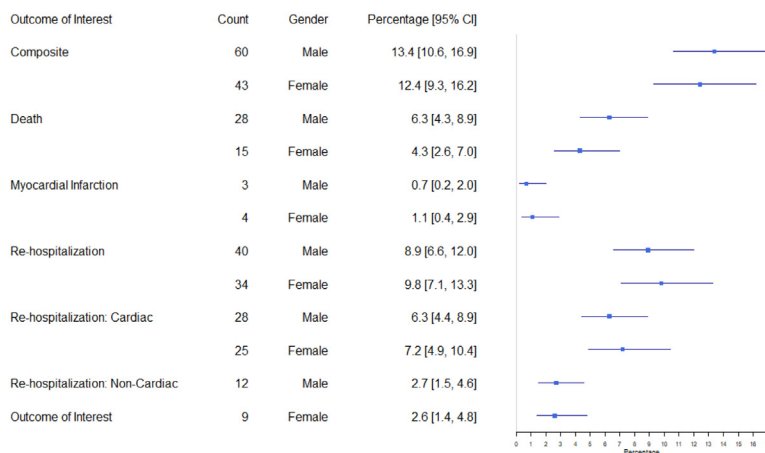
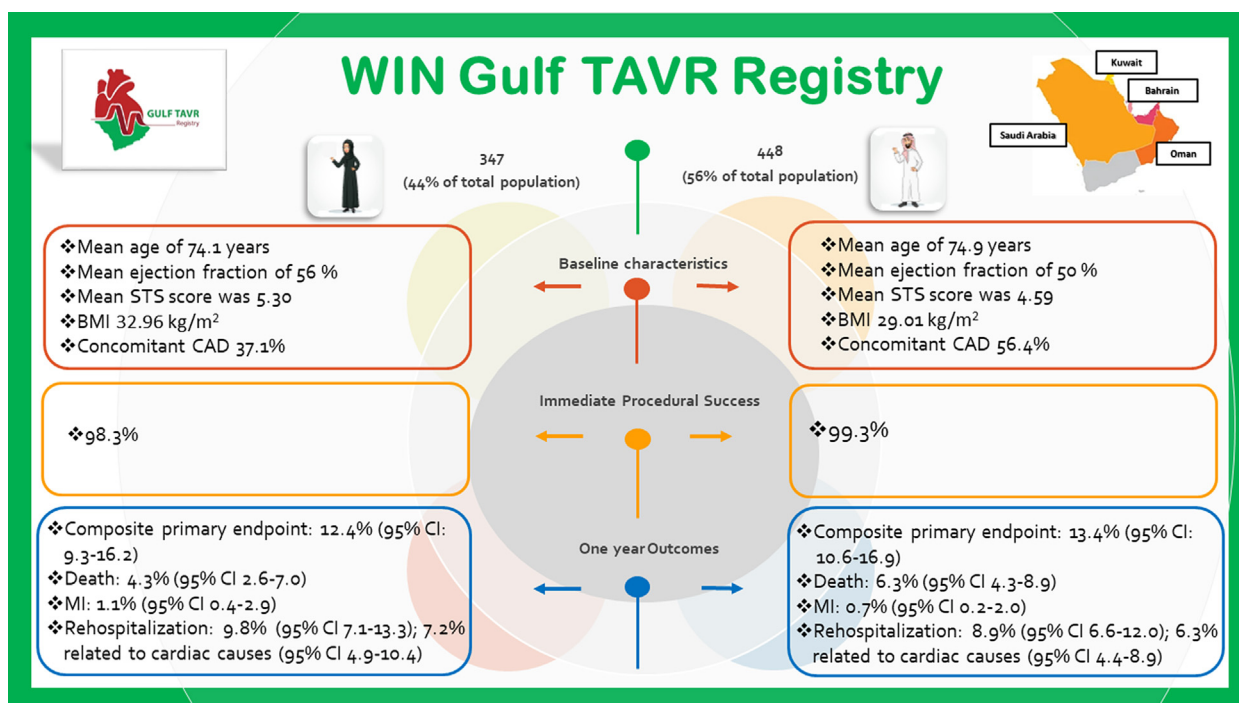


Figure 2. Forest plot depicting the primary and secondary outcomes in men and women.

the age of the patients (mean age of 74 years in the Gulf population vs 82 years in the Western population) and lower STS score (5.3 in the Gulf population vs 8.3 in the Western population). The remaining comorbidities were similar, including atrial fibrillation (21.8% in the Gulf population vs 19.6% in the Western population).⁴ Ethnic differences in platelet function and response to antiplatelets could be further elucidated through genetic testing, which was not performed in this study.

Although women had a higher mean STS score than that of men (4.59 for men vs 5.3 for women), this did not translate into a worse composite primary outcome (13.4% [95% CI, 10.6-16.9] in men and 12.4% [95% CI, 9.3-16.2] in women) in the Gulf cohort. In fact, survival in women was better, with a death rate of 4.3% [95% CI, 2.6-7.0] in women compared with 6.3% [95% CI, 4.3-8.9] in men (Figures 1 and 2). It is worthwhile considering the sex-specific differences in outcomes in the contemporary literature. Multiple observational studies and meta-analyses recognized that women have a different risk profile compared with men. After adjustment, there is a persistent paradox in multiple studies denoting better survival rates in

women despite the higher rate of procedural complications, especially vascular.⁵⁻⁸ The Gulf cohort did not register a higher periprocedural complication rate; whether this is a selection bias remains conjectural. Women had a higher BMI, which commonly adds to the risk of procedural complications, including vascular complications, but this was not the case in this study. Most of the Gulf patients received self-expanding valves (60.9% of the total, whereby 42.3% were implanted in women and 57.7% in men). The mean annular diameters were 25.1 and 27.4 mm, respectively, requiring small- and intermediate-sized transcatheter valve systems (Table 4). The smaller size valves, self-expanding and balloon expandable, were more commonly implanted in women (71.4% of those receiving a size 20 transcatheter heart valve [THV] and 66.8% of those receiving a size 23 THV compared with 16.7% of those receiving a size 29 THV). There was no direct association between the type or size of valve selected and the rate of complications between the men and women that offers a plausible explanation although there was a clear trend for women to have smaller annuli.



Central Illustration. Baseline characteristics, immediate procedural success and one year outcomes in men and women.

Finally, whether this low-risk cohort of women had outcomes that are comparable with surgical aortic valve replacement (SAVR) is unknown. Data from the Placement of Aortic Transcatheter Valves (PARTNER) trial demonstrated a lower late mortality rate with TAVR than SAVR in a population at high risk.³ European data noted similar results in low- and intermediate-risk women.⁸ These studies primarily evaluated patients undergoing transfemoral TAVR similar to the Gulf cohort (96.8%). However, the advantage of TAVR over SAVR in the Gulf population is yet to be confirmed through randomized trials. Current data note that women undergo surgical replacement of the aortic valve less frequently than men and encounter worse outcomes regarding in-hospital mortality and incur higher costs.⁹ A large retrospective analysis extracted from the Society of Thoracic Surgeons/American College of Cardiology Transcatheter Valve Therapy Registry along with several large meta-analyses pooling over 20,000 women demonstrated better survival rates in women compared with men after TAVR despite a higher incidence of comorbidities and advanced older age.^{6,7,10,11} These studies also reported higher rates of vascular complications, bleeding, and strokes. There have been several theories speculating on the better outcomes in women after TAVR that include lower rates of kidney injury, which increases mortality by 4-fold in published studies, and a lower incidence of concomitant aortic regurgitation, which also increases mortality.^{12,13} On examining the current body of evidence, survival rates of women in the Gulf cohort are consistent with those reported internationally. Women in the Gulf registry did not have a higher incidence of comorbidities except CKD, and their immediate postprocedural complications were lower including bleeding. This may be a selection bias whereby women deemed at higher risk during screening is not offered TAVR. The retrospective nature of the data collection in the Gulf TAVR registry makes it difficult to be conclusive and this remains speculative.

Limitations

A multivariate analysis was required to determine factors associated with the composite outcome of death or rehospitalization; however, it was limited given the low event rate at 1 year. Hence, although the baseline characteristics and procedural success were comparable between men and women in the Gulf cohort, the drivers of events could not be identified. In the absence of a comparator, men or SAVR, the observational nature of this study does not permit conclusions regarding the effect of sex on outcomes after aortic valve replacement (surgical or transcatheter). Finally, regional data cannot be extended to women of different backgrounds nor do they reflect the heterogeneous practices that could contribute to short- and intermediate-term events.

Conclusions

Women undergoing TAVR in the Gulf region had comparable outcomes and attributes to men in the Gulf TAVR registry. The WIN Gulf TAVR data were unable to detect significant predictors through a multivariate analysis. Numerically, women had higher rehospitalizations for cardiac causes and MI at 1 year; however, the overall survival was better. These observations warrant a

larger cohort to confirm these differences and identify the drivers of events.

Declaration of competing interest

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

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Ethics statement and patient consent

The registry adhered to the relevant ethical research guidelines. Patients enrolled in the Gulf TAVR Registry were consented appropriately and understood that their participation was purely voluntary with the right to withdraw at any time. Patients also understood that their data remains anonymous with no breach of confidentiality.

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