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Comparing access to, and outcomes following, TAVI by biological sex

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ABSTRACT

Introduction European valvular heart disease guidelines define women as a 'special group'. To explore what factors have led us to consider more than 50% of the global population special, we assessed access to transcatheter aortic valve implantation (TAVI) by sex on national and local levels and studied post-TAVI outcomes by sex within our centre.

Methods Population statistics from census data were compared against British Cardiovascular Intervention Society (BCIS) audit and local data.

Using the National Institute for Cardiovascular Outcomes Research TAVI database, a retrospective analysis of 1049 consecutive patients from 2013 to 2023 was conducted at our UK tertiary centre.

Primary outcomes were all-cause death, a three-point composite of major adverse cardiac events (MACE) comprising death, non-fatal myocardial infarction and non-fatal stroke during TAVI admission, and post-TAVI survival.

Results Nationally, females comprise 60% of over 75-year-olds; however, TAVI was performed more frequently in males: nationally (55.2% vs 44.8%, p<0.01) and locally (53.2% vs 46.8%, p<0.01). Males were 1.82 times more likely to undergo TAVI.

Locally, females undergoing TAVI were older and had worse renal function, higher frailty and greater transvalvular gradients. Males had more cardiovascular comorbidity.

In-hospital mortality and MACE did not differ by sex. Median survival was longer in females (1350 days vs 1728 days, p=0.02). Regression analysis demonstrated female sex as a predictor of increased survival (HR 0.73, 95% CI 0.61 to 0.88, p<0.01). Chronic obstructive pulmonary disease, atrial fibrillation, frailty and poor mobility were identified as predictors of reduced survival.

Conclusion In this retrospective, observational study, we have demonstrated an under-representation of females undergoing TAVI. This observation is likely of multifactorial cause, including different disease recognition, referral, investigation and treatment practices.

We observed no difference in procedural death or MACE, but longer female survival, despite higher baseline age, frailty and renal impairment.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Female sex is a predictor of worsened access to transcatheter aortic valve implantation (TAVI)/surgical aortic valve replacement, and women are defined as a special group in the European valvular heart disease guidelines. Whether survival by sex differs after TAVI is unclear. Existing literature on the topic is discordant.

WHAT THIS STUDY ADDS

⇒ Males are almost twice as likely as females to undergo TAVI both in our centre and in England and Wales. Females who undergo TAVI in our centre are older and frailer than males, but despite this have similar short-term outcomes and survive more than a year longer than male counterparts.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ Our study supports the notion that current selection criteria for TAVI procedures are inadequate. We suggest that there is a need for equitable access to TAVI by sex and to consider the development of a UK-validated, pre-procedure, TAVI-specific risk prediction score.

INTRODUCTION

There is an appropriate and increasing global interest in ensuring equality of access to healthcare across the sociodemographic spectrum. Concerningly, data from the USA and, more recently, the UK have shown that female biological sex is a predictor of worsened access to both transcatheter aortic valve implantation and surgical aortic valve replacement (TAVI/SAVR) for severe aortic stenosis (AS).[1 2] Moreover, women are now defined as a 'special group' in the European valvular heart disease guidelines.[3] This is because women are recognised to incur a higher mortality from AS than men. This finding is of significant concern, as AS is thought to occur with equal frequency in males and females, and there is no pathophysiological explanation for a more malignant disease process in females.[4] Instead, although incompletely understood, it is thought that disease recognition, heart team referral and treatment are delayed for women with severe AS.[3] Even once treated for AS with SAVR, women have been observed to experience poorer outcomes compared with men.[5 6] Recently presented randomised controlled trial data

have shown improved short-term outcomes for women with AS undergoing TAVI rather than SAVR.[7] It remains unclear, however, whether there is a discrepancy in outcomes by sex following treatment of severe AS with TAVI. There is significant discordance within the existing literature.[4 8–12] It is imperative we expedite the study of this issue to better understand what factors have led us to consider more than 50% of the global population 'special'.

To this end, in this paper, we have assessed the proportionality of TAVI procedures by sex both in our own centre and nationally. We also conducted a subsequent analysis of outcomes by sex in a consecutive cohort of patients treated with TAVI for AS at our single tertiary referral centre in the UK over the last decade.

METHODS

Study characteristics

This was a single-centre, retrospective, observational analysis of 1049 patients undergoing TAVI at St George's Hospital (SGH), Tooting, London, UK, from 1 January 2013 to 1 March 2023.

Sources of data

Data for patients undergoing TAVI at SGH were obtained from the prospectively held National Institute for Cardiovascular Outcomes Research database.[13]

The male to female sex ratio of the SGH TAVI population was compared with the sex ratio in over 75-year-olds from the local authorities referring most frequently to SGH Heart Team for consideration of TAVI. This was collected from 2011 NOMIS census data.

The national male to female sex ratio in those over 75 years old was determined from the 2011 census of England and Wales.[14] The national male to female sex ratio of those over 75 who had undergone TAVI from 2007 to 2022 was determined from published BCIS audit data. Long-term survival data was obtained from electronic health records.

TAVI procedure

All patients who underwent TAVI were assessed by the local SGH Heart Team prior to the procedure. The Heart Team included interventional cardiologists, cardiac surgeons, non-invasive and imaging cardiologists, anaesthetists and nurse practitioners. Preprocedural and postprocedural transthoracic echocardiographic (TTE) imaging was performed to assess the AS severity and the performance of the TAVI valve, respectively. Valve sizing was informed by preprocedural CT imaging. TAVI valves used were manufactured by Medtronic, Edwards and Boston Scientific. Preprocedural imaging with either TTE or transoesophageal echocardiography was also performed to assess valve positioning and for immediate complication. Almost all TAVI procedures were performed by interventional cardiologists via an ultrasound-guided transfemoral approach following local anaesthetic, although a minority were performed under general anaesthetic. Some procedures, particularly those done early in the database's history, were performed jointly by an interventional cardiologist and cardiac surgeon and/or vascular surgeon. A small number of procedures (n=17) were carried out via axillary, subclavian or direct aortic access following sternotomy. Following the TAVI procedure, haemostasis was achieved using a vascular closure device or surgical closure.

Outcome measures

Primary outcomes were prespecified as all-cause death before discharge on index admission, a three-point composite of major adverse cardiac events (MACE) (death from any cause, non-fatal myocardial infarction (MI) and non-fatal stroke) during index TAVI admission, and post-TAVI survival time.

Secondary outcomes were prespecified as any vascular access site or vascular access-related complication (including but not limited to aortic rupture, annulus rupture, left ventricle perforation, or new apical aneurysm/pseudoaneurysm dissection, stenosis, perforation, rupture, arteriovenous fistula, pseudoaneurysm, haematoma, irreversible nerve injury, compartment syndrome and percutaneous closure device failure), bleeding events (defined as per the Bleeding Academic Research Consortium, the details of which are published elsewhere), moderate or worse aortic regurgitation, stroke, MI and peri/postprocedural permanent cardiac pacing, acute kidney injury, new renal replacement therapy, valve not successfully deployed, valve malpositioning, valve-in-valve bailout, further valve intervention, tamponade, sternotomy and aortic valve area.[15]

Statistical analysis

Statistical analysis and data presentation was carried out using IBM SPSS Statistics V.29. Demographic and clinical variables were tested against gender at baseline and following TAVI as appropriate. Categorical variables were compared using a χ^2 test and continuous variables were compared using a Student's t-test. P values <0.05 were considered statistically significant.

Survival analysis was conducted using Kaplan-Meier curves to estimate survival probabilities over time and to compare survival distributions between groups. The log-rank test was used to assess statistical differences between survival curves. Additionally, Cox proportional hazards regression analysis was performed to evaluate the effect of multiple covariates on survival outcomes. HRs with 95% CIs were calculated to quantify the relative risk of events associated with each predictor. P values <0.05 were considered statistically significant.

Categorical findings are presented as (n (%) vs n (%), p value). Continuous variables are presented as (n±SE vs n±SE, p value). Outcome measures have been presented as (unadjusted OR, 95% CI, p value).

RESULTS

TAVI procedures by biological sex: the local and national picture

In 2011, there were 1 764 623 males and 2 605 617 females over the age of 75 in England and Wales (40.4%

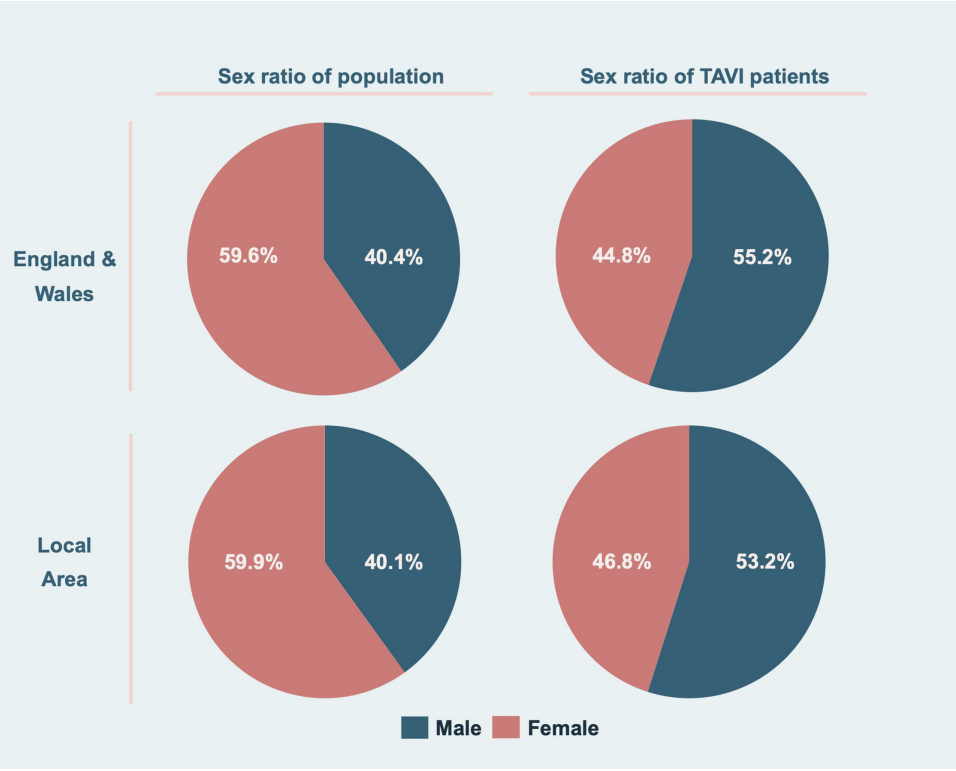

Figure 1 The sex composition of national and local populations of ≥75-year-old adults compared with the procedural proportion by sex. TAVI, transcatheter aortic valve implantation.

vs 59.6%, p<0.01). Despite the female predominance in the baseline population, from 2013 to 2023, significantly more males (n=20 834) than females (n=16 911) (55.2% vs 44.8%, p<0.01) underwent TAVI. This equated to 11 807 TAVI procedures per million within the male population and 6492 TAVI procedures per million within the female population. The national picture is echoed in our local data. In 2011, there were 87 483 males and 130 949 females over the age of 75 (40.1% vs 59.9%, p<0.01) in the boroughs most local to our hospital. Between 2013 and 2023, a total of 1049 TAVI procedures were performed in our centre, 558 were carried out in males and 491 in females (53.2% vs 46.8%, p<0.01). This equated to 6596 TAVI procedures per million within the male population and 3619 TAVI procedures per million within the female population. Males were 1.82 times more likely to undergo TAVI than females in both the national and local datasets (figure 1).

Local TAVI population: demographic data

The baseline characteristics of the 1049 patients who underwent TAVI at our centre from 2013 to 2023 are displayed in table 1. Of note, female patients were 1.48 years older (82.1 vs 83.5, p<0.01) at the time of TAVI than their male counterparts. Female patients had worse renal function (creatinine clearance (CrCl) 54.8±27.3 mL/min vs 50.3±21.2 mL/min, p<0.03), higher frailty scores (Rockwood Clinical Frailty Score 4.5 vs 5.0, p<0.001) and higher aortic gradients (peak aortic gradient 44.0±16.5 mm Hg vs 48.4±15.9 mm Hg, p<0.001) (mean aortic gradient 44.0±16.5 mm Hg vs 48.3±15.9 mm Hg, p<0.001). Male patients were more likely to have a history of smoking (258 (46.5%) vs 141 (28.7%), p<0.001), prior MI (142 (25.4%) vs 69 (14.1%), p<0.001), extracardiac arteriopathy (85 (15.2%) vs 47 (9.6%), p=0.007), cardiac surgery (110 (19.7%) vs 43 (8.8%), p<0.001), severely impaired left ventricular function (223 (40.2%) vs 119 (24.3%), p<0.001), a three-vessel coronary artery disease (79 (14.2%) vs 25 (5.1%), p<0.001) and left main stem disease (42 (7.5%) vs 8 (1.6%), p<0.01).

Periprocedural data

There was no sex-related difference in procedure urgency, non-elective cases (101 (18.1%) vs 69 (14.1%), p=0.07). Males received a larger mean valve size (29.04 mm vs 26.87 mm, p<0.01). Females were more likely to receive Medtronic valves (410 (73.5%) vs 419 (85.3%), p<0.001) and self-expanding valves (433 (77.7%) vs 427 (87.0%), p<0.001) (table 2).

Short-term outcomes by sex during index TAVI admission

Risk of death before discharge on index admission did not significantly differ between males and females (OR 0.59, 95% CI 0.26 to 1.35, p=0.24). Similarly, there was no difference between males and females in the three-point composite of MACE (death from any cause, non-fatal MI and stroke) before discharge (OR 0.71, 95% CI 0.41 to 1.25, p=0.26). Female patients did experience more vascular access site complications than their male counterparts (OR 1.956, 95% CI 1.22 to 3.13, p=0.005).

Table 1 Baseline demographics of patients undergoing TAVI at our centre

Variable*	All n=1049	Male n=558 (53.2)	Female n=491 (46.8)	P value†
Age (years)	82.8 (±7.2)	82.1 (±7.0)	83.5 (±7.2)	**<0.001**
White ethnicity	948 (90.0)	506 (91.0)	442 (90.0)	0.22
Height (m)	1.6 (±0.1)	1.7 (±0.1)	1.6 (±0.1)	**<0.001**
Weight (kg)	73.7 (±17.1)	79.1 (±15.7)	68.0 (±16.7)	**<0.001**
BMI (kg/m^2)	27.3 (±6.1)	27.1 (±5.1)	27.6 (±7.1)	0.21
Diabetes	289 (28.0)	164 (30.0)	125 (26.0)	0.15
Smoking history	399 (38.0)	258 (46.5)	141 (28.7)	**<0.001**
Creatinine clearance	52.6 (±24.7)	54.8 (±27.3)	50.3 (±21.2)	**0.003**
Pulmonary disease	258 (24.6)	149 (26.8)	109 (22.2)	0.10
Atrial fibrillation	280 (26.7)	166 (29.7)	114 (23.2)	**0.02**
CVA/TIA	108 (10.3)	56 (10.0)	52 (10.6)	0.84
Liver disease	8 (0.8)	5 (0.9)	3 (0.6)	0.56
NYHA score				
I	128 (12.2)	75 (13.4)	53 (10.8)	0.29
II	71 (6.8)	43 (7.7)	28 (5.7)	
III	519 (49.5)	271 (48.6)	248 (50.6)	
IV	330 (31.5)	169 (30.3)	161 (32.9)	
III–IV	849 (81.0)	440 (78.9)	409 (83.5)	0.06
Previous MI	211 (20.1)	142 (25.4)	69 (14.1)	**<0.001**
Extracardiac arteriopathy	132 (12.6)	85 (15.2)	47 (9.6)	**0.01**
Previous cardiac surgery				
Any (composite)	153 (14.6)	110 (19.7)	43 (8.8)	**<0.001**
CABG	113 (10.8)	88 (15.8)	25 (5.1)	**<0.001**
CABG+valve	15 (1.4)	10 (1.8)	5 (1.0)	0.44
Valve	25 (2.4)	12 (2.2)	13 (2.6)	0.69
Severely impaired LVEF (<30%)	342 (32.7)	223 (40.2)	119 (24.3)	**<0.001**
Coronary artery disease				
Presence of CAD	343 (33.3)	215 (39.2)	128 (26.6)	**<0.001**
Three-vessel CAD	104 (9.9)	79 (14.2)	25 (5.1)	**<0.001**
LMS disease	50 (4.8)	42 (7.5)	8 (1.6)	**<0.001**
Aortic annular dimension (mm)	23.9 (±2.5)	25.0 (±2.4)	22.6 (±2.0)	**<0.001**
Peak aortic gradient (mm Hg)	72.3 (±24.1)	69.7 (±24.5)	75.2 (±23.3)	**<0.001**
Mean aortic gradient (mm Hg)	46.0 (±16.4)	44.0 (±16.5)	48.3 (±15.9)	**<0.001**
Aortic valve area (cm^2)	0.7 (±0.2)	0.7 (±0.2)	0.6 (±0.2)	**<0.001**
Bicuspid valve	65 (6.2)	40 (7.2)	25 (5.1)	0.20
Preprocedural pacing	163 (15.6)	106 (19.0)	57 (11.6)	**0.001**
CCS angina grade				
0	765 (73.0)	402 (74.1)	363 (74.1)	0.48
I	26 (2.5)	14 (2.5)	12 (2.4)	
II	156 (14.9)	86 (15.4)	70 (14.3)	
III	85 (8.1)	44 (7.9)	41 (8.4)	
IV	16 (1.5)	12 (2.2)	4 (0.8)	
Clinical Frailty Scale score	4.8 (±1.4)	4.5 (±1.4)	5.0 (±1.3)	**<0.001**
Poor mobility‡	249 (23.8)	99 (17.7)	150 (30.6)	**<0.001**

Continued

Table 1 Continued

Variable*	All n=1049	Male n=558 (53.2)	Female n=491 (46.8)	P value†

*Categorical variables are presented as n (%). Continuous variables are presented as n (±SD).
†P values <0.05 (shown in bold) were considered significant.
‡Neurological or musculoskeletal dysfunction severely affecting mobility.
BMI, body mass index; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CCS, Canadian Cardiovascular Society; CVA, cerebrovascular accident; LMS, left main stem; LVEF, left ventricular ejection fraction; MI, myocardial infarction; NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation; TIA, transient ischaemic attack.

The statistical significance of these findings remained unchanged when adjusted for differences in the baseline populations.

Rates of moderate or worse aortic regurgitation (unadjusted OR 1.28, 95% CI 0.49 to 3.34, p=0.63), stroke (unadjusted OR 0.80, 95% CI 0.38 to 1.69, p=0.58), MI (unadjusted OR 1.14, 95% CI 0.16 to 8.10, p=1.00) and peri/postprocedural permanent cardiac pacing (unadjusted OR 1.05, 95% CI 0.73 to 1.50, p=0.86) were not significantly different between males and females. This remained true following statistical adjustment for differences in the baseline population.

Unadjusted rates of bleeding episodes were numerically higher in females, but this did not meet the threshold for statistical significance (unadjusted OR 1.58, 95% CI 1.00 to 2.49, p=0.05). This remained true after adjustment for differences in the baseline population (adjusted OR 1.37, 95% CI 0.85 to 2.20, p=0.20) (table 3).

Post-TAVI survival analysis by sex

Unadjusted post-TAVI median survival time was more than 1 year longer in female patients (1350 days (95% CI 1228 to 1473) vs 1728 days (95% CI 1547 to 1909), p=0.02) (figure 2A). In the multivariate Cox proportional hazards model, several factors demonstrated a significant interaction with post-TAVI survival time. Factors associated with increased survival time in this cohort were female biological sex (HR 0.73, 95% CI 0.61 to 0.88, p<0.01) (figure 2B) and higher levels of CrCl (HR 0.99, 95% CI 0.94 to 0.99, p<0.01). Factors associated with reduced survival time included presence of chronic obstructive pulmonary disease (HR 1.56, 95% CI 1.29 to 1.89, p<0.01), presence of atrial fibrillation (AF) (HR 1.62, 95% CI 1.34 to 1.95, p<0.01), higher frailty scores (HR 1.08, 95% CI 1.00 to 1.16, p=0.04) and poor mobility (HR 1.28, 95% CI 1.03 to 1.60, p=0.03). Of note, the presence of left ventricular impairment (HR 1.21, 95% CI 1.01 to 1.46, p=0.39) and older age at time of TAVI (HR 1.00, 95% CI 0.99 to 1.02, p=0.73) did not have a significant impact on post-TAVI survival time.

DISCUSSION

This study has described significant disproportionality in rates of TAVI by sex, both in our study cohort and in national practice. In adults over the age of 75 in England and Wales, women comprise 60% of the population but undergo only 45% of all TAVI procedures. Males are nearly two times more likely than females to undergo a TAVI procedure. Concerningly, this disparity does not appear to be confined to England and Wales. Recently published multinational European registry data have similarly demonstrated that women undergo aortic valve intervention at lower rates than men.[16] The reasons for these findings are not clear but are almost certainly multifactorial.[17] Addressing this disparity in access to TAVI by sex is both an ethical imperative and a practical necessity. This is particularly true in resource-limited healthcare systems, like the National Health Service, where the provision of 'high value' care at an individual and population level is essential.

Baseline population differences in those referred for consideration of TAVI may contribute to a degree to the male predominance in procedure volume. Assessment of factors influencing recognition of AS and timing of referral to the heart team were beyond the scope of this paper. However, females were older at the time of TAVI, with higher frailty scores and worse renal function. Age, frailty scores and renal function are routinely incorporated into cardiovascular risk prediction models, like the European System for Cardiac Operative Risk Evaluation II (EuroSCORE II). These scores are used to help select patients for TAVI procedures.[6] Thus, females who are older, frailer and have worse renal function than males referred for TAVI may be less likely to be judged suitable for aortic valve intervention by heart teams.

In our study, there was no observed difference in survival to discharge, or short-term MACEs, in females compared with males following TAVI. Females were observed to have significantly more vascular access-related complications, but this was in the absence of increased clinically relevant bleeding or increased MACE. This observation may relate to the technical challenge posed by smaller calibre access vasculature and increased sheath to artery ratios in females; this finding is not unique to our cohort and has been previously described in other published work.[11 18]

Despite baseline disadvantages in prognostically relevant characteristics, frailty and renal impairment, in our study cohort, females were observed to survive longer after TAVI than males. This finding was statistically robust and persisted following adjustment for baseline demographic differences between males and females. The

Table 2 Procedural characteristics by sex

Variable*	All n=1049	Male n=558 (53.2)	Female n=491 (46.8)	P value†
Procedure urgency				
Elective	879 (83.8)	457 (81.9)	422 (85.9)	
Non-elective	170 (16.2)	101 (18.1)	69 (14.1)	0.08
Anaesthesia type				
Non-GA	684 (65.2)	363 (65.1)	321 (65.4)	
GA	365 (34.8)	195 (34.9)	170 (34.6)	0.95
Unplanned conversion to GA	30 (2.9)	18 (3.2)	12 (2.4)	0.47
Aortic valvuloplasty prior	329 (31.4)	179 (32.1)	150 (30.5)	0.64
Manufacturer				
Medtronic	829 (79.0)	410 (73.5)	419 (85.3)	**<0.001**
Edwards	188 (17.9)	124 (22.2)	64 (13.0)	
Boston	31 (3.0)	23 (4.1)	8 (1.6)	
Valve model				
CoreValve	78 (7.4)	47 (8.4)	31 (6.3)	
R	287 (27.4)	166 (29.7)	121 (24.6)	
Pro	315 (30)	212 (21.7)	194 (39.5)	
Pro+	145 (13.8)	74 (13.3)	71 (14.5)	
Sapien 3	67 (6.4)	46 (8.2)	21 (4.3)	
Sapien 3 Ultra	118 (11.2)	76 (13.6)	42 (8.6)	
Lotus	31 (3.0)	23 (4.1)	8 (1.6)	
Valve type				
Self-expanding	860 (82.1)	433 (77.7)	427 (87.0)	**<0.001**
Balloon expanding	188 (17.9)	124 (22.3)	64 (13.0)	
Mean valve size (mm)	28.1 (±2.9)	29.2 (±2.9)	26.8 (±2.4)	**<0.001**
Postdilatation	146 (13.9)	80 (14.4)	66 (13.4)	0.72
Access route				
Femoral	1028 (98)	545 (97.7)	483 (98.4)	0.48
Surgical	5 (0.5)	2 (0.4)	3 (0.6)	
Axillary/subclavian	7 (0.7)	5 (0.9)	2 (0.4)	
Direct aortic	8 (0.8)	6 (0.6)	2 (0.2)	
Closure type				
Device	976 (93.0)	508 (91.0)	468 (95.3)	0.06
Surgical planned	12 (1.1)	7 (1.3)	5 (1.0)	
Surgical bailout	27 (2.6)	16 (2.9)	11 (2.2)	
Manual pressure	24 (2.3)	20 (3.6)	4 (0.8)	
Procedure time (min)	100.4 (±51.6)	100.4 (±53.0)	100.4 (±50.1)	0.999

*Categorical variables are presented as n (%). Continuous variables are presented as n (±SD).
†P values <0.05 (shown in bold) were considered significant.
GA, general anaesthetic.

reasons for this sex-related survival difference are not fully elucidated. However, it is notable that men exhibited higher rates of AF, which demonstrated significant interaction with post-TAVI survival in our modelling, as well as a greater prevalence of severely impaired left ventricular function and more extensive and severe coronary artery disease. Although these latter factors did not independently interact with survival in our analysis, their cumulative effect may nevertheless have contributed to reduced male survival, offsetting the baseline disadvantages of frailty and reduced renal function observed in women.

Table 3 Outcomes by sex following TAVI before discharge from index admission

Variable*	All n=1049	Male n=558 (53.2)	Female n=491 (46.8)	Unadjusted OR (95% CI)	Unadjusted P value‡	Adjusted† OR (95% CI)	Adjusted† P value
Death (before discharge)	26 (2.5)	17 (3.0)	9 (1.8)	0.59 (0.26 to 1.35)	0.24	0.60 (0.26 to 1.40)	0.24
3P MACE (death, MI, stroke)	54 (5.2)	33 (5.9)	21 (4.3)	0.71 (0.41 to 1.25)	0.26	0.72 (0.40 to 1.29)	0.27
Postprocedural stroke	29 (2.8)	17 (3.0)	12 (2.4)	0.80 (0.38 to 1.69)	0.58	0.85 (0.39 to 1.83)	0.67
Myocardial infarction	4 (0.4)	2 (0.4)	2 (0.4)	1.14 (0.16 to 8.10)	1	1.54 (0.20 to 11.91)	0.68
Vascular access site complication	79 (7.5)	30 (5.4)	49 (10.0)	1.96 (1.22 to 3.13)	**0.01**	1.84 (1.13 to 2.99)	**0.01**
Bleeding complications	82 (7.8)	35 (6.3)	47 (9.6)	1.58 (1.00 to 2.49)	0.05	1.37 (0.85 to 2.20)	0.2
Moderate or worse aortic regurgitation	17 (1.6)	8 (1.4)	9 (1.8)	1.28 (0.49 to 3.34)	0.63	1.21 (0.45 to 3.25)	0.7
AKI	67 (6.4)	43 (7.7)	24 (4.9)	0.61 (0.67 to 1.03)	0.08	0.61 (0.36 to 1.04)	0.07
New renal replacement therapy	12 (1.1)	6 (1.1)	6 (1.2)	1.14 (0.37 to 3.55)	1	1.16 (0.35 to 3.84)	0.81
Valve not successfully deployed	15 (0.01)	11 (2.0)	4 (0.8)	0.41 (0.13 to 1.29)	0.36	0.50 (0.14 to 1.74)	0.27
Valve malpositioning	13 (1.2)	9 (1.6)	4 (0.8)	0.50 (0.15 to 1.63)	0.28	0.55 (0.16 to 1.84)	0.33
Valve-in-valve bailout	9 (0.9)	7 (1.3)	2 (0.4)	0.32 (0.07 to 1.55)	0.19	0.34 (0.07 to 1.68)	0.18
Tamponade	8 (0.8)	5 (0.9)	3 (0.6)	0.68 (0.16 to 2.86)	0.74	0.68 (0.15 to 3.04)	0.61
Permanent pacemaker	140 (13.4)	73 (13.1)	67 (13.6)	1.05 (0.73 to 1.50)	0.86	1.01 (0.70 to 1.47)	0.94
Peak gradient (mm Hg)	15.4 (±9.2)	15.3 (±8.1)	15.7 (±8.4)	1.00 (1.00 to 1.01)	0.45	1.00 (1.00 to 1.00)	0.9
Mean gradient (mm Hg)	8.1 (±4.3)	8.0 (±4.4)	8.1 (±4.3)	1.00 (0.99 to 1.01)	0.63	1.00 (0.99 to 1.01)	0.98
Aortic valve area (cm^2)	1.58 (±0.34)	1.60 (±0.37)	1.55 (±0.30)	0.89 (0.81 to 0.98)	**0.02**	0.91 (0.83 to 1.00)	**0.05**

Raw values and adjusted values following multivariate analysis are displayed.
*Categorical variables are presented as n (%). Continuous variables are presented as mean (SD).
†Adjusted values are from logistic or linear regression models.
‡P values <0.05 are bolded in the original table.
AKI, acute kidney injury; MACE, major adverse cardiac event; MI, myocardial infarction; 3P, three-point; TAVI, transcatheter aortic valve implantation.

Our findings, which should prompt wider UK validation, support the notion that current selection criteria for TAVI procedures are inadequate. Non-TAVI-specific preoperative risk prediction tools may be contributing to this problem. There is evidence, in non-UK patients, that non-TAVI-specific risk prediction models, such as the EuroSCORE II, overestimate mortality risk from TAVI procedures.[19] Continued use of these scoring systems could further polarise access to TAVI by sex. We suggest that there is a need

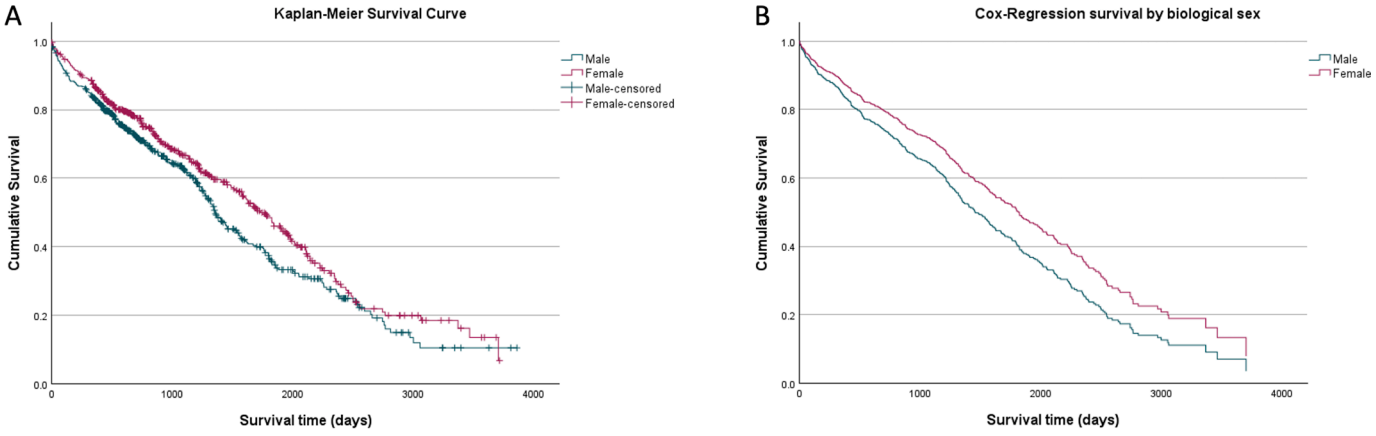

Figure 2 (A) Kaplan-Meier survival curve comparing male and female median survival time following TAVI. Unadjusted post-TAVI median survival time was more than 1 year longer in female patients (1350 days (95% CI 1228 to 1473) vs 1728 days (95% CI 1547 to 1909), p=0.02). (B) Survival by sex following covariate analysis and statistical correction by Cox regression modelling. Female sex was independently associated with increased survival time (HR 0.73, 95% CI 0.61 to 0.88, p=0.001). TAVI, transcatheter aortic valve implantation.

to consider the development of a UK-validated, pre-procedure, TAVI-specific risk prediction score. Developing and implementing such a score could help equalise procedure rates by sex and better identify those with most to gain from TAVI.

Our study has some limitations; these are largely inherent to its single-centre, observational, retrospective and registry-based design. Our analysis was therefore limited to only the patients included in the registry and further influenced by the completeness and accuracy of the data collected. Moreover, due to the study design, caution is warranted when drawing causal inferences from our work, as the potential influence of residual or unrecognised confounding on the observed results cannot be definitively excluded.

Although our study was based in a single centre, our local rates of TAVI by sex per million people are identical to those observed in England and Wales as a whole. This could suggest wider generalisability of our work. Finally, although we have collected and analysed data in our local TAVI population for more than a decade, the sex ratios of the local and national populations are derived from census data, collected at a single time point.

CONCLUSION

In this study, we have demonstrated a significant disproportionality in TAVI rates by sex, and although males are almost twice as likely to undergo a TAVI procedure, females have significantly better long-term survival following TAVI.

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