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Gender-based outcomes following aortic valve replacement: A multicentre propensity score matching analysis



Background / Study Objective

- Surgical aortic valve replacement (SAVR) might represent a greater risk for females than for males. Certain baseline comorbidities and anatomical differences may be responsible for such disparities.¹
- INDURE & IMPACT real-world observational prospective registries enrolled a total of 993 patients (2019-2021) undergoing SAVR across 41 centers in Europe and Canada.
- **The aim of the present merged analysis was to compare the 3-year clinical outcomes, ventricular function and quality of life of SAVR in female vs. male patients.**

1. Caponcello MG, Banderas LM, Ferrero C, Bramlage C, Thoenes M, Bramlage P. Gender differences in aortic valve replacement: is surgical aortic valve replacement riskier and transcatheter aortic valve replacement safer in women than in men? J Thorac Dis. 2020 Jul;12(7):3737-3746



Methods

- **Inclusion:** ≥ 18 years of age undergoing SAVR w/ or w/out concomitant CABG, supracoronary tube graft and/or root replacement. Valve model 11500a
 - **Exclusion:** Prior AVR, active endocarditis and/or myocarditis ≤ 3 months, double valve procedure
 - **Follow-up:** Annually up to 5 years with core-lab adjudication at 1 and 5 years
 - **Adjudication** of outcomes by an independent clinical event committee
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- 1021 enrolled patients from two prospective observational multicentre registries were merged
 - After the exclusion of 31 patients not meeting the inclusion criteria*, the remaining 993 patients were divided according to their gender (Female group N= 258; Males group N=735)
 - Nearest neighbour propensity score 1:2 matching, with a calliper width equal to 0.2 times the standard deviation of the PS logit, resulted in 689 patients which were divided in two groups (Female group N=247; Male group N=442)

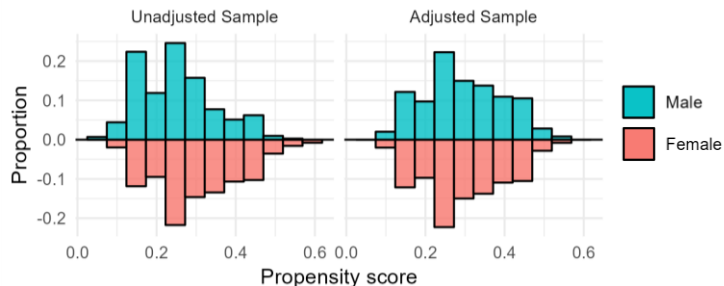
Edwards Lifesciences funding: HVT-I18-331 / HVT-I19-091 - ClinicalTrials.gov identifier NCT04053088 / NCT03666741

*Reasons: Not meeting inclusion/exclusion criteria (n=9); Not receiving valve model 11500a (n=10); Double valve procedure (replacement or repair; n=10), Withdrew from the study (n=2)



Patients: Propensity score matching

Distribution balance for the propensity matching

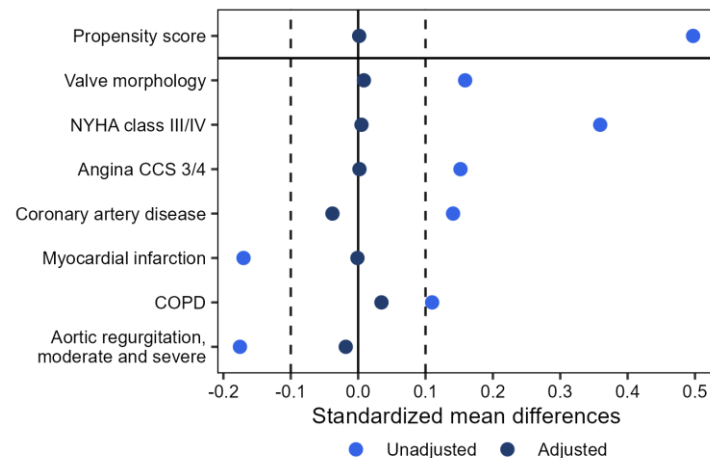


Baseline characteristics – before adjustment

% or mean \pm SD	Female (n=247)	Male (n=442)	p-value*
Age [years]	59.9 \pm 9.6	60.1 \pm 8.6	0.700
BMI [kg/m ²]	27.9 \pm 6.3	28.7 \pm 4.8	0.003
NYHA class III or IV, %	45.7	37.6	0.036
Angina CCS 3/4, %	6.1	2.9	0.046
EuroSCORE II [%]	2.4 \pm 3.1	1.6 \pm 1.7	<0.001
STS score [%]	1.8 \pm 1.7	1.3 \pm 2.0	<0.001
LVEF [%]	60.4 \pm 10.0	57.4 \pm 10.2	<0.001

* Continuous: Mann-Whitney U test; Categorical: Pearson's Chi-squared test

Covariate balance

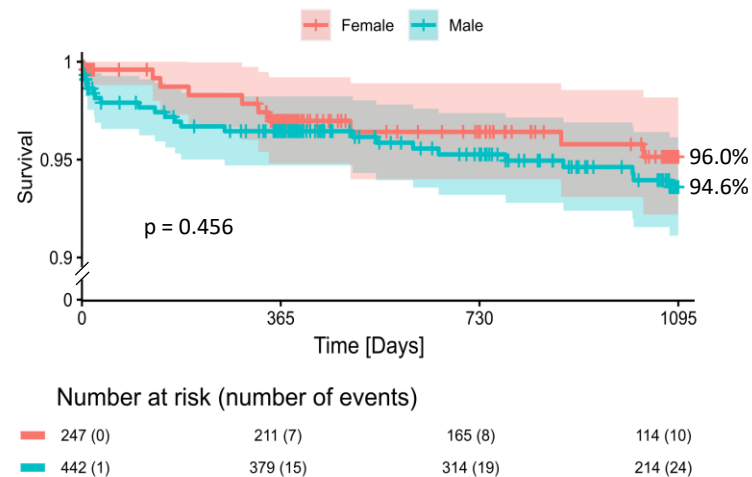


Results 1: Clinical outcomes at 3 years

n (%)	Early events (≤30 days) n (%)		Late events (up to 3 years) n (linearized rate/vy)		Log rank p-value
	Females (n=247)	Males (n=442)	Females (553 vy)	Males (1016 vy)	
All-cause mortality	1 (0.4)	8 (1.8)	9 (1.6)	16 (1.6)	0.456
CV mortality	1 (0.4)	8 (1.8)	3 (0.5)	10 (1.0)	0.087
Valve-related mortality	0	4 (0.9)	2 (0.4)	6 (0.6)	0.169
Endocarditis	0	0	2 (0.4)	8 (0.8)	0.301
Thromboembolic events	4 (1.6)	17 (3.8)	4 (0.7)	4 (0.4)	0.459
Stroke	4 (1.6)	11 (2.5)	1 (0.5)	0	0.815
Valve thrombosis	0	0	5 (0.9)	3 (0.3)	0.102
Valve-related dysfunction	0	1 (0.2)	6 (1.1)	3 (0.3)	0.102
Repeated procedure	0	2 (0.5)	3 (0.5)	1 (0.1)	0.465
Permanent pacemaker implant	9 (3.6)	16 (3.6)	4 (0.7)	3 (0.3)	0.570
Valve-related bleeding	30 (12.1)	48 (10.9)	3 (0.5)	3 (0.3)	0.504
SVD stage 2	0	0	6 (1.1)	8 (0.8)	0.531
SVD Stage 3	0	0	0	0	-

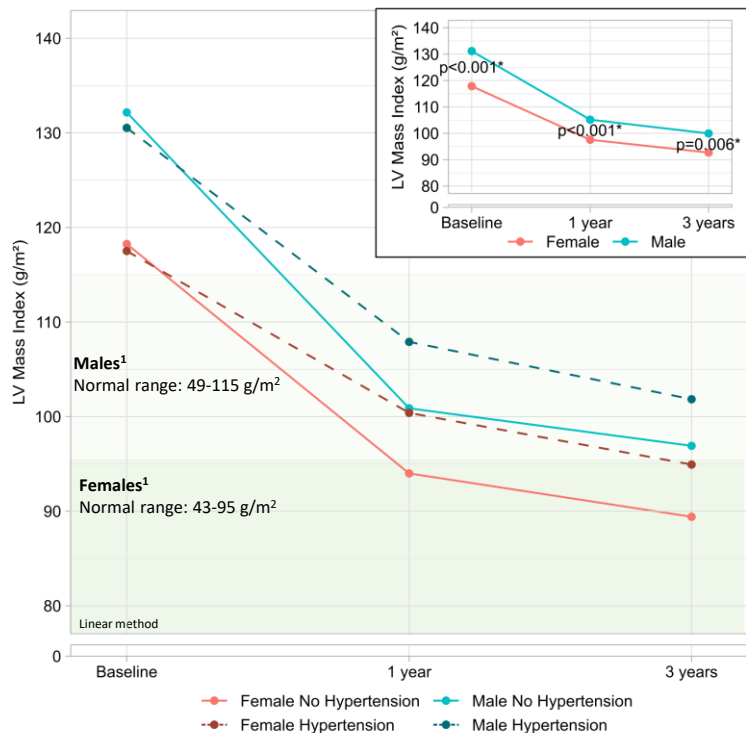
vy, valve years; CV, cardiovascular; SVD, structural valve deterioration

Survival at 3-year follow-up by gender



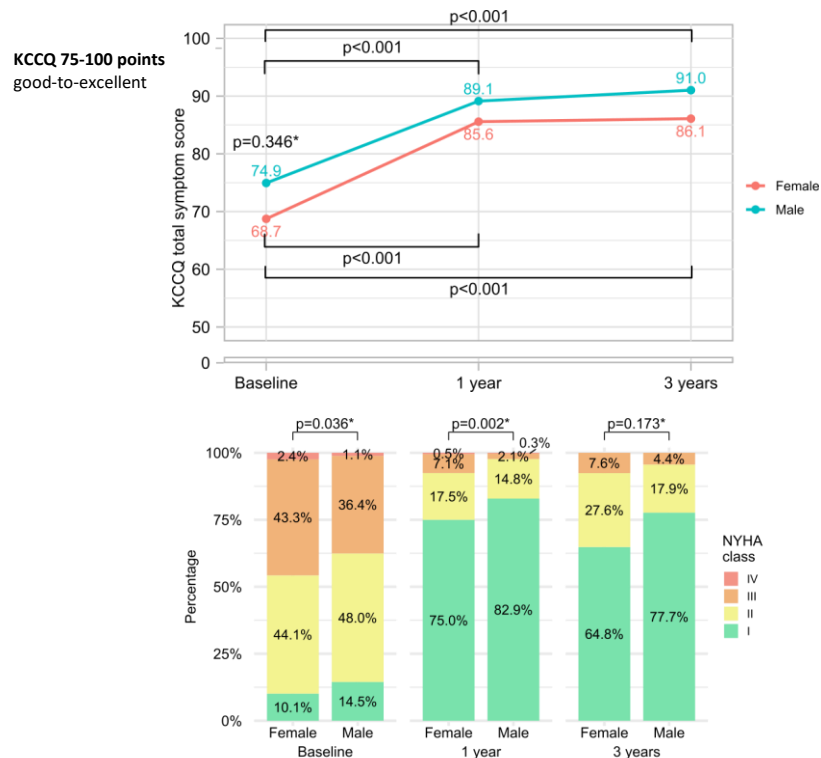
Results 2: LV mass regression and quality of life by gender at 3 years

LV mass regression



¹Pairwise comparison between genders. Mixed-effects ANOVA: Time effect: $p < 0.001$; Gender effect: $p = 0.002$; HNT effect: $p = 0.561$; Interaction effects: Not significant - 1 Lang et al 2015 Jan;28(1):1-39.e14.

Quality of life and NYHA class changes



* Mixed-effects ANOVA: Time effect: $p < 0.001$ - Gender effect: $p = 0.342$ - Interaction effects: Not significant
** Pairwise comparison between genders for grouped NYHA classes III and IV

Conclusion

- In young patients undergoing SAVR, female patients were referred with a worse functional status and had a greater preoperative risk
- After propensity matching, 3-year freedom from mortality, adverse events rates and valve performance all remained very satisfactory regardless of the gender
- LV mass regression was observed at each time point of the follow up reaching a normal range, with significant differences between females and males
- The presence of hypertension slowed the LV mass regression, mildly affecting LV restoration in women for up to 3 years, with no significant gender interactions
- Although female patients appear to exhibit a lower quality of life compared to males, both KCCQ and NYHA status were restored within 1 year, and maintained up to 3 years

