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Transcatheter versus surgical aortic valve replacement in patients with morbid obesity: a multicentre propensity score-matched analysis

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KEYWORDS

- aortic stenosis
- morbid obesity
- SAVR
- TAVR

Abstract

Background: Morbidly obese (MO) patients are increasingly undergoing transcatheter aortic valve replacement (TAVR) and surgical aortic valve replacement (SAVR) for severe aortic stenosis (AS). However, the best therapeutic strategy for these patients remains a matter for debate.

Aims: Our aim was to compare the periprocedural and mid-term outcomes in MO patients undergoing TAVR versus SAVR.

Methods: A multicentre retrospective study including consecutive MO patients (body mass index ≥40 kg/m^2, or ≥35 kg/m^2 with obesity-related comorbidities) from 18 centres undergoing either TAVR (n=860) or biological SAVR (n=696) for severe AS was performed. Propensity score matching resulted in 362 pairs.

Results: After matching, periprocedural complications, including blood transfusion (14.1% versus 48.1%; p<0.001), stage 2-3 acute kidney injury (3.99% versus 10.1%; p=0.002), hospital-acquired pneumonia (1.7% versus 5.8%; p=0.005) and access site infection (1.5% versus 5.5%; p=0.013), were more common in the SAVR group, as was moderate to severe patient-prosthesis mismatch (PPM; 9.9% versus 39.4%; p<0.001). TAVR patients more frequently required permanent pacemaker implantation (14.4% versus 5.6%; p<0.001) and had higher rates of ≥moderate residual aortic regurgitation (3.3% versus 0%; p=0.001). SAVR was an independent predictor of moderate to severe PPM (hazard ratio [HR] 1.80, 95% confidence interval [CI]: 1.25-2.59; p=0.002), while TAVR was not. In-hospital mortality was not different between groups (3.9% for TAVR versus 6.1% for SAVR; p=0.171). Two-year outcomes (including all-cause and cardiovascular mortality, and readmissions) were similar in both groups (log-rank p>0.05 for all comparisons). Predictors of all-cause 2-year mortality differed between the groups; moderate to severe PPM was a predictor following SAVR (HR 1.78, 95% CI: 1.10-2.88; p=0.018) but not following TAVR (p=0.737).

Conclusions: SAVR and TAVR offer similar mid-term outcomes in MO patients with severe AS, however, TAVR offers some advantages in terms of periprocedural morbidity.

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Abbreviations

AKI	acute kidney injury
AS	aortic stenosis
BMI	body mass index
BSA	body surface area
eGFR	estimated glomerular filtration rate
EOA	effective orifice area
MO	morbidly obese
PPM	patient-prosthesis mismatch
SAVR	surgical aortic valve replacement
STS	Society of Thoracic Surgeons
TAVR	transcatheter aortic valve replacement

Introduction

Worldwide, the obesity epidemic continues to grow across low-, middle- and high-income countries. The World Health Organization (WHO) has reported a tripling in the prevalence of obesity between 1975 and 2016[1]. In the United States, it is estimated that by 2030, 50% of the population will be obese, with 25% having severe obesity (body mass index [BMI] ≥35 kg/m^2)[2]. Together with this growing obesity problem, our population is ageing, with increased rates of age-related degenerative diseases such as aortic stenosis (AS). Treatment of such diseases in obese patients is increasing in frequency and presents a significant challenge. Surgical aortic valve replacement (SAVR) in obese patients can result in a number of periprocedural difficulties, including problems with ventilation during anaesthesia[3], respiratory infections[4], impaired wound and sternotomy healing, access site and sternal infections[5-7], and prolonged hospital stays[7]. Transcatheter aortic valve replacement (TAVR) has rapidly evolved to become a viable alternative treatment for symptomatic severe AS with at least comparable, and in some studies superior, outcomes to SAVR, across a wide spectrum of low- to high-risk patients[8]. Among these trials, however, morbidly obese (MO) patients are underrepresented, and extrapolating these findings to MO populations may not be fully supported by evidence. A recent multicentre registry showed comparable mid-term outcomes in MO patients undergoing TAVR versus their non-obese counterparts, although major vascular complications were more common in the MO group[9]. This suggests a significant potential benefit for TAVR in this population, circumventing many of the periprocedural difficulties associated with SAVR in MO patients. Furthermore, TAVR, in comparison to SAVR, is associated with less prosthesis-patient mismatch (PPM), a commonly encountered phenomenon in MO patients. As PPM has been associated with poorer outcomes in SAVR populations[10-12], procedures such as TAVR, with less PPM, may be of significant value in this population. Nevertheless, outcome data directly comparing TAVR to SAVR in this group are scarce and limited to "moderately obese" (BMI ~30-35 kg/m^2) patients treated with early-generation TAVR valves[13]. We, therefore, aimed to compare periprocedural and mid-term outcomes in MO patients undergoing TAVR or SAVR for symptomatic severe AS.

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Methods

This was a retrospective multicentre, observational study involving 18 tertiary care centres in Europe and North America, including consecutive MO patients undergoing TAVR between 2008 and 2019. In addition, 8 centres provided data on consecutive MO patients undergoing SAVR, as a comparator group. The decision to perform either TAVR or SAVR was made at each individual centre, according to current guidelines and local protocols. All commercially available TAVR and biological SAVR valves were included. Patients with valve-in-valve procedures were excluded. Patients who underwent mechanical aortic valve implantation or concomitant replacement of other cardiac valves were also excluded, as were those requiring concomitant repair of the thoracic aorta. Patients undergoing SAVR or TAVR with concomitant coronary revascularisation were included. Both TAVR and SAVR were performed, as previously described, using manufacturers' recommendations for deployment in the case of TAVR[14,15]. Patients undergoing TAVR by all access routes were included, along with those undergoing SAVR by midline sternotomy and mini-sternotomy. Other procedure-related aspects were at the operators´ discretion. All patients signed informed consent for the procedure, and the study was performed in accordance with the institutional review board of the participating centres.

BMI was calculated as: weight in kg/height in metres squared (m²). Morbid obesity was defined as BMI ≥40 kg/m^2, or ≥35 kg/m^2 with obesity-related comorbidities[16,17]. All data, including baseline, periprocedural and clinical follow-up data, were prospectively collected in a dedicated database at each participating centre, and statistical analysis was performed by the coordinating centre. Periprocedural events were defined using the Valve Academic Research Consortium-2 (VARC-2) criteria[18].

PPM was defined using the VARC-3 criteria[19]. For this calculation, previously defined predicted effective orifice area (EOA) for each valve type and size were used[20,21] and indexed (iEOA) to body surface area (BSA), calculated from the Dubois formula. Predicted EOA was chosen due to its closer association with transprosthetic gradients[22]. BMI-specific cut-offs were used to determine the presence of PPM; as such, PPM was considered to be: none, if iEOA was >0.70 cm^2/m^2; moderate, if iEOA was 0.56-0.70 cm^2/m^2; and severe, if iEOA was ≤0.55 cm^2/m^2[19,21,23]. Clinical follow-up was at 30 days, 6 months, and yearly thereafter. Mid-term outcomes were assessed at 24 months.

The primary outcome was 2-year all-cause mortality. Secondary outcomes included in-hospital mortality, periprocedural complications, valve performance and patient-prosthesis mismatch.

STATISTICAL ANALYSIS

Categorical variables were expressed as numbers and percentages, while continuous variables were expressed as mean and standard deviation (SD), or median and interquartile range (IQR, 25th-75th percentile), according to their distribution. Normality was assessed using the Kolmogorov-Smirnov test. For the comparison of study groups (TAVR versus SAVR), qualitative variables were analysed

using the chi-squared or the Fisher´s exact test, and differences in continuous variables were analysed using a 2-sided Student´s t-test or Kruskall-Wallis test for the unmatched comparison. A non-parsimonious propensity score-matched analysis was performed between the 2 groups. A propensity score was estimated using a logistic regression model. The treatment group (TAVR or SAVR) was the dependent variable; independent variables were those baseline characteristics found to have statistically significant differences between TAVR and SAVR groups, and other variables considered to be clinically relevant. The final variables included in the propensity matching were: age, sex, BMI, pre-existing coronary artery disease (CAD), prior coronary artery bypass grafting (CABG), estimated glomerular filtration rate (eGFR), risk score, pre-existing peripheral vascular disease, chronic obstructive pulmonary disease (COPD), and atrial fibrillation. The Society of Thoracic Surgeons (STS) score or EuroSCORE II were used as risk scores. Risk categories were defined as: low risk (score <4), or intermediate to high risk (score ≥4). A propensity score-matched cohort was then created with a 1:1 ratio of TAVR and SAVR patients using a "nearest neighbour" match without replacement. A caliper width of <0.1 x the SD of the logistic score was applied. The appropriateness of the matching was assessed in several ways: first, smoothed kernel density plots of the logistic score were computed in order to visually assess the balance between groups before and after matching **(Supplementary Figure 1)**. Then, standardised mean differences (SMD) were calculated for all covariates (both those included and not included in the logistic score calculation) in order to assess for potential imbalances between TAVR and SAVR cohorts. Comparison of continuous and categorical variables between the matched groups were as previously stated for unmatched groups. Freedom from mortality and readmission curves were calculated using the Kaplan-Meier method and compared using the stratified log-rank test in the matched cohorts[24]. Post-match adjustment for variables found to have significant imbalances by variance ratio after matching was also performed as an additional calculation, using multivariable Cox regression. To reflect more contemporary practices, a second analysis was performed restricting the population to only those patients who underwent TAVR or SAVR after 2014. Propensity score matching in this more contemporary population was performed as previously outlined.

Predictors of 2-year all-cause mortality were also assessed separately for the TAVR and SAVR groups using Cox regression analysis. Variables with a p-value of <0.1 on univariable analysis were entered into the multivariable analysis, and those with resulting p-values <0.05 were considered statistically significant. Logistic regression analysis was used to assess predictors of PPM in the overall cohort in a similar fashion. All data were analysed with Stata 15.1 (StataCorp).

Results

PATIENT POPULATION

A total of 1,556 consecutive MO patients were included: 860 in the TAVR group, and 696 in the SAVR group. Baseline characteristics of the overall population are summarised in **Table 1**. A number of baseline characteristics differed significantly between the groups. TAVR patients were older (77 versus 71 years; p<0.001), more commonly female (67.3 versus 52.6; p<0.001) and more frequently had other significant comorbidities, including higher rates of hypertension, previous CAD, COPD and lower baseline eGFR (p<0.05 for all variables). Consequently, surgical risk scores were higher in the TAVR group when compared to SAVR. Procedural data for both groups are summarised in **Table 2**. The transfemoral approach was used in 86% of the TAVR cohort with midline sternotomy access being used in 94.2% of the SAVR population. Smaller valve sizes (18-23 mm) were more frequently used in the SAVR group (20.5% in TAVR versus 79.3%; p<0.001). The type of bioprosthesis used is outlined in **Table 2** and **Supplementary Table 1**.

MATCHED COHORT

Propensity score matching resulted in 362 matched pairs. Close matching was observed as depicted in **Supplementary Figure 1**, although some differences remained, with SMD being >0.10 for some variables. The TAVR group continued to have higher overall surgical risk scores **(Table 1)**. However, both cohorts were predominantly defined as low risk. Additionally, the TAVR group had higher rates of multivalvular disease, with more patients having moderate to severe mitral regurgitation (11.7% versus 5.4%; p=0.002) at baseline.

IN-HOSPITAL OUTCOMES

Table 3 summarises the in-hospital outcomes for both the matched and unmatched populations. After matching, in-hospital mortality was numerically more common in the SAVR group (3.9% versus 6.1%, for TAVR and SAVR, respectively), but this did not reach statistical significance (p=0.171). No differences in vascular complications, or life-threatening or major bleeding were found between groups. However, the SAVR group required significantly more blood transfusions (14.1% versus 48.1%; p<0.001). Stage 2-3 acute kidney injury (AKI) was more common in the SAVR group (3.99% versus 10.1%; p=0.002), as was hospital-acquired pneumonia (1.7% versus 5.8%; p=0.005), and access site infection (1.5% versus 5.5%; p=0.013), while TAVR patients more commonly required permanent pacemaker implantation during the index admission (14.4% versus 5.6%, for TAVR and SAVR, respectively; p<0.001) **(Central illustration)**. Regarding valve performance, residual ≥moderate aortic regurgitation was higher following TAVR (3.3% versus 0% in SAVR; p=0.001). Higher post-procedural mean aortic valve gradients (10.5 versus 15 mmHg; p<0.001), with higher rates of mean gradient >20 mmHg (8% versus 26.3%; p<0.001) and increased rates of moderate to severe PPM (9.9% versus 39.4%; p<0.001) were found in the SAVR group. Predictors of PPM in the overall cohort included SAVR (HR 1.80, 95% CI: 1.25-2.59; p=0.002), elevated BMI, hypertension and use of smaller prosthesis size (18-23 mm) **(Table 4)**. Overall, SAVR patients had longer inpatient admissions than TAVR patients (median 5 versus 9 days for SAVR; p<0.001).

Table 1. Baseline characteristics of the matched and unmatched cohorts of morbidly obese TAVR and SAVR patients.

	Pre-matching				Post-matching			
	TAVR (n=860)	SAVR (n=696)	*p*-value	SMD	TAVR (n=362)	SAVR (n=362)	*p*-value	SMD
Age, years	77 (7.24)	71.12 (7.7)	<0.001	0.788	73.99 (7.06)	74.20 (6.38)	0.677	0.031
Female sex	579 (67.33%)	366 (52.59%)	0.001	0.304	213 (58.84%)	218 (60.22%)	0.705	0.023
Body mass index, kg/m^2	39.54 (5.21)	38.31 (3.17)	<0.001	0.285	39.08 (3.82)	38.82 (3.60)	0.340	0.071
Diabetes mellitus	465 (54.07%)	366 (44.04%)	0.560	0.024	182 (50.28%)	192 (53.04%)	0.457	0.045
Insulin use	174 (40.75%)	140 (38.25%)	0.473	0.021	65 (37.57%)	76 (39.58%)	0.694	0.05
Hypertension	803 (93.37%)	622 (89.37%)	0.005	0.121	335 (92.54%)	326 (90.06%)	0.235	0.074
Hyperlipidaemia	610 (73.85%)	554 (79.60%)	0.008	0.110	265 (75.50%)	293 (80.94%)	0.078	0.106
Smoking	194 (24.13%)	262 (37.64%)	<0.001	0.247	97 (28.28%)	131 (36.19%)	0.025	0.140
Baseline eGFR (ml/min/1.73 m^2)	57.29 [42.12-74.61]	72.21 [57-87.29]	<0.001	0.537	66.64 [49.01-85.51]	67.09 [52-81.54]	0.951	0.034
eGFR <30 mls/min/1.73m^2	72 (8.46%)	17 (2.44%)	<0.001	0.201	22 (6.08%)	13 (3.59%)	0.119	0.091
Coronary artery disease	366 (42.56%)	260 (37.36%)	0.037	0.087	151 (41.71%)	151 (41.71%)	1.00	0
Previous MI	105 (12.30%)	82 (11.78%)	0.758	0.013	42 (11.60%)	48 (13.26%)	0.517	0.040
Previous PCI	130 (15.12%)	71 (10.20%)	0.004	0.118	66 (18.23%)	42 (11.60%)	0.012	0.148
Prior CABG	28 (3.37%)	16 (2.30%)	0.209	0.051	7 (1.93%)	9 (2.49%)	0.613	0.031
Previous valve surgery	16 (1.86%)	22 (3.16%)	0.098	0.07	5 (1.38%)	10 92.76%)	0.297*	0.084
Atrial fibrillation	301 (35.08%)	141 (20.26%)	<0.001	0.267	93 (25.69%)	96 (26.52%)	0.800	0.015
Previous permanent pacemaker	77 (8.97%)	28 (4.02%)	<0.001	0.156	21 (5.82%)	13 (3.59%)	0.157	0.083
COPD	253 (29.42%)	115 (16.52%)	<0.001	0.245	88 (24.31%)	74 (20.44%)	0.212	0.075
Previous cerebrovascular accident/TIA	93 (10.81%)	49 (7.04%)	0.010	0.105	34 (9.39%)	36 (9.94%)	0.801	0.015
Peripheral vascular disease	105 (12.21%)	54 (7.76%)	0.004	0.118	27 (7.46%)	31 (8.56%)	0.584	0.034
NYHA Functional Class III-IV	618 (71.86%)	356 (51.15%)	<0.001	0.362	242 (66.85%)	196 (54.14%)	<0.001	0.216
Baseline haemoglobin (g/dL)	12 (1.65)	12.99 (4.80)	<0.001	0.277	12.24 (1.56)	12.60 (1.58)	0.002	0.228
STS score	3.94 [2.7-6.0]	1.77 [1.26-2.71]	<0.001	0.907	2.94 [1.98-4.1]	2.67 [1.63-3.3]	<0.001	0.301
EuroSCORE II	3.40 [2.07-5.51]	1.95 [1.24-3.20]	<0.001	0.337	2.56 [1.73-4.4]	2.46 [1.49-3.91]	0.187	0.023
Low risk	446 (51.86%)	578 (83.05%)	<0.001	0.551	267 (73.76%)	275 (75.97%)	0.493	0.041
Intermediate-high risk	414 (48.14%)	118 (16.95%)	<0.001	0.551	95 (26.24%)	87 (24.03%)	0.493	0.041
Preprocedure ECHO								
LVEF, %	60 [55-64]	60 [55-65]	0.001	0.223	60 [55-63]	60 [55-65]	0.121	0.152
LVEF <30%	31 (3.60%)	10 (1.44%)	0.008	0.106	10 (2.76%)	4 (1.10%)	0.175*	0.092
Mean aortic gradient, mmHg	46 [39.5-56]	48 [42-58]	0.962	0.156	47.25 [40-57]	46 [41-56]	0.181	0.031
Aortic valve area, cm^2	0.72 (0.19)	0.73 (0.21)	0.64	0.026	0.75 (0.20)	0.72 (0.19)	0.006	0.172
Moderate or severe mitral regurgitation	119 (14.91%)	32 (4.79%)	<0.001	0.262	40 (11.7%)	19 (5.44%)	0.003	0.174
Moderate or severe aortic regurgitation	78 (9.75%)	98 (14.71%)	0.004	0.128	31 (9.06%)	49 (14.16%)	0.037	0.135

Values are expressed as mean (SD), median [IQR] or n (%). *Fisher's exact test used. CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; IQR: interquartile range; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SAVR: surgical aortic valve replacement; SD: standard deviation; SMD: standardised mean difference; STS: Society of Thoracic Surgeons; TAVR: transcatheter aortic valve replacement; TIA: transient ischaemic attack

MID-TERM OUTCOMES

The median follow-up was 33.2 months (IQR 12.9-61.6). Kaplan-Meier graphs depicting mid-term outcomes for the matched cohort are shown in **Figure 1A-Figure 1D**. At 2 years, the primary outcome of freedom from all-cause mortality was similar for both TAVR and SAVR groups (84.1% versus 85.8%, log-rank p=0.651), as was cardiovascular (CV) mortality (89.9% versus 89%, log-rank p=0.686, for TAVR and SAVR, respectively). Similarly, all-cause and CV readmissions were not different between matched TAVR and SAVR groups. Kaplan-Meier curves for the unmatched cohort are shown in **Supplementary Figure 2**. After adjusting mid-term outcomes for those variables whose variance ratio was different between groups (eGFR, left ventricular ejection fraction [LVEF] and risk score), no differences in all-cause and CV mortality were

Table 2. Procedural aspects in morbidly obese TAVR and SAVR cohorts.

	Pre-matching			Post-matching		
	TAVR (n=860)	SAVR (n=696)	*p*-value	TAVR (n=362)	SAVR (n=362)	*p*-value
Procedural data						
Urgent/emergent	49 (6.36%)	38 (5.46%)	0.468	21 (6.63%)	26 (7.12%)	0.669
TAVR access site						
Transfemoral	739 (85.93%)	–	–	313 (86.46%)	–	–
Transapical	40 (4.65%)	–	–	16 (4.42%)	–	–
Other access	81 (9.42%)	–	–	33 (9.12%)	–	–
SAVR access site						
Full midline sternotomy	–	656 (94.25%)	–	–	335 (92.54%)	–
Mini-sternotomy	–	40 (5.75%)	–	–	27 (7.46%)	–
Concomitant coronary revascularisation (CABG)	–	236 (33.91%)	–	–	138 (38.12%)	–
Prosthesis size						
18-23 mm	175 (20.47%)	531 (76.29%)	<0.001	69 (19.17%)	293 (80.94%)	<0.001
24-28 mm	390 (45.61%)	158 (22.70%)	<0.001	154 (42.78%)	64 (17.68%)	<0.001
29-34 mm	290 (33.92%)	7 (1.01%)	<0.001*	137 (38.06%)	5 (1.38%)	<0.001*
TAVR prosthesis type						
Balloon-expandable	403 (46.9%)	–	–	178 (49.17%)	–	–
Self-expanding	449 (52.21%)	–	–	180 (49.72%)	–	–
SAVR prosthesis type						
Stented	–	613 (88%)	–	–	305 (84.3%)	–
Stentless	–	18 (2.6%)	–	–	5 (1.4%)	–
Sutureless	–	65 (9.3%)	–	–	52 (14.4%)	–
Other procedural aspects						
General anaesthesia	321 (37.33%)	696 (100%)	<0.001	135 (37.29%)	362 (100%)	<0.001
Prior balloon valvuloplasty	476 (61.10%)	–	–	208 (62.65%)	–	–
Balloon post-dilatation	104 (12.31%)	–	–	44 (12.29%)	–	–

Values are expressed as n (%). *Fisher's exact test used. CABG: coronary artery bypass graft; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement

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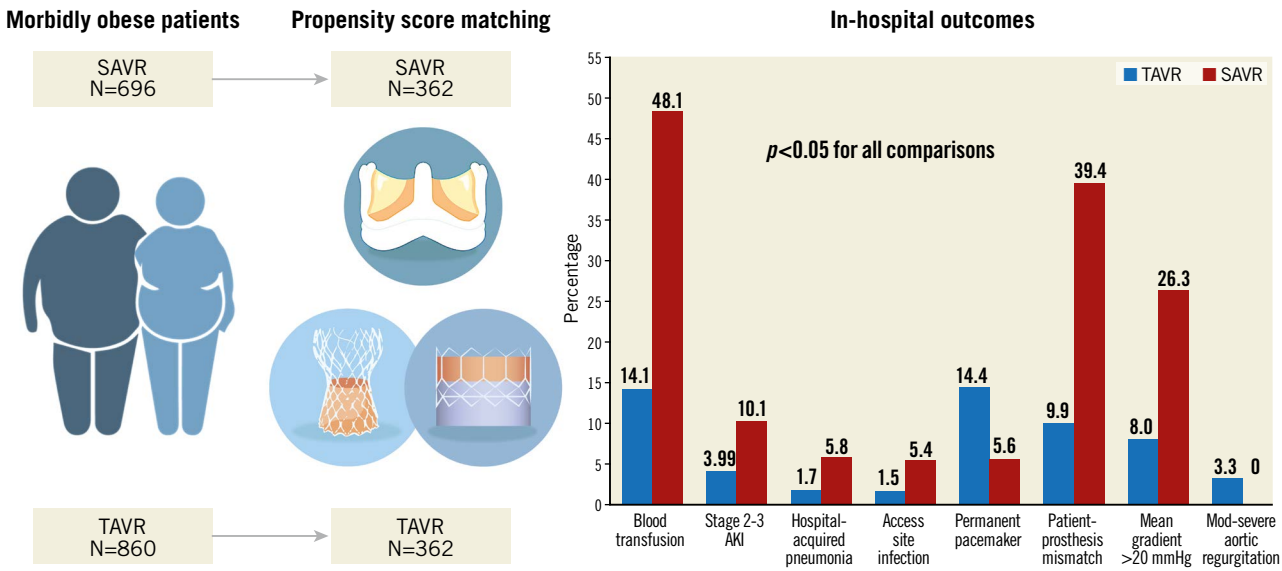
CENTRAL **ILLUSTRATION** **In-hospital outcomes following propensity score matching of morbidly obese patients undergoing TAVR versus SAVR.**



AKI: acute kidney injury; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement

Table 3. Clinical endpoints and echocardiographic data post-procedure for morbidly obese TAVR and SAVR cohorts.

Clinical endpoints		Pre-matching			Post-matching		
		TAVR (n=860)	SAVR (n=696)	*p*-value	TAVR (n=362)	SAVR (n=362)	*p*-value
In-hospital mortality		34 (3.95%)	33 (4.74%)	0.446	14 (3.87%)	22 (6.08%)	0.171
In-hospital or 30-day mortality		44 (5.12%)	37 (5.32%)	0.860	19 (5.25%)	25 (6.91%)	0.351
Major vascular complications		56 (6.51%)	44 (6.32%)	0.879	27 (7.46%)	22 (6.08%)	0.459
Bleeding complications	Life-threatening bleeding	21 (2.44%)	51 (7.94%)	<0.001	10 (2.76%)	22 (6.81%)	0.012
	Major bleeding	50 (5.81%)	13 (2.03%)	<0.001	22 (6.08%)	10 (3.11%)	0.066
	Life-threatening or major	71 (8.26%)	64 (10.00%)	0.243	32 (8.84%)	32 (9.94%)	0.623
Any blood transfusion		113 (14.93%)	264 (37.99%)	<0.001	46 (14.07%)	147 (48.07%)	<0.001
Acute kidney injury	Stage I	116 (15.14%)	186 (27.43%)	<0.001	45 (13.80%)	103 (28.77%)	<0.001
	Stage II and III	29 (3.79%)	58 (8.55%)	<0.001	13 (3.99%)	36 (10.06%)	0.002
	Any stage	145 (18.93%)	244 (35.99%)	<0.001	58 (17.79%)	139 (38.83%)	<0.001
Periprocedural stroke		14 (1.63%)	10 (1.44%)	0.761	6 (1.66%)	6 (1.66%)	1.00*
Hospital-acquired pneumonia		11 (1.31%)	39 (5.61%)	<0.001	6 (1.70%)	21 (5.82%)	0.005*
New permanent pacemaker implantation¶		119 (13.84%)	33 (4.82%)	<0.001	52 (14.36%)	20 (5.57%)	<0.001
Access site infection		9 (1.51%)	26 (4.70%)	0.002*	4 (1.51%)	17 (5.54%)	0.013
ECHO parameters (0-30 days)	Moderate-severe aortic valve regurgitation	15 (1.89%)	2 (11.76%)	0.012*	11 (3.27%)	0 (0%)	0.001*
	Post-procedural mean aortic valve gradient (mmHg)	10 [7-14]	15 [11.5-20]	<0.001	10.5 [8-14]	15 [11-30]	<0.001
	Mean gradient >20 mmHg	62 (7.72%)	165 (27.68%)	<0.001	27 (7.96%)	83 (26.27%)	<0.001
	Moderate-severe PPM	75 (9.54%)	241 (34.98%)	<0.001	32 (9.88%)	141 (39.39%)	<0.001
Length of hospital stay (days)		5 [3-8]	8 [6-12]	<0.001	5 [2-7]	9 [6-13]	<0.001

Values are expressed as mean (SD), median [IQR] or n (%). *Fisher's exact test used, ¶calculated only for patients without pre-existing permanent pacemakers. CV: cardiovascular; ECHO: echocardiogram; IQR: interquartile range; PPM: patient-prosthesis mismatch; SAVR: surgical aortic valve replacement; SD: standard deviation; TAVR: transcatheter aortic valve replacement

found between groups. However, all-cause readmissions were higher in the SAVR group (HR 1.45, 95% CI: 1.04-2.02; p=0.029) **(Supplementary Table 2)**.

Predictors of all-cause 2-year mortality in the whole cohort of SAVR patients were: age, low baseline haemoglobin, and major vascular complications, AKI stage 2-3, and moderate to severe PPM **(Table 5)**. Within the TAVR group, predictors of all-cause 2-year mortality were: low baseline haemoglobin, life-threatening or major bleeding, periprocedural stroke, and AKI stage 2-3 **(Table 6)**. PPM was not a predictor of 2-year mortality in the TAVR group (p=0.737).

PATIENTS UNDERGOING TAVR OR SAVR BETWEEN 2014-2019

Considering only the propensity score-matched cohort of patients who underwent either TAVR or SAVR between 2014 and 2019, findings were similar to those for the whole cohort **(Supplementary Table 3-Supplementary Table 5, Supplementary**

Table 4. Predictors of moderate-severe prosthesis patient mismatch in the whole cohort (n=1,556).

Variable	Univariable analysis OR (95% CI)	*p*-value	Multivariable analysis OR (95% CI)	*p*-value
SAVR	5.10 (3.84-6.78)	<0.001	1.80 (1.25-2.59)	0.002
TAVR	0.20 (0.15-0.26)	<0.001		
Age	0.97 (0.96-0.99)	<0.001		
Female gender	1.40 (1.08-1.82)	0.011		
BMI per kg/m^2 increase	1.06 (1.03-1.09)	<0.001	1.14 (1.10-1.18)	<0.001
BSA	1.70 (0.98-2.96)	0.058		
Hypertension	1.54 (0.94-2.52)	0.088	2.09 (1.21-3.61)	0.008
Hypercholesterolaemia	1.52 (1.10-2.08)	0.010		
Urgent/emergent procedure	1.52 (0.94-2.45)	0.085		
Valve size 18-23 mm	26.49 (16.89-41.54)	<0.001	29.06 (17.12-49.33)	<0.001

BMI: body mass index; BSA: body surface area; CABG: coronary artery bypass graft; CI: confidence interval; OR: odds ratio; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement

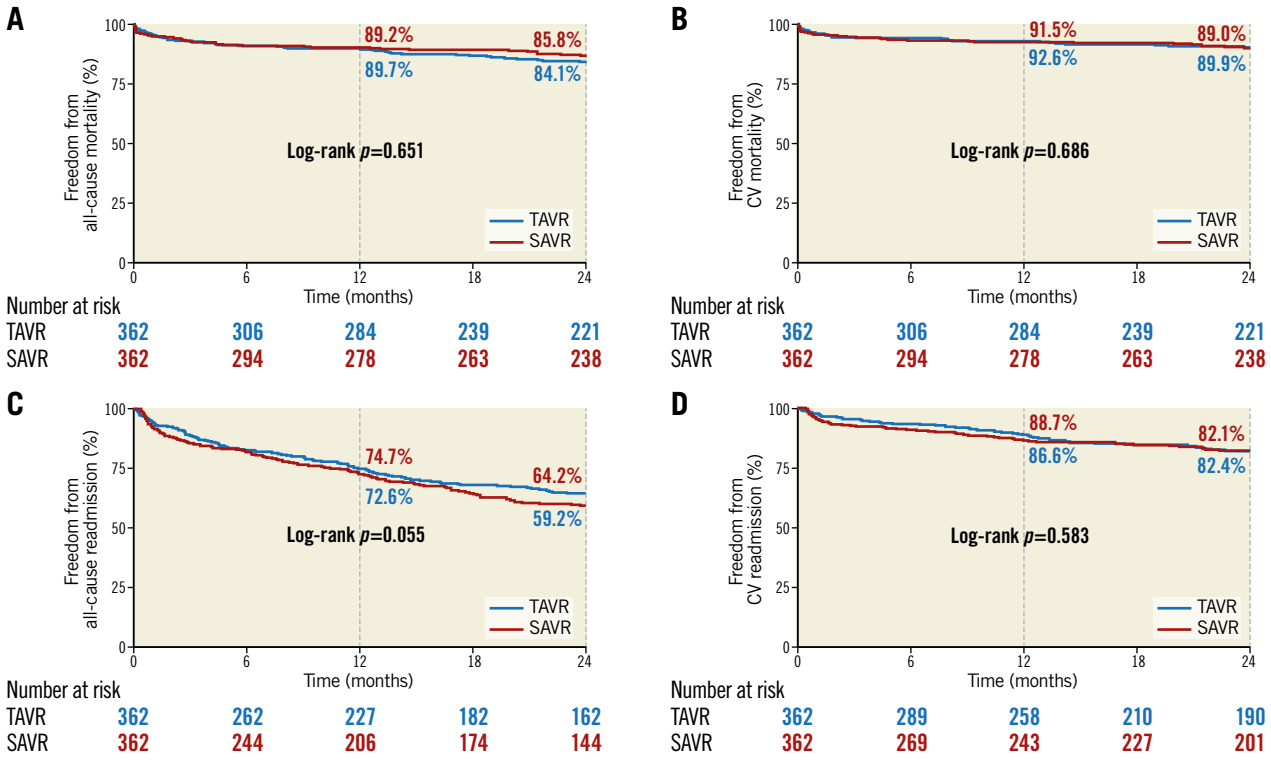


Figure 1. *Kaplan-Meier graph demonstrating 2-year all-cause (A) and cardiovascular (B) mortality and 2-year all-cause (C) and cardiovascular (D) readmission in the propensity score-matched analysis for morbidly obese TAVR and SAVR groups. CV: cardiovascular; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement*

Figure 3, Supplementary Figure 4). Blood transfusions, AKI and moderate to severe PPM remained higher in the SAVR group. Interestingly, however, rates of permanent pacemaker implantation were not different between groups, in these more contemporary patients (11.1% versus 7.83%, for TAVR and SAVR, respectively; p=0.227). Mid-term outcomes, including all-cause mortality, CV mortality, all-cause readmission and CV readmission were not different between groups (log-rank p>0.05 for all comparisons).

Table 5. Predictors of all-cause mortality at 2 years in the SAVR cohort (n=696).

	Univariable analysis		Multivariable analysis	
	HR (95% CI)	*p*-value	HR (95% CI)	*p*-value
Age	1.05 (1.02-1.09)	0.003	1.04 (1.01-1.08)	0.013
Female gender	2.33 (1.40-3.88)	0.001		
Hypertension	8.81 (1.22-63.42)	0.031		
Dialysis	62.23 (8.03-482.04)	<0.001		
eGFR <30 mls/min/1.73 m^2	3.35 (1.22-9.18)	0.019		
Baseline creatinine (mg/dL)	1.87 (1.02-3.43)	0.043		
Baseline haemoglobin*	1.88 (1.42-2.48)	<0.001	1.65 (1.21-2.25)	0.002
Urgent/emergent	2.56 (1.23-5.34)	0.012		
Hospital-acquired pneumonia	3.23 (1.65-6.31)	0.001		
Access site infection	2.23 (0.89-5.61)	0.088		
Major vascular complication	3.92 (2.14-7.15)	<0.001	4.54 (2.44-8.43)	<0.001
Life threatening or major bleeding	3.43 (1.98-5.94)	<0.001		
Blood transfusion	2.27 (1.41-3.62)	0.001		
AKI stage 2-3	5.63 (3.34-9.49)	<0.001	4.09 (2.34-7.13)	<0.001
Moderate-severe PPM	1.82 (1.41-2.90)	0.012	1.78 (1.10-2.88)	0.018

*for every 2 gram/dL decrease. AKI: acute kidney injury; CI: confidence interval; eGFR: estimated glomerular filtration rate; HR: hazard ratio; PPM: patient-prosthesis mismatch; SAVR: surgical aortic valve replacement

Table 6. Predictors of all-cause mortality at 2 years in the TAVR cohort (n=860).

	Univariable analysis HR (95% CI)	*p*-value	Multivariable analysis HR (95% CI)	*p*-value
COPD	1.42 (1.02-1.99)	0.037		
Previous peripheral vascular disease	1.52 (1.00-2.32)	0.052		
eGFR <30 mls/min/1.73 m^2	1.61 (0.99-2.64)	0.057		
Baseline haemoglobin*	1.36 (1.12-1.66)	0.002	1.50 (1.21-1.86)	<0.001
Non-transfemoral TAVR	1.50 (1.00-2.25)	0.051		
Major vascular complication	2.30 (1.41-3.77)	0.001		
Life threatening or major bleeding	3.01 (1.99-4.54)	<0.001	2.96 (1.21-1.86)	<0.001
Blood transfusion	2.54 (1.74-3.69)	<0.001		
Periprocedural stroke	4.27 (2.00-9.13)	<0.001	4.27 (1.73-10.55)	0.002
AKI stage 2-3	3.83 (2.16-6.79)	<0.001	3.41 (1.90-6.12)	<0.001
Mod-severe PPM	1.09 (0.64-1.87)	0.737		

*for every 2 gram/dL decrease. AKI: acute kidney injury; CI: confidence interval; COPD: chronic obstructive pulmonary disease; eGFR: estimated glomerular filtration rate; HR: hazard ratio; PPM: patient prosthesis mismatch; TAVR: transcatheter aortic valve replacement

Discussion

Our study compares the in-hospital and mid-term outcomes in MO patients with symptomatic severe AS undergoing either TAVR or SAVR. The main findings are as follows: 1) MO TAVR patients have lower periprocedural complications, except for a higher rate of permanent pacemaker implantation; 2) higher residual mean gradient and moderate to severe PPM were more frequently found following SAVR, and SAVR was an independent predictor of moderate to severe PPM; 3) TAVR patients have more residual moderate to severe aortic regurgitation than SAVR patients; 4) no difference in mid-term outcomes were seen between the TAVR and SAVR groups on propensity score matching, except for an increased all-cause readmissions at 2 years in SAVR patients in the matched, adjusted analysis; and 5) moderate to severe PPM was associated with 2-year all-cause mortality in the SAVR group but not in the TAVR group.

Outcomes in obese patients undergoing TAVR or SAVR have previously been heavily debated. Previous studies in obese versus normal weight patients undergoing SAVR, with and without coronary revascularisation, have shown conflicting results regarding in-hospital and 30-day mortality[7,25,26]. In the context of TAVR, our research group has previously shown no differences regarding in-hospital or 30-day mortality for MO versus normal weight patients[9]. Studies comparing TAVR versus SAVR in this group are few. An analysis of the Nationwide Inpatient Sample database (NIS) in the United States showed no differences regarding in-hospital mortality between TAVR and SAVR patients with BMI ≥30kg/m^2, or when the population was restricted to patients with BMI ≥40 kg/m^2, although perioperative complications were more common in the SAVR group[13]. Our results are reflective of these findings. The less invasive nature of TAVR, particularly when performed via the femoral route (>85% in this study), likely explains the reduced in-hospital complications and significantly shorter in-hospital stay in the TAVR MO cohort. The ability to circumvent these periprocedural complications may suggest that TAVR in this particular population could be considered a more appropriate option for the treatment of symptomatic severe AS. It should be noted that while in-hospital mortality was not significantly different between groups, there was a trend towards greater in-hospital mortality in the SAVR group, with an absolute difference of 2.2%. Lack of statistical significance relating to this variable may reflect a lack of power in our study, and further larger studies should aim to definitively answer this question.

Conduction disorders and the need for permanent pacemaker implantation continue to be higher following TAVR, compared to SAVR. Consistent with previous studies, TAVR patients had a 2½-fold increased requirement for permanent pacemaker implantation than the SAVR cohort[8]. More recently, changes to implantation techniques, particularly with self-expanding TAVR valves, have shown promise in reducing pacemaker implantation rates[27,28]. This is reflected in our analysis of patients who underwent TAVR and SAVR from 2014 to 2019. No differences were found between groups regarding permanent pacemaker requirement, and this is most likely due to current TAVR implantation techniques aimed at reducing pacemaker requirement. This represents an important finding given that pacemaker implantation is often considered a significant drawback of TAVR procedures.

Prosthesis-patient mismatch is known to occur in both TAVR and SAVR. In obese patients, the effect of PPM on outcomes was noted to be attenuated after SAVR and led to the use of BMI-adjusted cut-offs[21,29], which have now also been widely adopted in the assessment of PPM for patients undergoing TAVR procedures[10,19,22]. Given that increased BMI and obesity is a known risk factor[30], increased PPM may be expected in our cohort. However, rates in this study were similar or lower than previously reported in other TAVR and SAVR trials[10,30,31]. This may be explained by the use of predicted, rather than measured, EOA across both TAVR and SAVR groups, which has been shown to result in lower rates of PPM[10,22] and to correlate more closely with transvalvular mean gradient[22]. Nonetheless, our study demonstrated higher

residual mean gradients and a 4-fold higher rate of moderate to severe PPM in those who underwent SAVR, consistent with previous studies comparing SAVR to both balloon- and self-expanding TAVR valves[10,31,32]. Smaller valve sizes were implanted more frequently in the SAVR group and were significantly associated with PPM in our study, as in other studies[31]. Implantation of larger-sized prostheses in TAVR patients compared to SAVR patients may be explained by the use of computed tomography (CT)-based sizing for TAVR valves, which is now widely accepted as standard practice[33]. A CT subanalysis of the SURTAVI trial demonstrated this by dividing patients by indexed annulus size into small, medium and large annuli. Across these subgroups, the size of implanted TAVR valves increased accordingly, while the size of implanted SAVR valves remained unchanged[32]. This suggests that the accurate annulus sizing, as provided by CT, used in TAVR populations most likely contributes to the choice of larger valve sizes and lower PPM in this group.

PPM is not a benign entity, and in our study moderate to severe PPM was associated with an increased risk of all-cause mortality at 2 years in the SAVR group, but not in the TAVR group. Analysis of the PARTNER 1 and 2 trials have similarly shown an association between PPM and mortality in the SAVR, but not the TAVR, group[10,31], although only severe PPM using predicted EOA values were associated with poorer outcomes in the analysis of PARTNER 2 (HR 3.30, 95% CI: 1.76-6.21; p<0.0001 for all-cause mortality and rehospitalisation)[10]. Likewise, in a large meta-analysis of TAVR and SAVR trials, no association with mortality was seen in patients with PPM following TAVR implantation[34]. Furthermore, PPM has been associated with structural valve deterioration in surgical bioprostheses[35], and more recently been linked to subclinical valve thrombosis in TAVR, which may be a contributing factor to valve degeneration[36]. These findings highlight the need to avoid PPM, if possible, when performing TAVR or SAVR. Our findings, consistent with other studies of reduced rates of PPM following TAVR, may suggest an advantage of TAVR over SAVR in MO patients who are at particular risk of this complication.

Despite differences in periprocedural complications, mid-term outcomes were similar in both the propensity score-matched and adjusted analysis, except for all-cause rehospitalisation, which after adjustment for eGFR, LVEF and risk score, was more common in the SAVR group. Our matched cohort consisted of predominantly low-risk (~75%) patients, due to low numbers of high-risk patients in the surgical cohort overall. These results are important in the current TAVR era, where there is no direct randomised comparison between SAVR and TAVR in MO patients, and TAVR is expanding to younger and lower-risk populations.

Predictors of 2-year mortality were analysed separately for the TAVR and SAVR cohorts. Stage 2-3 AKI was a significant predictor of 2-year mortality across both groups. The rate of AKI across both groups was higher than in other studies of low- to intermediate-risk patients. This may reflect the comorbidity burden of our cohort, with high rates of diabetes, hypertension and underlying chronic kidney disease. Nonetheless, while stage 2-3 AKI predicted 2-year all-cause mortality in both groups, its significantly higher incidence in the SAVR group is worth considering when choosing between SAVR and TAVR in MO patients. Readmission rates were high with the majority being non-cardiac in nature, consistent with previous literature[37]. Further studies should centre on initiatives aimed at reducing readmission rates.

Limitations

A number of limitations must be recognised. Firstly, this is a retrospective analysis of prospectively collected data and, as such, has limitations inherent to this observational design. Although propensity score matching aims to eliminate significant differences between groups, the presence of unidentified confounding factors cannot be excluded. Long-term echo data regarding valve performance were not available, so an assessment of structural valve deterioration or haemodynamic dysfunction cannot be reliably assessed. Therefore, our findings should be considered as hypothesis generating and require confirmation in future studies. However, the most clinically important CV comorbidities and potential confounders were included in the propensity score analysis, and matching resulted in well-balanced groups. Propensity matching, however, results in a reduced number of patients being included, which may limit the power to detect differences between groups. Lastly, median follow-up was close to 3 years, therefore, longer follow-up is necessary to determine potential differences in valve durability and survival across both groups.

Conclusions

In our population of predominantly low-risk MO patients, TAVR resulted in less periprocedural complications than those undergoing SAVR, however, rates of new permanent pacemaker implantation and significant aortic regurgitation were higher. Moderate to severe PPM was more common in the SAVR group and was associated with 2-year all-cause mortality in this group. Both therapeutic options resulted in similar mid-term outcomes, including all-cause mortality, CV mortality, all-cause readmission and CV readmission. However, after adjustment, all-cause readmissions were more common among SAVR patients. Our study suggests that TAVR in MO patients offers advantages over SAVR, in terms of periprocedural morbidity, with similar mid-term outcomes.

Impact on daily practice

Morbidly obese patients have been largely underrepresented in clinical trials to date comparing TAVR and SAVR. This study demonstrates that in a predominantly low-risk group of patients, TAVR results in less periprocedural morbidity with equivalent mid-term outcomes to SAVR. Furthermore, patient-prosthesis mismatch was more common in SAVR patients and has a significant impact on mid-term mortality. Therefore, TAVR can circumvent many of the complications associated with SAVR in MO patients and should be considered in MO patients of low or moderate risk presenting with severe AS.

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Conflict of interest statement

I. Amat-Santos is a proctor for Boston Scientific and Meril Life Sciences. S. Toggweiler reports institutional grant support from Boston Scientific, Fumedica, and Biosensors; financial fees from Boston Scientific, Medtronic, Biosensors, Medira, AtHeart Medical, Shockwave, Teleflex, and Veosource; and holds equity in Hi-D Imaging. F. Saia is a proctor for Edwards Lifesciences; and received consulting and lecture fees from Abbott Vascular, Edwards Lifesciences, and Medtronic. H. Ribeiro is a consultant for Edwards Lifesciences, Medtronic, and Boston Scientific. A. Regueiro is a proctor for Abbott. M. Barbanti is a consultant for Edwards Lifesciences, and Boston Scientific. G. Tirado-Conte holds a research-training contract "Rio Hortega" (CM21/00091) from the Spanish Ministry of Science and Innovation (Instituto de Salud Carlos III). N. Gonzalo has received speaker and consultancy fees from Abbot Vascular, Boston Scientific, and Philips. L. Nombela-Franco is a proctor for Abbott Vascular; and has received speaker honoraria from Edwards Lifesciences, and Boston Scientific. He also holds a research grant (INT19/00040) from the Spanish Ministry of Science and Innovation (Instituto de Salud Carlos III). S. Mohammadi is a a proctor for Edwards Lifesciences, and Medtronic. The other authors have no conflicts of interest to declare.

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Supplementary data

Supplementary Table 1. Bioprosthesis brands included for TAVR and SAVR.

Supplementary Table 2. Unadjusted and adjusted hazard ratio for all-cause mortality, cardiovascular mortality, all-cause readmission and cardiovascular readmission after propensity score matching.

Supplementary Table 3. Baseline characteristics of the matched and unmatched cohorts of morbidly obese TAVR and SAVR patients treated from 2014 to 2019.

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Supplementary Figure 1. Kernel Density plots representing the pre- (A) and post- (B) matching.

Supplementary Figure 2. Kaplan-Meier graph demonstrating 2-year all-cause (A) and cardiovascular (B) mortality and 2-year all-cause (C) and cardiovascular (D) readmission for the entire cohort of morbidly obese TAVR and SAVR groups.

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The supplementary data are published online at: https://eurointervention.pcronline.com/doi/10.4244/EIJ-D-21-00891

Supplementary data

Supplementary Table 1. Bioprosthesis brands included for TAVR and SAVR.

	Pre-matching		Post-matching	
	TAVR (n=860)	**SAVR (n=696)**	**TAVR (n=362)**	**SAVR (n=362)**
Bioprosthesis brand				
TAVR				
SAPIEN/XT (Edwards)	165 (19.2%)		62 (17.1%)	
SAPIEN 3 (Edwards)	238 (27.7%)		116 (32%)	
CoreValve (Medtronic)	189 (22%)		66 (18.2%)	
Evolut R/Pro (Medtronic)	197 (22.9%)		81 (22.3%)	
Accurate Neo (Boston Scientific)	47 (5.5%)		23 (6.4%)	
Portico (Abbott)	13 (1.5%)		8 (2.2%)	
Other	11 (1.2%)		6 (1.7%)	
SAVR				
Magna (Edwards)		231 (33.2%)		107 (29.6%)
Magna Ease (Edwards)		56 (8%)		32 (8.8%)
Perimount (Edwards)		60 (8.6%)		31 (8.6%)
Trifecta/EPIC (St Jude)		70 (10.1%)		39 (10.8%)
MitroFlow (Sorin)		77 (11%)		39 (10.8%)
Mosaic (Medtronic)		58 (8.3%)		37 (10.2%)
Perceval (LivaNova)		39 (5.6%)		30 (8.3%)
Other		105 (15%)		47 (13%)

SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement

Supplementary Table 2. Unadjusted and adjusted hazard ratio for all-cause mortality, cardiovascular (CV) mortality, all-cause re-admission and CV re-admission after propensity score (PS) matching.

	Unadjusted hazard ratio (95% CI)	**Adjusted hazard ratio (95% CI)***
All-cause mortality	0.90 (0.57-1.41), p=0.651	0.97 (0.60-1.57), p=0.917
CV mortality	1.11 (0.66-1.89), p=0.686	1.18 (0.65-2.16), p=0.582
All-cause readmission	1.36 (0.99-1.86), p=0.057	1.45 (1.04-2.02), p=0.029
CV readmission	1.13 (0.74-1.72), p=0.588	1.27 (0.81-1.99), p=0.298

*Adjusted for variables whose variance ratio suggested imbalance between groups following PS matching (eGFR, LVEF and risk score) CI: confidence interval; eGFR: estimated glomerular filtration rate; LVEF: left ventricular ejection fraction

Supplementary Table 3. Baseline characteristics of the matched and unmatched cohorts of morbidly obese TAVR and SAVR patients treated from 2014 to 2019.

	Pre-matching				Post-matching			
	TAVR (n=641)	**SAVR (n=399)**	**p-value**	**SMD**	**TAVR (n=234)**	**SAVR (n=234)**	**p-value**	**SMD**
Age, years	76.76 (7.45)	70.43 (7.59)	<0.001	0.841	72.67 (6.91)	73.52 (6.27)	0.685	0.037
Female sex	414 (64.59%)	185 (46.37%)	<0.001	0.307	129 (55.13%)	126 (53.85%)	0.781	0.021
Body mass index, kg/m^2	39.75 (5.56)	38.18 (3.23)	<0.001	0.346	38.85 (3.44)	38.69 (3.60)	0.609	0.047
Diabetes mellitus	344 (53.67%)	214 (53.63%)	0.992	0.001	117 (50%)	128 (54.70%)	0.309	0.077
-Insulin use	134 (40.98%)	76 (35.51%)	0.202	0.049	40 (34.78%)	47 (36.72%)	0.753	0.060
Hypertension	603 (94.07%)	354 (88.72%)	0.002	0.164	220 (94.02%)	205 (87.61%)	0.016	0.193
Hyperlipidaemia	468 (76.22%)	317 (79.45%)	0.229	0.063	179 (79.91%)	185 (79.06%)	0.822	0.017
Smoking	160 (26.76%)	150 (37.59%)	<0.001	0.194	63 (29.30%)	89 (38.03%)	0.051	0.153
Baseline eGFR (ml/min/1.73m^2)	58.58 [42.79-75.72]	74.71 [60.91-89.29]	<0.001	0.578	66.86 [52.77-83.36]	69.48 [56.06-82.79]	0.490	0.022
eGFR <30 mls/min/1.73m^2	54 (8.53%)	11 (2.76%)	<0.001	0.191	11 (4.70%)	9 (3.85%)	0.648	0.034
Coronary artery disease	262 (40.87%)	153 (38.35%)	0.418	0.042	98 (41.88%)	102 (43.59%)	0.709	0.028
Previous MI	65 (10.14%)	43 (10.78%)	0.744	0.017	25 (10.68%)	30 (12.82%)	0.473	0.055
Previous PCI	87 (13.57%)	40 (10.03%)	0.089	0.088	42 (17.95%)	29 (12.93%)	0.094	0.123
Prior CABG	20 (3.12%)	12 (3.01%)	0.919	0.005	3 (1.28%)	5 (2.14%)	0.724*	0.056
Atrial fibrillation	232 (36.31%)	86 (21.55%)	<0.001	0.262	68 (29.06%)	58 (24.79%)	0.297	0.078
Previous permanent pacemaker	52 (8.12%)	12 (3.01%)	0.001	0.171	13 (5.56%)	7 (2.99%)	0.170	0.099
COPD	175 (27.30%)	68 (17.04%)	<0.001	0.180	49 (20.94%)	44 (18.80%)	0.562	0.043
Previous cerebrovascular accident/TIA	69 (10.76%)	27 (6.77%)	0.030	0.112	16 (6.84%)	19 (8.12%)	0.598	0.040
Peripheral vascular disease	78 (12.17%)	27 (6.77%)	0.005	0.145	19 (8.12%)	23 (9.83%)	0.518	0.049
NYHA Functional Class III and IV	432 (67.39%)	188 (47.12%)	<0.001	0.346	147 (62.82%)	111 (47.44%)	0.001	0.257
Baseline haemoglobin (g/dL)	11.99 (1.67)	13.22 (6.18)	<0.001	0.270	12.23 (1.63)	12.74 (1.64)	<0.001	0.313
STS score	3.76 [2.62-5.6]	1.73 [1.24-2.50]	<0.001	0.896	2.75 [1.88-3.96]	2.2 [1.6-3.2]	<0.001	0.265
EuroSCORE II	3.18 [1.99-5.19]	1.83 [1.19-2.98]	<0.001	0.403	2.49 [1.63-4.25]	2.15 [1.37-3.50]	0.016	0.097
Low risk	357 (55.69%)	336 (84.21%)	<0.001	0.510	180 (76.92%)	183 (78.21%)	0.740	0.025
Intermediate-high risk	284 (44.31%)	63 (15.79%)	<0.001	0.510	54 (23.08%)	51 (21.79%)		
Preprocedure ECHO								
LVEF, %	60 [55-61]	60 [55-65]	<0.001	0.300	60 [55-62]	60 [55-65]	0.045	0.225
LVEF <30%	26 (4.06%)	2 (0.50%)	<0.001*	0.175	10 (4.35%)	2 (0.85%)	0.020*	0.163
Mean aortic gradient, mmHg	46.88 [40-55]	47 [41-56]	0.379	0.109	48 [40-57.65]	45 [40.35-55]	0.319	0.097
Aortic valve area, cm^2	0.73 (0.20)	0.75 (0.21)	0.185	0.092	0.76 (0.22)	0.74 (0.21)	0.290	0.107
Moderate or severe mitral regurgitation	80 (13.63%)	19 (4.95%)	<0.001	0.231	29 (12.83%)	12 (5.33%)	0.006	0.203
Moderate or severe aortic regurgitation	59 (10.07%)	69 (18.02%)	<0.001	0.196	29 (12.83%)	43 (19.11%)	0.078	0.140

Values are expressed as mean (SD), median [IQR] or n (%). *Fisher's exact test used.
CABG: coronary artery bypass graft; COPD: chronic obstructive pulmonary disease; ECHO: echocardiogram; eGFR: estimated glomerular filtration rate; IQR: interquartile range; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NYHA: New York Heart Association; PCI: percutaneous coronary intervention; SAVR: surgical aortic valve replacement; SD: standard deviation; SMD: standardised mean difference; STS: Society of Thoracic Surgeons; TAVR: transcatheter aortic valve replacement; TIA: transient ischaemic attack

Supplementary Table 4. Procedural aspects in morbidly obese TAVR and SAVR cohorts treated from 2014 to 2019.

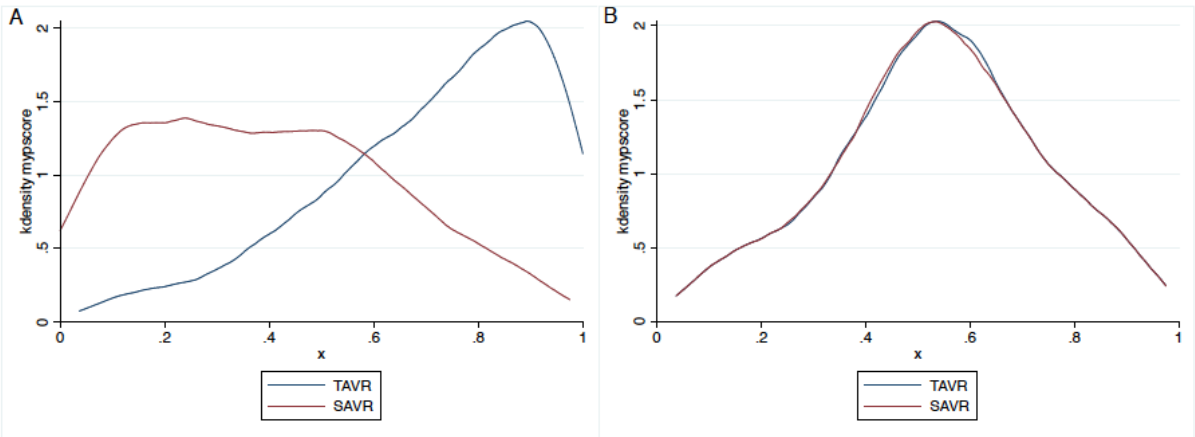
	Pre-matching			Post-matching		
	TAVR (n=641)	**SAVR (n=399)**	**p-value**	**TAVR (n=234)**	**SAVR (n=234)**	**p-value**
Procedural data						
Urgent/emergent	40 (6.83%)	19 (4.76%)	0.180	15 (6.85%)	10 (4.27%)	0.230
TAVR access site						
Transfemoral	564 (87.99%)	-		206 (88.03%)		
Transapical	14 (2.18%)	-		7 (2.99%)		
Other access	63 (9.83%)	-		21 (8.97%)		
SAVR access site						
Full midline sternotomy	-	359 (89.97%)			208 (88.89%)	
Mini-sternotomy	-	40 (10.03%)			26 (11.11%)	
Concomitant coronary revascularisation (CABG)	-	129 (32.33%)			83 (35.47%)	
Prosthesis size						
18–23 mm	122 (19.15%)	285 (71.43%)	<0.001	38 (16.38%)	174 (74.36%)	<0.001
24–28 mm	282 (44.27%)	109 (27.32%)	<0.001	106 (45.69%)	56 (23.93%)	<0.001
29–34 mm	233 (36.58%)	5 (1.25%)	<0.001	88 (37.93%)	4 (1.71%)	<0.001*
TAVR prosthesis type						
Balloon-expandable	304 (47.43%)	-		116 (49.57%)		
Self-expanding	329 (52.33%)	-		115 (49.15%)		
SAVR prosthesis type						
Stented		336 (84.2%)			182 (77.8%)	
Stentless		4 (1%)			4 (1.7%)	
Sutureless		59 (14.8%)			48 (20.5%)	
Other procedural aspects						
General anaesthesia	214 (33.39%)	399 (100%)	<0.001	73 (31.20%)	234 (100%)	<0.001
Prior balloon valvuloplasty	331 (55.35%)			136 (60.44%)		
Balloon post-dilatation	75 (11.94%)			21 (9.13%)		

Values are expressed as mean (SD), median [IQR] or n (%)
CABG: coronary artery bypass graft; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement

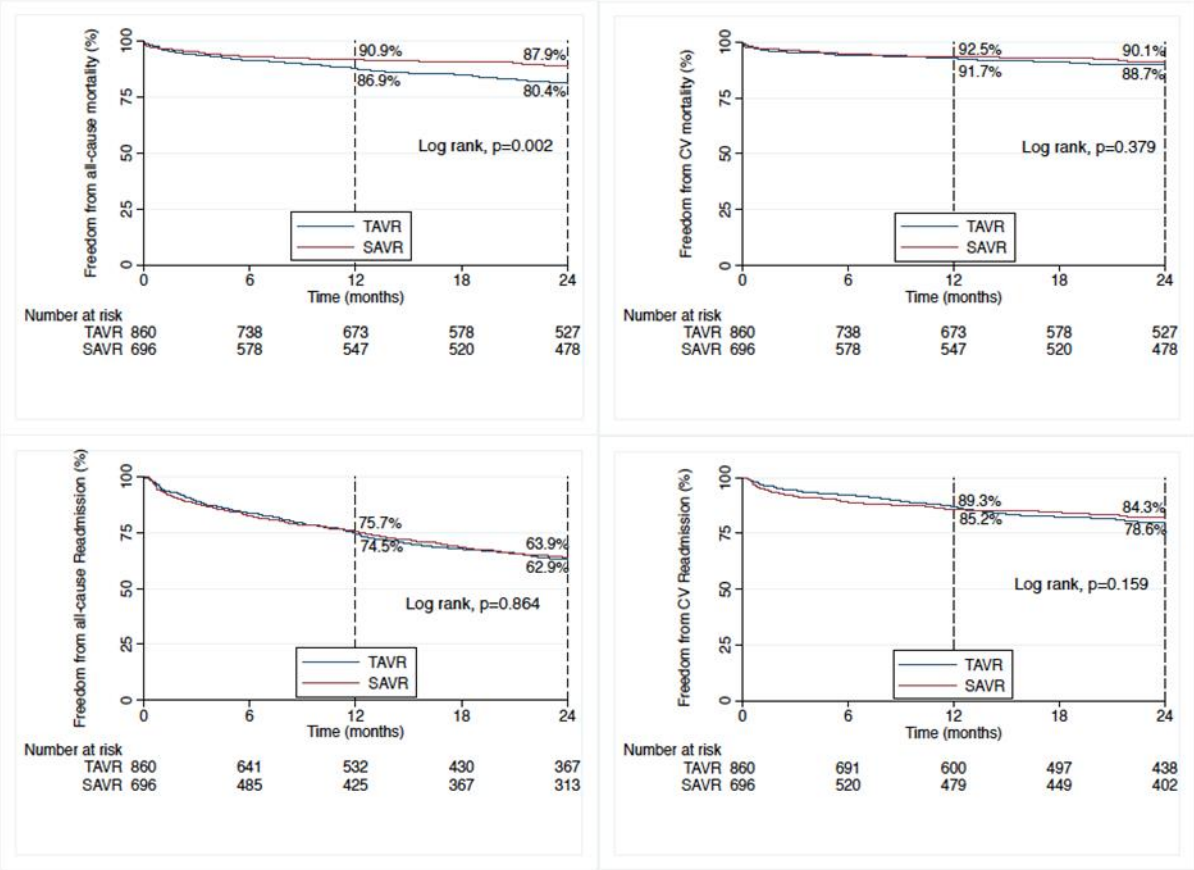
Supplementary Table 5. Clinical endpoints and echocardiographic data post procedure for morbidly obese TAVR and SAVR cohorts treated from 2014 to 2019.

	Pre-matching			Post-matching		
Clinical endpoints	**TAVR (n=641)**	**SAVR (n=399)**	**p-value**	**TAVR (n=234)**	**SAVR (n=234)**	**p-value**
In-hospital mortality	20 (3.12%)	15 (3.76%)	0.578	8 (3.42%)	14 (5.98%)	0.190
In-hospital or 30-day mortality	28 (4.37%)	16 (4.01%)	0.780	12 (5.13%)	15 (6.41%)	0.552
Major vascular complications	33 (5.15%)	23 (5.76%)	0.669	12 (5.13%)	16 (6.84%)	0.436
Bleeding complications						
Life-threatening bleeding	13 (2.03%)	24 (6.30%)	<0.001	3 91.28%)	17 (7.62%)	0.001
Major bleeding	29 (4.52%)	4 (1.05%)	0.002*	14 (5.98%)	3 (1.35%)	0.009
Life-threatening or major	42 (6.55%)	28 (7.37%)	0.618	17 (7.26%)	20 (8.97%)	0.505
Any blood transfusion	65 (11.32%)	129 (32.41%)	<0.001	20 (9.39%)	84 (36.05%)	<0.001
Acute kidney injury						
Stage I	78 (13.66%)	113 (28.54%)	<0.001	22 (10.43%)	70 (30.30%)	<0.001
Stage II and III	22 (3.85%)	33 (8.33%)	0.003	10 (4.74%)	26 (11.26%)	0.012
Any stage	100 (17.51%)	146 (36.87%)	<0.001	32 (5.17%)	96 (41.56%)	<0.001
Periprocedural stroke	9 (1.41%)	4 (1.10)	0.776*	4 (1.71%)	2 (0.86%)	0.685*
Hospital-acquired pneumonia	8 (1.27%)	24 (6.03%)	<0.001	1 (0.43%)	14 (6.01%)	0.001*
New permanent pacemaker implantation †	83 (12.95%)	19 (4.91%)	<0.001	26 (11.11%)	18 (7.83%)	0.227
Access site infection	4 (0.83%)	8 (2.44%)	0.078*	2 (1.06%)	5 (2.73%)	0.297
ECHO parameters (0-30 days)						
Moderate-severe aortic valve regurgitation	10 (1.69%)	2 (0.59%)	0.228*	7 (3.20%)	(0%)	0.015*
Post-procedural mean aortic valve gradient (mmHg)	10 [7-14]	14.55 [11-19]	<0.001	10 [7.6-14]	14 [10-18]	<0.001
Mean gradient >20 mmHg	48 (7.97%)	81 (23.01%)	<0.001	19 (8.64%)	40 (19.90%)	0.001
Moderate-severe PPM	63 (11.09%)	120 (30.23%)	<0.001	15 (7.58%)	71 (30.60%)	<0.001
Length of hospital stay (days)	5 [2-7]	8 [6-11]	<0.001	4 [2-7]	8 [6-12]	<0.001

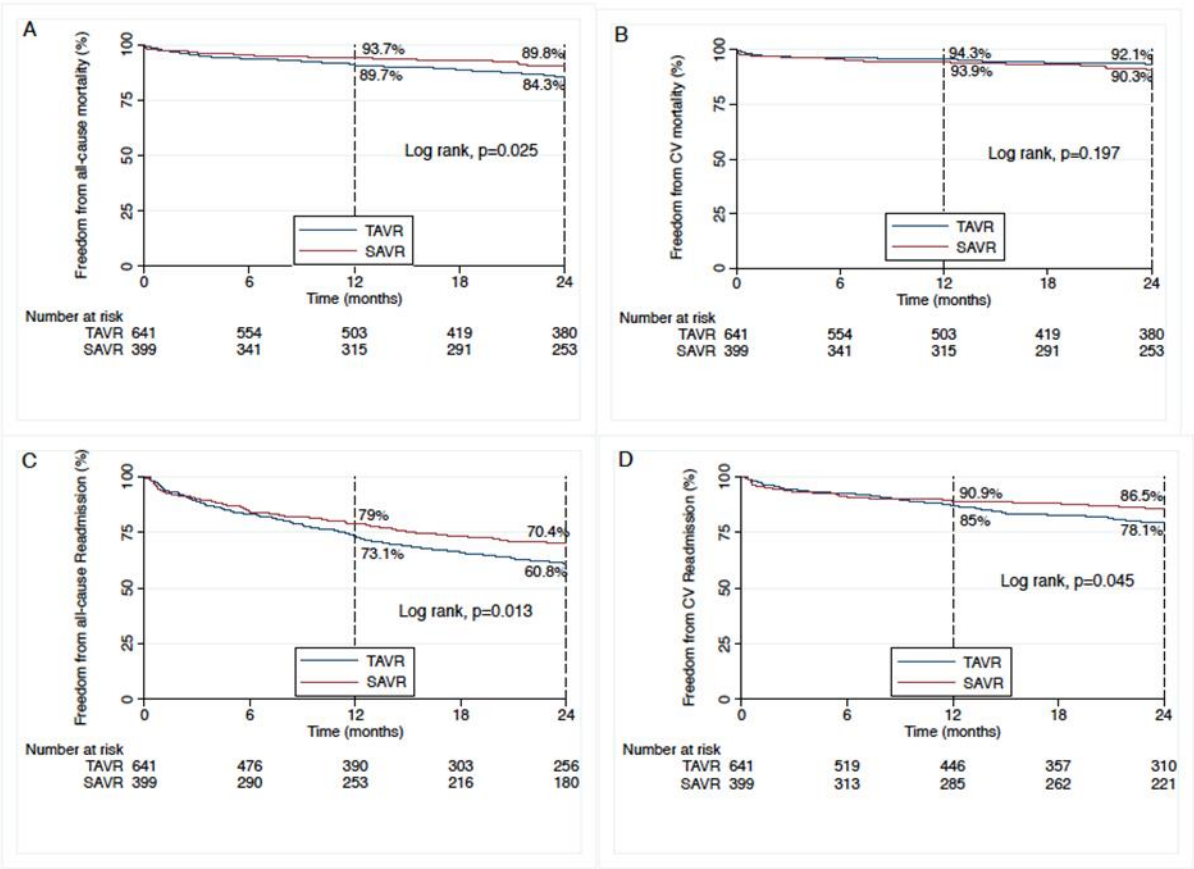
Values are expressed as mean (SD), median [IQR] or n (%). *Fisher's exact test used, † calculated only for patients without pre-existing permanent pacemakers. CV: cardiovascular; ECHO: echocardiogram; IQR: interquartile range; PPM: patient-prosthesis mismatch; SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement



Supplementary Figure 1. Kernel Density plots representing the pre- (A) and post- (B) matching. Patients were matched based on the following variables: age, sex, BMI, pre-existing coronary artery disease, prior coronary artery bypass grafting, estimated glomerular filtration rate, risk score, pre-existing peripheral vascular disease, chronic obstructive pulmonary disease and atrial fibrillation. SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement



Supplementary Figure 2. Kaplan Meier graph demonstrating 2-year all-cause (A) and cardiovascular (B) mortality and 2-year all-cause (C) and cardiovascular (D) readmission for the entire cohort of morbidly obese TAVR and SAVR groups. SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement



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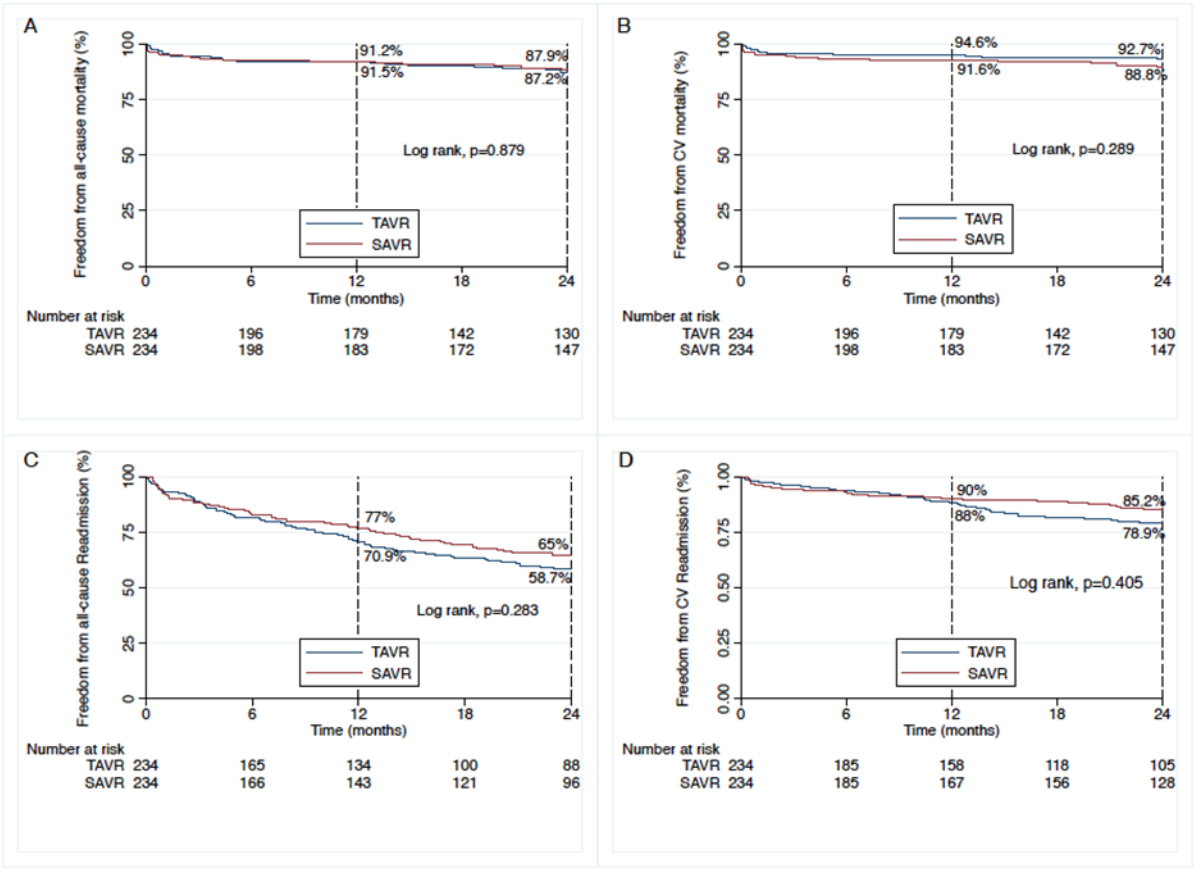

Supplementary Figure 4. Kaplan Meier graph demonstrating 2-year all-cause (A) and cardiovascular (B) mortality and 2-year all-cause (C) and cardiovascular (D) readmission for the matched cohort of morbidly obese TAVR and SAVR groups treated from 2014-2019. SAVR: surgical aortic valve replacement; TAVR: transcatheter aortic valve replacement