**Supplemental material**

**Early and mid-term outcome of patients with low-flow – low-gradient aortic stenosis treated with newer-generation transcatheter aortic valves**

Fraccaro C et al.

**Supplemental Table 1. Baseline characteristics of patients with LFLG AS treated with TAVR or SAVR.**

|  |  |  |  |
| --- | --- | --- | --- |
| Clinical variables | SAVR  (N=401) | TAVR  (N=389) | P Value |
| Age, years | 73.5 ± 9.1 | 80.9 ± 6.5 | <0.001 |
| Female Sex | 127 (31.7) | 138 (35.5) | 0.258 |
| BMI | 26.8 ± 4.5 | 25.8 ± 4.4 | <0.001 |
| Diabetes | 128 (31.9) | 125 (32.2) | 0.929 |
| CAD  1-vessel  2-vessels  3-vessels/LM | 67 (16.7)  48 (12.0)  89 (22.2) | 64 (16.6)  26 (6.7)  44 (11.4) | <0.001 |
| Previous AMI  <90 days  >90 days | 39 (9.9)  57 (14.5) | 9 (2.3)  92 (23.7) | <0.001 |
| Previous PCI | 40 (10.0) | 88 (22.7) | <0.001 |
| Previous cardiac surgery | 25 (6.3) | 99 (25.4) | <0.001 |
| Previous CABG | 12 (3.0) | 76 (19.5) | <0.001 |
| Prior aortic surgery | 17 (4.3) | 16 (4.1) | 0.912 |
| Previous other cardiac surgery | 12 (3.0) | 34 (8.7) | <0.001 |
| COPD | 61 (15.2) | 77 (19.8) | 0.090 |
| Home oxygen therapy | 10 (2.5) | 15 (3.9) | 0.282 |
| e-GFR classification  ≥90  ≥60-90  ≥45-60  ≥30-45  ≥15-30  <15 | 54 (13.7)  156 (39.5)  102 (25.8)  51 (12.9)  16 (4.1)  16 (4.1) | 23 (5.9)  117 (30.2)  104 (26.8)  99 (25.5)  29 (7.5)  16 (4.1) | <0.001 |
| Dialysis | 14 (3.5) | 17 (4.4) | 0.520 |
| Neurological dysfunction | 10 (2.5) | 8 (2.1) | 0.665 |
| Peripheral vasculopathy | 77 (19.4) | 95 (24.6) | 0.078 |
| Liver disease | 10 (2.5) | 4 (1.0) | 0.115 |
| Pulmonary hypertension | 35 (9.5) | 32 (8.2) | 0.534 |
| Active cancer | 5 (1.3) | 15 (3.9) | 0.020 |
| EuroSCORE II | 6.0 ± 7.4 | 11.4 ± 9.8 | <0.001 |
| EuroSCORE II >4 | 172 (48.0) | 322 (84.3) | <0.001 |
| Frailty class  0  1  2 | 329 (82.0)  47 (11.7)  25 (6.2) | 217 (55.8)  92 (23.7)  80 (20.6) | <0.001 |
| Urgent status | 29 (7.2) | 32 (8.2) | 0.593 |
| NYHA functional class  I  II  III  IV | 23 (5.8)  150 (37.9)  173 (43.7)  50 (12.6) | 2 (0.5)  75 (19.4)  273 (70.5)  37 (9.6) | <0.001 |
| Unstable Angina | 38 (9.6) | 25 (6.4) | 0.100 |
| Hb level, gr/dl | 12.5 ± 1.7 | 11.9 ± 1.8 | <0.001 |
| Albumin level, gr/l | 3.7 ± 0.9 | 3.9 ± 0.7 | <0.001 |
| Need for concomitant coronary revascularization | 164 (41.9) | 30 (7.7) | <0.001 |
| Mitral regurgitation  no/trivial  mild  moderate  severe | 136 (33.9)  181 (45.1)  72 (18.0)  12 (3.0) | 31 (8.0)  167 (43.0)  150 (38.7)  40 (10.3) | <0.001 |
| LVEF <30% | 45 (11.2) | 64 (16.5) | 0.033 |
| LVEF, % | 40.3 ± 8.0 | 37.5 ± 8.6 | <0.001 |
| AVA, cmq | 0.8 ± 0.3 | 0.7 ± 0.3 | <0.001 |
| AV pick gradient, mmHg | 54.7 ± 15.2 | 50.0 ± 13.6 | <0.001 |
| AV mean gradient, mmHg | 31.6 ± 7.8 | 29.5 ± 7.8 | <0.001 |

Continuous variables are reported as mean and standard deviation. Categorical variables are reported as counts and percentages (in parentheses).

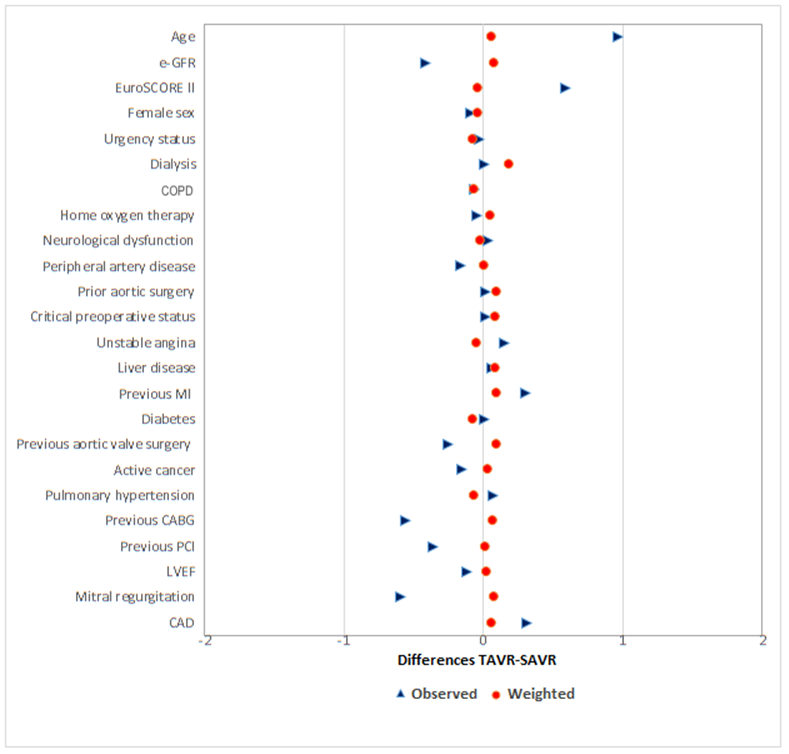
AV = aortic valve; AVA = aortic valve area; BMI = body mass index; CAD = coronary artery disease; CABG = coronary artery bypass graft; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; LVEF = left ventricular ejection fraction; NYHA = New York Heart Association; PCI = percutaneous coronary intervention; SAVR = surgical aortic valve replacement; TAVR = transcatheter aortic valve replacement.

**Propensity score analysis**

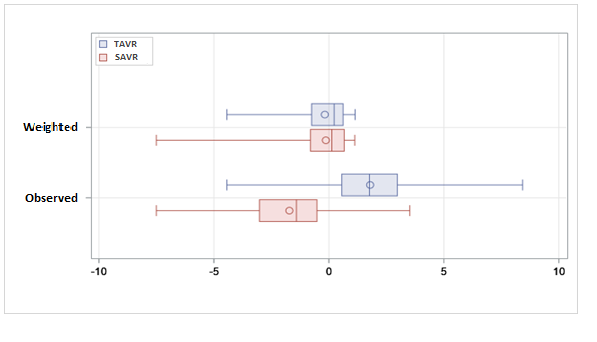
A propensity score analysis using the inverse probability of treatment weighting (IPTW) method was used to adjust for differences in the baseline characteristics of patients who underwent SAVR or TAVR. A logistic regression model with a non-parsimonious approach was used to estimate the propensity score. Patients characteristics used to estimate the propensity score were the following: age, gender, EuroSCORE II, body mass index (BMI), dialysis, chronic obstructive pulmonary disease, neurological dysfunction, peripheral vasculopathy, home oxygen therapy, previous aortic intervention, critical pre-operative clinical status, unstable angina, liver disease, previous myocardial infarction, diabetes, active cancer, pulmonary hypertension, previous percutaneous coronary intervention, previous coronary artery bypass graft, left ventricle ejection fraction, frailty, NYHA functional class, coronary artery disease, mitral regurgitation, eGFR, urgency status, prior aortic surgery.

Being p the propensity score, a weight equal to 1 was used for patients treated with TAVI and equal to p/(1-p) for patients treated with SAVR. To address the issue of extreme weights, that often occurs when a treatment is not suitable for all members of the population, stabilized weights were used, truncating the weights to a defined threshold. A recursive method was used to select the best threshold of propensity score to be used. Observations with a p>0.75 were excluded.

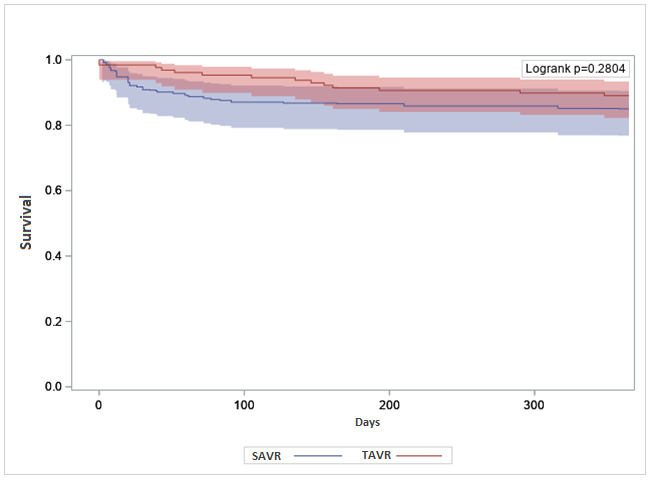
**Supplemental Figure 1.** Standardized mean differences.



**Supplemental Figure 2. Log-PS distribution**

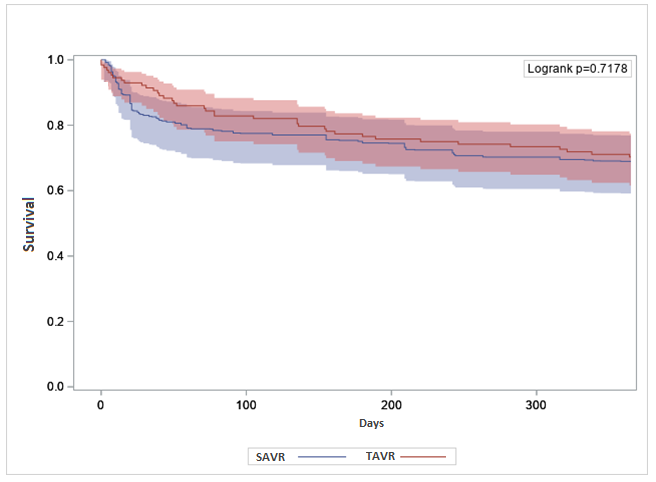
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**Supplemental Figure 3.** Overall survival in the study cohorts.



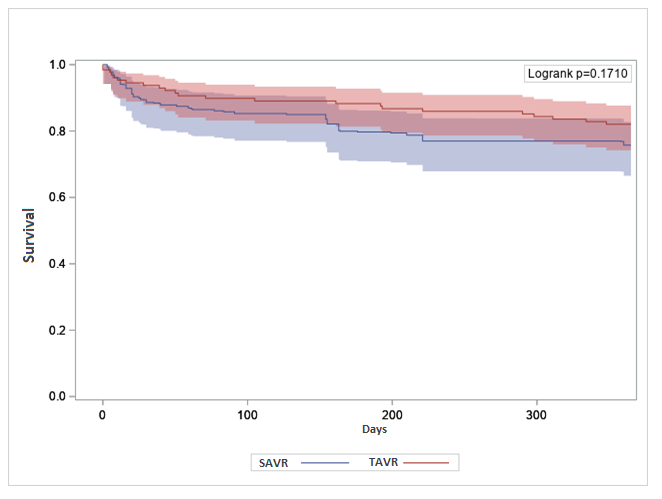
|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Hazard ratio | p-value | 95%CI | |
|
| TAVR | 0.69 | 0.295 | 0.350 | 1.375 |

**Supplemental Figure 4.** All cause death +CHF



|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Hazard ratio | p-value | 95%CI | |
|
| TAVR | 0.92 | 0.698 | 0.590 | 1.424 |

**Supplemental Figure 5.** MACCE



|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Hazard ratio | p-value | 95%CI | |
|
| TAVR | 0.71 | 0.207 | 0.415 | 1.209 |

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The **Research Group and participating centers of the OBSERVANT I study** have been previously listed in: Barbanti M, Tamburino C, D'Errigo P, et al. Five-year outcomes of transfemoral transcatheter aortic valve replacement or surgical aortic valve replacement in a real world population. Circ Cardiovasc Interv. 2019;12:e007825 - Supplemental Material.