One-year clinical outcomes of transcatheter aortic valve implantation with the latest iteration of self-expanding or balloon-expandable devices: insights from the OPERA-TAVI registry

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KEYWORDS

- aortic stenosis
- degenerative valve
- TAVI

Abstract

Background: Midterm comparative analyses of the latest iterations of the most used Evolut and SAPIEN platforms for transcatheter aortic valve implantation (TAVI) are lacking.

Aims: We aimed to compare 1-year clinical outcomes of TAVI patients receiving Evolut PRO/PRO+ (PRO) or SAPIEN 3 Ultra (ULTRA) devices in current real-world practice.

Methods: Among patients enrolled in the OPERA-TAVI registry, patients with complete 1-year follow-up were considered for the purpose of this analysis. One-to-one propensity score matching was used to compare TAVI patients receiving PRO or ULTRA devices. The primary endpoint was a composite of 1-year all-cause death, disabling stroke and rehospitalisation for heart failure. Five prespecified subgroups of patients were considered according to leaflet and left ventricular outflow tract calcifications, annulus dimensions and angulation, and leaflet morphology.

Results: Among a total of 1,897 patients, 587 matched pairs of patients with similar clinical and anatomical characteristics were compared. The primary composite endpoint did not differ between patients receiving PRO or ULTRA devices (Kaplan-Meier [KM] estimates 14.0% vs 11.9%; log-rank p=0.27). Patients receiving PRO devices had higher rates of 1-year disabling stroke (KM estimates 2.6% vs 0.4%; log-rank p=0.001), predominantly occurring within 30 days after TAVI (1.4% vs 0.0%; p=0.004). Outcomes were consistent across all the prespecified subsets of anatomical scenarios (all $p_{interaction}$>0.10).

Conclusions: One-year clinical outcomes of patients undergoing transfemoral TAVI and receiving PRO or ULTRA devices in the current clinical practice were similar, but PRO patients had higher rates of disabling stroke. Outcomes did not differ across the different anatomical subsets of the aortic root.

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Abbreviations

BE balloon-expandable
LVOT left ventricular outflow tract
PSM propensity score matching
PVR paravalvular regurgitation
SE self-expanding
TAVI transcatheter aortic valve implantation

Introduction

Transcatheter aortic valve implantation (TAVI) has become the treatment of choice for elderly patients with severe symptomatic aortic stenosis, regardless of their surgical risk profile[1]. Different refinements have been brought to the most used self-expanding (SE) and balloon-expandable (BE) TAVI platforms over the past decade, leading to a marked improvement in patient outcomes[2]. The OPERA-TAVI registry compared the acute performances of the latest iterations of the Evolut PRO/PRO+ (PRO; Medtronic) and the SAPIEN 3 Ultra (ULTRA; Edwards Lifesciences) valves according to the Valve Academic Research Consortium (VARC)-3 criteria[3]. The aim of the present analysis was to assess 1-year clinical outcomes of patients enrolled in the OPERA-TAVI registry, investigating potential differences between the two platforms in different prespecified challenging anatomies.

Methods

REGISTRY DESIGN

The OPERA-TAVI (Comparative Analysis of Evolut PRO vs SAPIEN 3 Ultra Valves for Transfemoral Transcatheter Aortic Valve Implantation) is an investigator-initiated, multicentre registry which enrolled consecutive patients undergoing transfemoral TAVI with PRO or ULTRA devices at 15 centres in Europe and North America from September 2017 to January 2022. Details of the registry design have been previously published[3].

STUDY OUTCOMES

The primary outcome of the analysis was a composite of all-cause death, disabling stroke and rehospitalisation for heart failure (HF) at 1 year. Secondary outcomes included 1-year all-cause death, disabling stroke and HF rehospitalisation, individually.

STATISTICAL ANALYSIS

Categorical variables are reported as counts and percentages. Continuous variables are reported as medians and interquartile ranges (IQRs). Continuous variables were compared with a t-test or Mann-Whitney U test, and categorical variables were compared with the chi-square statistics, Fischer's exact or McNemar tests as appropriate.

Propensity score matching (PSM) was used to account for possible confounding bias due to the non-randomised design of the study. The propensity score was estimated using a logistic regression model according to a non-parsimonious approach. The variables selected were sex, age, body mass index (BMI), diabetes, hypertension, peripheral artery disease (PAD), chronic obstructive pulmonary disease (COPD), renal failure (defined as estimated glomerular filtration rate <30 ml/min/1.73 m^2), prior coronary artery bypass grafting (CABG), prior myocardial infarction (MI), prior stroke, prior pacemaker (PM) implantation, New York Heart Association (NYHA) Functional Class, atrial fibrillation (AF), baseline right bundle branch block (RBBB), Society of Thoracic Surgeons (STS) mortality score, left ventricular ejection fraction (LVEF), transaortic mean gradient, leaflet and left ventricular outflow tract (LVOT) calcification, bicuspid aortic valve, horizontal aorta, and area/perimeter-derived aortic annulus diameter <23 mm assessed at preprocedural computed tomography (CT) analysis.

Five subgroups of patients were prespecified and tested for interaction for primary and secondary outcomes: moderate to severe aortic leaflet calcifications, moderate to severe LVOT calcifications, area/perimeter-derived annulus diameter <23 mm, horizontal aorta (defined as an angle between the horizontal plane and the aortic annulus ≥48°) and bicuspid aortic valve.

Time-to-event curves for the primary and co-primary outcomes were estimated using the Kaplan-Meier (KM) method. Landmark analyses were performed for each outcome of interest; 30 days after TAVI was considered as the cut-off date of interest. Cox regression analysis was performed for each outcome of interest. Results were reported as hazard ratio (HR) with 95% confidence interval (CI).

All statistical tests were performed two-tailed, and a p-value<0.05 was considered as the threshold for statistical significance (p-value<0.10 was the threshold for the interaction test). All statistical analyses were performed with R software, version 3.6.3 (R Foundation for Statistical Computing).

Results

BASELINE CHARACTERISTICS

A total of 3,518 consecutive patients undergoing transfemoral TAVI were enrolled in the OPERA-TAVI registry. Exclusion criteria for the analysis were as follows: patients who were not eligible for both PRO and ULTRA devices according to the manufacturers' instruction for annular dimensions, and TAVI in pure aortic valve regurgitation and in degenerated surgical bioprosthetic valves. Patients without preprocedural CT and 1-year follow-up data were also excluded. Given a total of 1,897 patients in the prematched population, 1,098 patients received the PRO transcatheter aortic valve, whereas 799 patients received the ULTRA device. Baseline characteristics of the prematched population are reported in **Supplementary Table 1**.

After adjustment for clinical and anatomical characteristics, 587 matched pairs treated with PRO or ULTRA devices were compared. Baseline characteristics were well balanced between the two study groups, with all standardised mean differences (SMDs) below 10%.

Baseline characteristics of the matched population are reported in **Table 1**.

Table 1. Baseline characteristics of the matched population.

	Overall (n=1,174)	PRO (n=587)	ULTRA (n=587)	SMD
Age, years	82.0 [77.8, 86.1]	82.0 [78.0, 86.0]	82.0 [77.0, 86.3]	0.054
Female sex	662 (56.4)	338 (57.6)	324 (55.2)	0.048
BMI, kg/m²	26.4 [23.4, 30.0]	26.3 [23.2, 30.0]	26.4 [23.6, 29.8]	0.006
Hypertension	1,004 (85.5)	503 (85.7)	501 (85.3)	0.010
Diabetes mellitus	332 (28.3)	168 (28.6)	164 (27.9)	0.015
Renal failure	114 (9.7)	62 (10.6)	52 (8.9)	0.081
CAD	457 (38.9)	220 (37.5)	237 (40.4)	0.059
Prior MI	122 (10.4)	61 (10.4)	61 (10.4)	0.034
Prior CABG	65 (5.5)	32 (5.5)	33 (5.6)	0.007
Prior PM	92 (7.8)	47 (8.0)	45 (7.7)	0.013
PAD	152 (12.9)	75 (12.8)	77 (13.1)	0.010
AF	294 (25.0)	147 (25.0)	147 (25.0)	<0.001
Prior stroke	121 (10.3)	57 (9.7)	64 (10.9)	0.039
COPD	134 (11.4)	67 (11.4)	67 (11.4)	0.066
NYHA Functional Class				0.121
I	38 (3.2)	15 (2.6)	23 (3.9)	
II	425 (36.2)	202 (34.4)	223 (38.0)	
III	639 (54.4)	331 (56.4)	308 (52.5)	
IV	64 (5.5)	34 (5.8)	30 (5.1)	
NA	8 (0.7)	5 (0.9)	3 (0.5)	
NYHA Class >2	703 (59.9)	365 (62.2)	338 (57.6)	0.100
Prior RBBB	88 (7.5)	40 (6.8)	48 (8.2)	0.067
STS mortality score	3.2 [2.1, 4.7]	3.3 [2.3, 4.6]	3.2 [2.0, 4.7]	0.053
Echocardiographic characteristics				
LVEF, %	60.0 [55.0, 65.0]	60.0 [55.0, 65.0]	60.0 [55.0, 65.0]	0.002
Aortic peak gradient, mmHg	73.0 [58.8, 86.0]	73.5 [59.3, 88.8]	71.0 [58.0, 85.0]	0.058
Aortic mean gradient, mmHg	44.0 [36.0, 53.0]	44.0 [36.0, 54.0]	44.0 [36.0, 52.0]	0.018
AVA, cm²	0.7 [0.6, 0.8]	0.7 [0.6, 0.8]	0.7 [0.6, 0.8]	0.042

Data are presented as n (%) or median [IQR]. AF: atrial fibrillation; AVA: aortic valve area; BMI: body mass index; CABG: coronary artery bypass grafting; CAD: coronary artery disease; COPD: chronic obstructive pulmonary disease; IQR: interquartile range; LVEF: left ventricular ejection fraction; MI: myocardial infarction; NA: not available; NYHA: New York Heart Association; PAD: peripheral artery disease; PM: pacemaker; RBBB: right bundle branch block; SMD: standardised mean difference; STS: Society of Thoracic Surgeons

The median age of the matched population was 82 years. Patients had low-to-intermediate surgical risk as predicted by the STS mortality score, with a median value of 3.2% (IQR 2.1-4.7%).

After analysis of the preprocedural CT characteristics, patients receiving SE devices had smaller sinotubular junctions (STJ; mean diameter 27.5 mm [IQR 25.4-29.9 mm] vs 28.5 mm [IQR 26.6-30.0 mm]; p<0.001), sinuses of Valsalva (SoV; mean diameter 30.5 mm [IQR 28.5-33.0 mm] vs 31.1 mm [IQR 29.0-33.0 mm]; p=0.010) and aortic annuli (perimeter 73.5 mm [IQR 69.0-77.1 mm] vs 74.2 [IQR 70.5-78.3 mm]; p<0.001).

Preprocedural CT characteristics are reported in **Supplementary Table 2**.

PROCEDURAL CHARACTERISTICS

Procedural details of the matched population are reported in **Supplementary Table 3**.

Patients treated with the PRO devices more frequently had pre- (42.9% vs 27.5%; p<0.001) and post-dilatation (26.5% vs 5.9%; p<0.001), compared to ULTRA patients.

Moreover, PRO recipients had greater valve oversizing (perimeter oversizing 18.4% vs 3.1%; p<0.001) and received a higher dose of contrast dye during the procedure (median 120 ml vs 100 ml; p<0.001).

STUDY OUTCOMES

In-hospital outcomes and the echocardiographic performance of the bioprostheses in the matched groups are reported in **Supplementary Table 4** and **Supplementary Table 5**.

The primary composite endpoint of 1-year all-cause death, HF rehospitalisation or disabling stroke did not differ between PRO and ULTRA patients (KM estimates 14.0% vs 11.9%; log-rank p=0.27).

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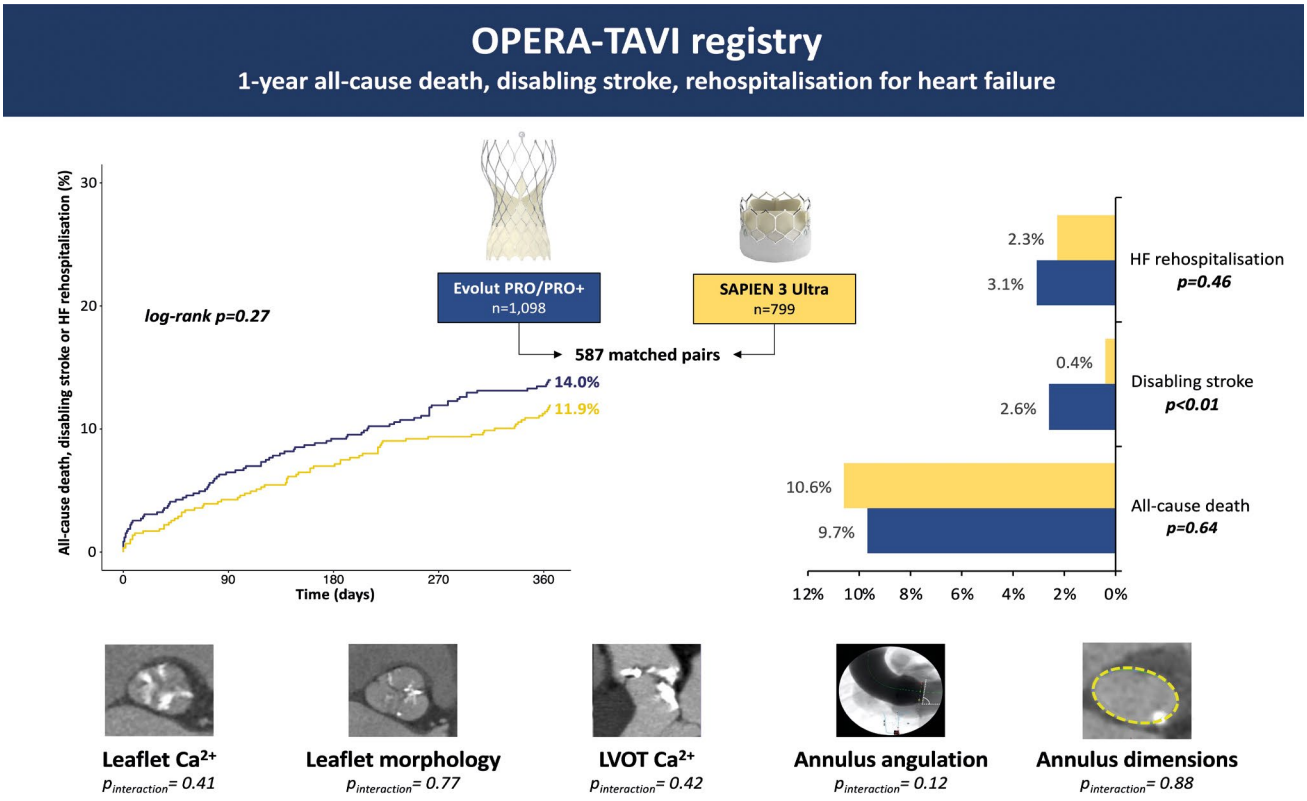
CENTRAL **ILLUSTRATION** OPERA-TAVI registry: 1-year all-cause death, disabling stroke, rehospitalisation for heart failure.



Ca^{2+}: calcium; HF: heart failure

Table 2. One-year clinical outcomes of the matched population.

	PRO (n=587)	ULTRA (n=587)	HR (95% CI)	*p*-value
Composite endpoint	14.0	11.9	0.84 (0.61-1.15)	0.274
All-cause death	9.7	10.6	1.09 (0.76.1.56)	0.645
Disabling stroke	2.6	0.4	0.13 (0.03-0.58)	0.007
Rehospitalisation for HF	3.1	2.3	0.76 (0.37-1.57)	0.457

Data are presented as %. CI: confidence interval; HF: heart failure; HR: hazard ratio

Rates of 1-year all-cause death (KM estimates 9.7% vs 10.6%; log-rank p=0.65) and HF rehospitalisation (KM estimates 3.1% vs 2.3%; log-rank p=0.46) were similar between the PRO and ULTRA recipients. Patients treated with PRO devices had higher rates of disabling stroke at 1 year (KM estimates 2.6% vs 0.4%; log-rank p=0.001).

One-year clinical outcomes are reported in the **Central illustration** and **Table 2**.

In the 30-day landmark analyses, a greater incidence of disabling stroke was observed, primarily within 30 days of the procedure (1.4% PRO vs 0.0% ULTRA; p=0.004). Subsequently, there was only a trend towards a higher rate of disabling stroke in ULTRA patients (1.3% PRO vs 0.4% ULTRA; p=0.091) **(Figure 1)**.

SUBGROUP ANALYSIS

Primary and secondary outcomes were analysed separately according to patients' native annulus dimensions and angulation, leaflet morphology, LVOT and leaflet calcification grades.

Outcomes in each subgroup of patients were consistent with those reported in the whole study population (all $p_{interaction}$>0.10) **(Figure 2, Supplementary Figures 1-5)**.

Discussion

During the last fifteen years, several studies have compared clinical outcomes and device performance in patients undergoing TAVI with different device iterations[4-9]. OPERA-TAVI was the first registry to report outcomes of patients undergoing TAVI who received the latest PRO or ULTRA TAVI platforms[3]. In the present analysis, we aimed to compare the midterm clinical outcomes of patients receiving these two platforms. Additionally, we sought to investigate potential differences in specific anatomical subsets that present challenges, for which one platform has

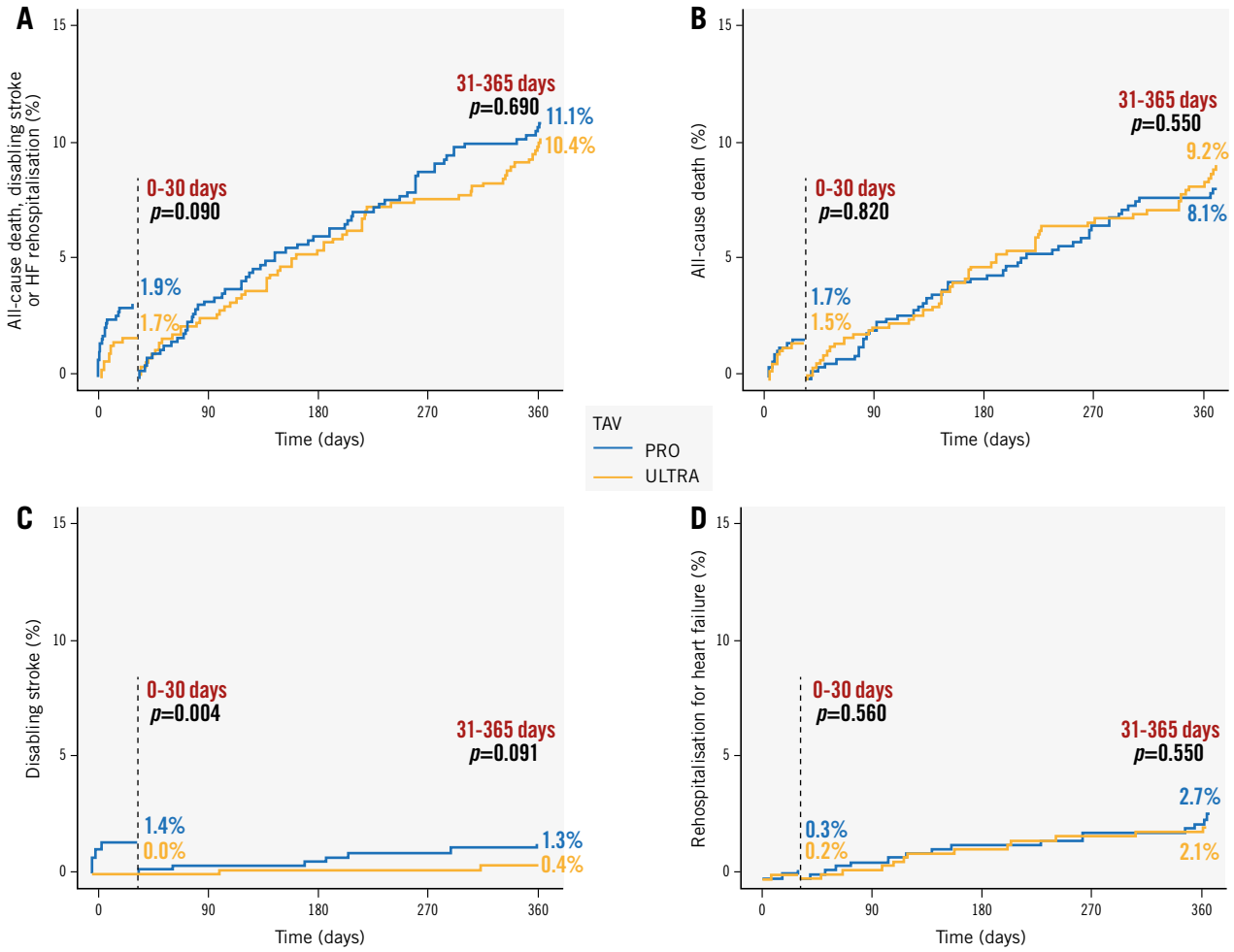


Figure 1. *Thirty-day landmark analyses for the composite primary endpoint and its individual components. A) Composite primary endpoint, B) all-cause death, C) disabling stroke and D) rehospitalisation for heart failure. HF: heart failure; TAV: transcatheter aortic valve*

been hypothesised to potentially outperform the other, and vice versa.

The main findings of the study were as follows:

1) At 1 year, PRO and ULTRA patients exhibited comparable rates of the composite outcome, which included all-cause mortality, disabling stroke, and rehospitalisation due to HF.

2) Patients receiving PRO devices had higher rates of disabling stroke, with the higher incidence predominantly confined to the first 30 days after TAVI.

3) Across all prespecified anatomical subgroups of patients, clinical outcomes did not differ between the two study groups.

4) Differences in bioprosthetic haemodynamics did not have an impact on clinical outcomes.

A total of 1,174 consecutive patients at low-to-intermediate surgical risk undergoing transfemoral TAVI in real-world practice with PRO or ULTRA devices were compared in the present analysis. At 1 year, the primary composite endpoint of all-cause death, disabling stroke or HF rehospitalisation did not differ between patients receiving PRO or ULTRA TAVI devices (14.0% vs 11.9%; log-rank p=0.27). The rate of all-cause death was not statistically different between the study devices at 1 year, nor the rate of HF rehospitalisation. Nevertheless, patients receiving the PRO devices showed higher rates of disabling stroke (2.6% vs 0.4%). This datum was in contrast with that previously reported in the SOLVE-TAVI (CompariSon of secOnd-generation seLf-expandable vs. balloon-expandable Valves and gEneral vs. local anesthesia in Transcatheter Aortic Valve Implantation) randomised clinical trial, which reported significantly higher stroke rates in patients receiving previous-generation BE valves (BE: 6.1% vs SE: 0.8%, HR 6.63; p=0.013)[6]. The landmark analysis showed that the increased risk of stroke was mostly confined to the first 30 days after TAVI (1.4 % vs 0.0%; p=0.004), with no significant difference after 30 days (p=0.091). As previously discussed in the analysis of the OPERA-TAVI registry[3], the higher rates of pre- and post-dilatation observed in the PRO groups could have affected this finding in our analysis[10,11]. Besides, one can speculate that this difference might be related to the difference in flexibility of the two delivery systems. Indeed, the PRO

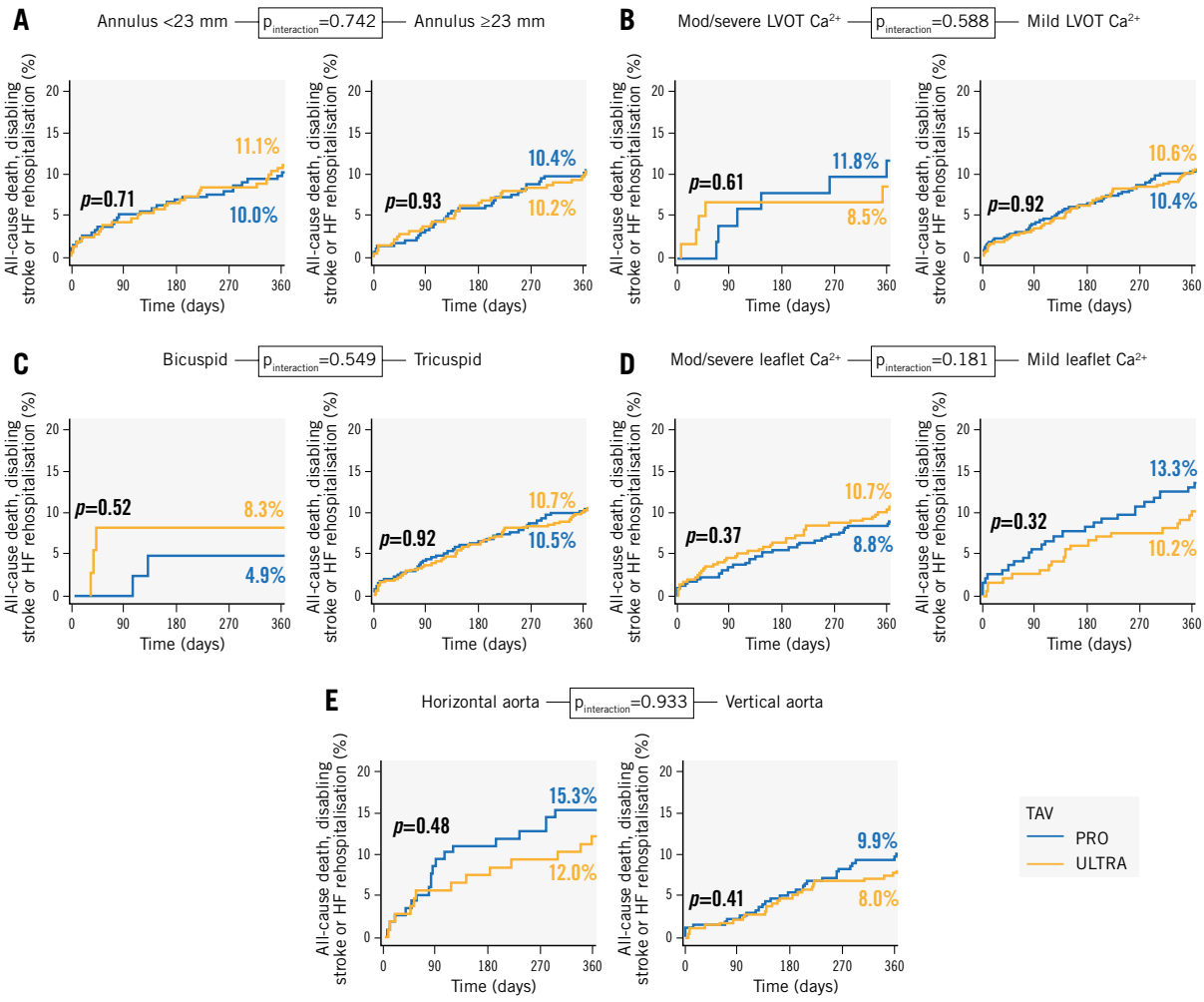


Figure 2. *Subgroup analysis of the primary composite endpoint in the five prespecified anatomical subsets. A) Annulus dimension. B) LVOT calcifications. C) Leaflet morphology. D) Leaflet calcifications. E) Annulus angulation. Ca²: calcium; HF: heart failure; LVOT: left ventricular outflow tract*

delivery system is more rigid than that of the ULTRA device, which also has the possibility to mechanically flex its distal part to facilitate the crossing of the aortic arch. It is also possible that the PRO system scratches the aortic arch during crossing manoeuvres, displacing calcium particles and debris that may embolise in the cerebral vessels. Similarly, the PRO system might displace calcium particles during the crossing of the native aortic valve, as this device is more difficult to centre and to place coaxially compared to the ULTRA TAVI platform. The next-generation Evolut FX (Medtronic) TAVI system promises to significantly improve this key aspect and, therefore, improve patient outcomes.

We assessed clinical outcomes in five prespecified subgroups of patients with different anatomical characteristics that might have lead to intrinsic procedural challenges and, therefore, suboptimal results[12-16]. At 1 year, clinical outcomes of each subgroup were similar to those of the whole study population. No significant interactions in annuli dimensions and angulation, leaflet and LVOT calcification grades, and leaflet morphologies with valve-specific outcomes were detected. Based on the results of our analysis, it can be assumed that both the PRO and ULTRA devices were equally safe and effective, even in challenging anatomies, when TAVI is performed by expert operators. Along with the technical improvements brought by TAVI platform iterations, the increasing expertise in pre-TAVI computed tomography angiography assessment and procedural planning may play an important role in the optimisation of TAVI procedures in real-world practice.

Despite comparable midterm outcomes, residual transprosthetic gradients were significantly lower in patients treated with the PRO devices; these patients exhibited larger indexed effective orifice areas. This evidence confirmed the benefit of the supra-annular design of the PRO devices, in line with previous studies comparing the two TAVI platforms[17]. Remarkably, the ULTRA device had higher rates of mean residual transprosthetic gradients greater than 20 mmHg. This datum is of particular interest, as it was shown to be associated with higher rates of long-term mortality[18]. However, despite higher rates of patient-prosthesis mismatch (PPM) after

TAVI in patients receiving the ULTRA device, no difference in patients with severe grade of PPM was encountered between PRO and ULTRA recipients[19].

Contrarily, the device performances in terms of paravalvular regurgitation (PVR) were favourable to the ULTRA device.

Of note, the rates of moderate-to-severe PVR were similar between the two devices, with lower 1-year rates for PRO recipients when compared to those reported for its predecessor in the SOLVE-TAVI trial[6]. Nevertheless, the overall PVR rate was significantly lower in ULTRA recipients, attributable to the lower number of patients with mild PVR.

Although the role of moderate to severe PVR after TAVR on midterm outcomes has been largely investigated[15,20-25], the clinical impact of residual mild PVR after TAVI is a matter of ongoing debate. In the PARTNER-1 trial[26], mild PVR was associated with higher mortality at 5 years after TAVI in a high-risk population. On the contrary, the results of the PARTNER-2 trial, which enrolled intermediate-risk patients, did not show an association between mild PVR and long-term clinical outcomes[27]. A recent meta-analysis showed that mild PVR was associated with a higher risk of mortality and rehospitalisation in the long term, regardless of the type of transcatheter aortic valve implanted, and that the impact of mild PVR on clinical outcomes increases over the years[28].

Longer-term, robust follow-up data from prospective, randomised studies are awaited to analyse the real impact of devices' haemodynamic differences on clinical outcomes.

Limitations

This was an observational study without independent adjudication of events or independent core laboratory imaging analysis. Although PSM adjustment resulted in 2 groups for comparison with homogeneous baseline characteristics, unmeasured confounders might have remained and could have potentially affected the results because of the non-randomised nature of the study. Finally, the registry did not collect data regarding specific procedural challenges (i.e., aortic arch angulation and stretchability), which could have influenced clinical outcomes.

Conclusions

In the real-world OPERA-TAVI registry, patients undergoing TAVI using PRO and ULTRA devices exhibited comparable rates of the composite endpoint of all-cause mortality, rehospitalisation for heart failure, or disabling stroke at 1 year. However, those who received the PRO devices had higher rates of disabling stroke, particularly within the initial 30 days following the procedure. These results remained uniform across various anatomical subsets of the aortic root. In spite of these similar clinical outcomes, the PRO devices demonstrated higher rates of PVR, while exhibiting lower transprosthetic gradients after the TAVI procedure. *Ad hoc* randomised clinical trials are required to validate the findings of this study and to specifically compare the two devices in peculiar anatomical subsets.

Impact on daily practice

Different refinements in TAVI platforms have contributed to the improvement of patient outcomes seen in randomised clinical trials over the past decade. OPERA-TAVI was the first registry to compare the latest PRO and ULTRA devices in consecutive patients undergoing transfemoral TAVI in current real-world practice. In this analysis, the two TAVI iterations showed similar 1-year clinical outcomes in terms of all-cause death, disabling stroke or rehospitalisation for heart failure, but the PRO devices yielded higher rates of disabling stroke, with the increased risk confined to the first 30 days after the procedure. Outcomes were consistent across different subsets of aortic root anatomies. Longer-term follow-up data from prospective studies are eagerly awaited to analyse the impact of devices' haemodynamic differences on clinical outcomes.

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Conflict of interest statement

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Supplementary data

Supplementary Table 1. Baseline characteristics of the study population before propensity score matching.

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Supplementary Figure 1. One-year Kaplan-Meier curves for secondary outcomes in patients according to aortic leaflet morphology

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Supplementary data

Supplementary Table 1. Baseline characteristics of the study population before propensity score matching.

	Overall (n=1897)	PRO (n=1098)	ULTRA (n=799)	p-value
Age, years, median [IQR]	82.2 [78.0, 86.2]	83.0 [78.8, 86.4]	81.8 [77.0, 86.0]	0.001
Female sex, n (%)	1102 (58.1)	679 (61.8)	423 (52.9)	<0.001
BMI, median [IQR]	26.4 [23.5, 30.0]	26.4 [23.3, 29.7]	26.6 [23.9, 30.1]	0.033
Hypertension, n (%)	1617 (85.2)	920 (83.8)	697 (87.2)	0.052
Diabetes mellitus, n (%)	547 (28.8)	316 (28.8)	231 (28.9)	0.699
Renal failure, n (%)	194 (10.2)	126 (11.5)	68 (8.5)	0.001
CAD, n (%)	729 (38.4)	376 (34.2)	353 (44.2)	<0.001
Prior MI, n (%)	206 (10.9)	81 (7.4)	125 (15.6)	<0.001
Prior CABG, n (%)	104 (5.5)	46 (4.2)	58 (7.3)	0.006
Prior PM, n (%)	167 (8.8)	101 (9.2)	66 (8.3)	0.471
PAD, n (%)	237 (12.5)	119 (10.8)	118 (14.8)	0.009
AF, n (%)	469 (24.7)	259 (23.6)	210 (26.3)	0.064
Prior stroke, n (%)	178 (9.4)	92 (8.4)	86 (10.8)	0.154
COPD, n (%)	217 (11.4)	107 (9.7)	110 (13.8)	0.001
NYHA functional class, n (%)				0.122
I	66 (3.5)	39 (3.6)	27 (3.4)	
II	688 (36.3)	372 (33.9)	316 (39.5)	
III	1027 (54.1)	614 (55.9)	413 (51.7)	
IV	105 (5.5)	65 (5.9)	40 (5.0)	
NA	11 (0.6)	8 (0.7)	3 (0.4)	
NYHA functional class > 2, n (%)	1132 (59.7)	679 (61.8)	453 (56.7)	0.037
Prior RBBB, n (%)	148 (7.8)	86 (7.8)	62 (7.8)	0.120
STS mortality score, median [IQR]	3.3 [2.2, 5.0]	3.4 [2.4, 5.3]	3.1 [2.0, 4.7]	<0.001
Echocardiographic characteristics				
LVEF, median [IQR]	60.0 [55.0, 65.0]	60.0 [55.0, 65.0]	60.0 [54.0, 65.0]	0.488
Aortic peak gradient, median [IQR]	73.0 [60.0, 88.0]	76.0 [62.0, 93.0]	70.0 [56.0, 82.0]	<0.001
Aortic mean gradient, median [IQR]	45.0 [36.0, 55.0]	47.0 [39.0, 58.0]	43.0 [34.0, 50.0]	<0.001
AVA, median [IQR]	0.7 [0.5, 0.8]	0.7 [0.5, 0.8]	0.7 [0.6, 0.8]	<0.001

Abbreviation: AF, Atrial Fibrillation; AVA, Aortic Valve Area; BMI, Body Mass Index; CABG, Coronary Artery Bypass Grafting; CAD, Coronary Artery Disease; COPD, Chronic Obstructive Pulmunary Disease; LVEF, Left Ventricular Ejection Fraction; MI, Myocardial Infarction; PAD, Peripheral Artery Disease; PM, PaceMaker; NA, Not Available; NYHA, New York Heart Association; RBBB, Right Bundle Branch Block; STS, Society of Thoracic Surgeons.

Supplementary Table 2. Preprocedural CT characteristics of the matched population.

	PRO (n=587)	ULTRA (n=587)	p-value
Annulus area, mm^2, median [IQR]	413.0 [360.0, 460.0]	423.6 [380.0, 470.0]	0.001
Annulus perimeter, mm, median [IQR]	73.5 [69.0, 77.1]	74.20 [70.5, 78.3]	<0.001
LM height, mm, median [IQR]	14.0 [12.0, 16.0]	14.00 [12.0, 16.0]	0.479
RCA height, mm, median [IQR]	15.9 [13.2, 18.0]	16.00 [13.4, 18.9]	0.212
Leaflet calcification, n (%)			0.299
Absent/trace	22 (3.8)	29 (5.0)	
Mild	169 (29.0)	163 (28.0)	
Moderate	211 (36.2)	183 (31.4)	
Severe	175 (30.0)	199 (34.2)	
NA	6 (1.0)	8 (1.4)	
LVOT calcification, n (%)			<0.001
Absent/trace	359 (61.7)	424 (73.0)	
Mild	138 (23.7)	70 (12.0)	
Moderate	22 (3.8)	33 (5.7)	
Severe	29 (5.0)	26 (4.5)	
NA	34 (5.8)	28 (4.8)	
STJ mean diameter, mm, median [IQR]	27.5 [25.4, 29.9]	28.5 [26.6, 30.0]	<0.001
SoV mean diameter, mm, median [IQR]	30.5 [28.5, 33.0]	31.1 [29.0, 33.0]	0.010
Horizontal aorta, n (%)	118 (20.1)	108 (18.4)	0.527
Bicuspid aortic valve, n (%)	41 (7.0)	36 (6.1)	0.493

Abbreviation: IQR, Interquartile range; LM, Left Main; LVOT, Left Ventricular Outflow Tract; NA, Not Available; RCA, Right Coronary Artery; STJ, Sinotubular junction; SoV, Sinus of Valsalva.

Supplementary Table 3. Procedural characteristics of the matched population.

	PRO (n=587)	ULTRA (n=587)	p-value
General anesthesia, n (%)	44 (7.5)	32 (5.5)	0.192
Area oversizing, % [IQR]	45.1 [36.7, 54.7]	9.3 [2.4, 16.8]	<0.001
Perimeter oversizing, % [IQR]	18.4 [15.0, 22.4]	3.1 [-0.5, 5.9]	<0.001
Valve type			
PRO, n (%)			
23mm	12 (2.0)	-	-
26mm	198 (33.8)	-	-
29mm	264 (45.0)	-	-
PRO+, n (%)			
23mm	11 (1.9)	-	-
26mm	33 (5.6)	-	-
29mm	62 (10.6)	-	-
34mm	8 (1.4)	-	-
ULTRA, n (%)			
20mm	-	15 (2.6)	-
23mm	-	288 (49.1)	-
26mm	-	285 (48.6)	-
Concomitant PCI, n (%)	26 (4.4)	26 (4.4)	1.000
Predilatation, n (%)	236 (42.9)	154 (27.5)	<0.001
Postdilatation, n (%)	144 (26.3)	33 (5.9)	<0.001
TAV recapturing/repositioning, n (%)	67 (15.3)	0 (0.0)	-
Two TAVs implanted, n (%)	4 (0.7)	5 (0.9)	1.000
Annular rupture, n (%)	1 (0.2)	4 (0.7)	0.374
Coronary obstruction, n (%)	2 (0.3)	0 (0.0)	0.500
Contrast dye, mL, median [IQR]	120.0 [85.0, 160.0]	100.0 [78.0, 150.0]	0.001

Abbreviation: PCI, percutaneous coronary intervention; TAV, transcatheter aortic valve.

Supplementary Table 4. In-hospital outcomes of the matched population.

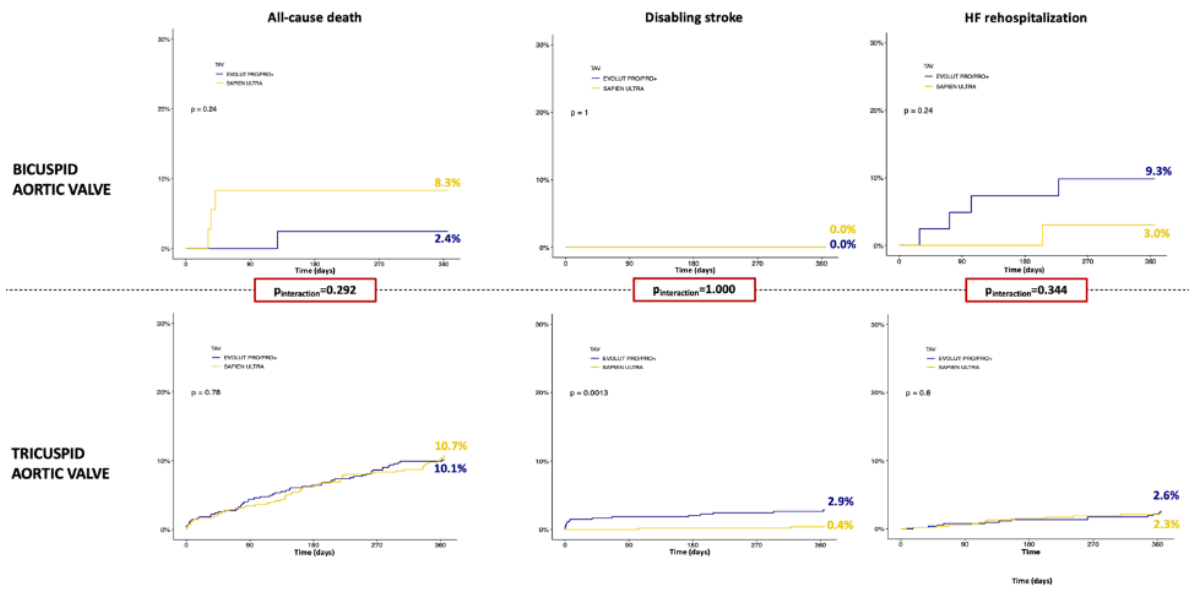
	Overall (n=1174)	PRO (n=587)	ULTRA (n=587)	p-value
All-cause death, n (%)	13 (1.1)	7 (1.2)	6 (1.0)	1.000
Disabling stroke, n (%)	7 (0.6)	7 (1.2)	0 (0.0)	0.015
Not disabling stroke, n (%)	3 (0.3)	1 (0.2)	2 (0.3)	1.000
TIA, n (%)	5 (0.4)	2 (0.3)	3 (0.5)	1.000
Major vascular complication, n (%)	40 (3.4)	24 (4.1)	16 (2.7)	0.260
PPI, n (%)	156 (13.3)	102 (17.4)	54 (9.2)	<0.001
MI, n (%)	4 (0.3)	1 (0.2)	3 (0.5)	0.624
New onset LBBB, n (%)	196 (18.4)	141 (27.0)	55 (10.1)	<0.001
New onset AF, n (%)	43 (3.7)	24 (4.1)	19 (3.2)	0.475
Major bleeding, n (%)	44 (3.7)	32 (5.5)	12 (2.0)	0.003
Life-threatening bleeding, n (%)	21 (1.8)	13 (2.2)	8 (1.4)	0.379
AKI grade, n (%)				0.235
1	34 (2.9)	19 (3.2)	15 (2.6)	
2	10 (0.9)	8 (1.4)	2 (0.3)	
3	20 (1.7)	9 (1.5)	11 (1.9)	

Abbreviations: AF, Atrial fibrillation; AKI, Acute kidney injury; LBBB, Left bundle branch block; MI, Myocardial infarction; PPI, Permanent pacemaker implantation; TIA, Transient Ischemic Attack.

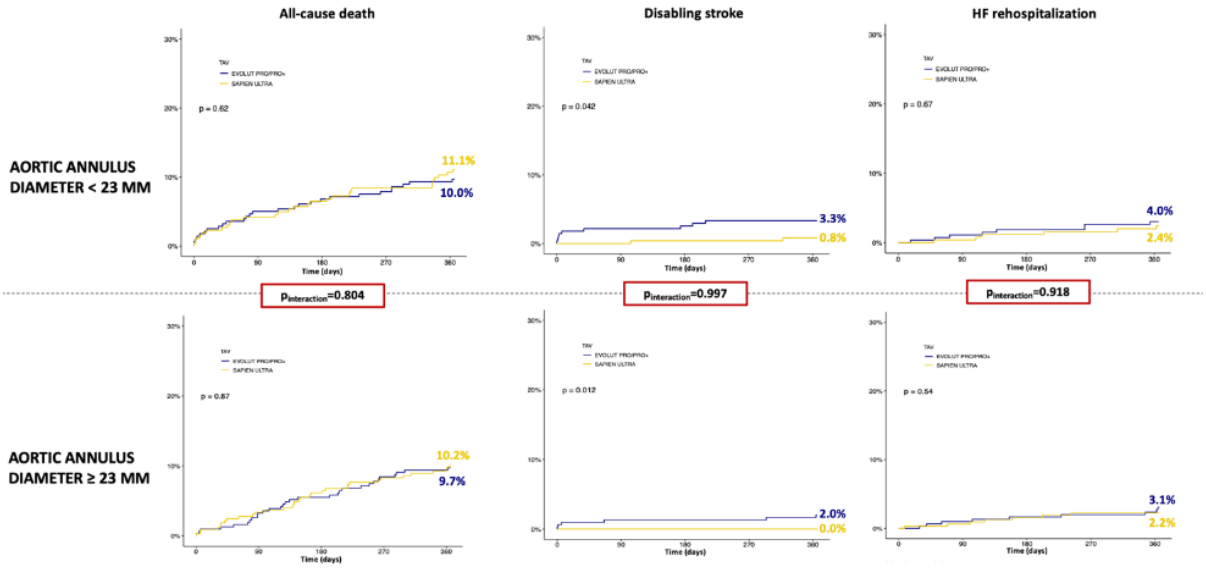
Supplementary Table 5. Echocardiographic assessment of the matched population at 30 days.

	PRO (n=587)	ULTRA (n=587)	p-value
EOA, cm^2, median [IQR]	1.8 [1.5, 2.2]	1.5 [1.3, 1.7]	<0.001
Index EOA, cm^2/m^2, median [IQR]	1.0 [0.9, 1.2]	0.9 [0.8, 1.0]	<0.001
PPM, n (%)	34 (18.9)	72 (40.7)	<0.001
Moderate PPM, n (%)	29 (16.1)	64 (36.2)	<0.001
Severe PPM, n (%)	5 (2.8)	8 (4.5)	0.412
Transprothesic mean gradient, mmHg, median [IQR]	7.0 [5.0, 10.0]	12.0 [9.0, 15.0]	<0.001
Transprothesic mean gradient ≥ 20, mmHg, median [IQR]	5 (1.1)	38 (9.3)	<0.001
PVR, n (%)			<0.001
None/trace	257 (54.4)	332 (81.2)	
Mild	200 (42.4)	71 (17.4)	
Moderate	15 (3.2)	5 (1.2)	
Severe	0 (0.0)	1 (0.2)	
Moderate-to-severe PVR n (%)	15 (3.2)	6 (1.5)	0.122

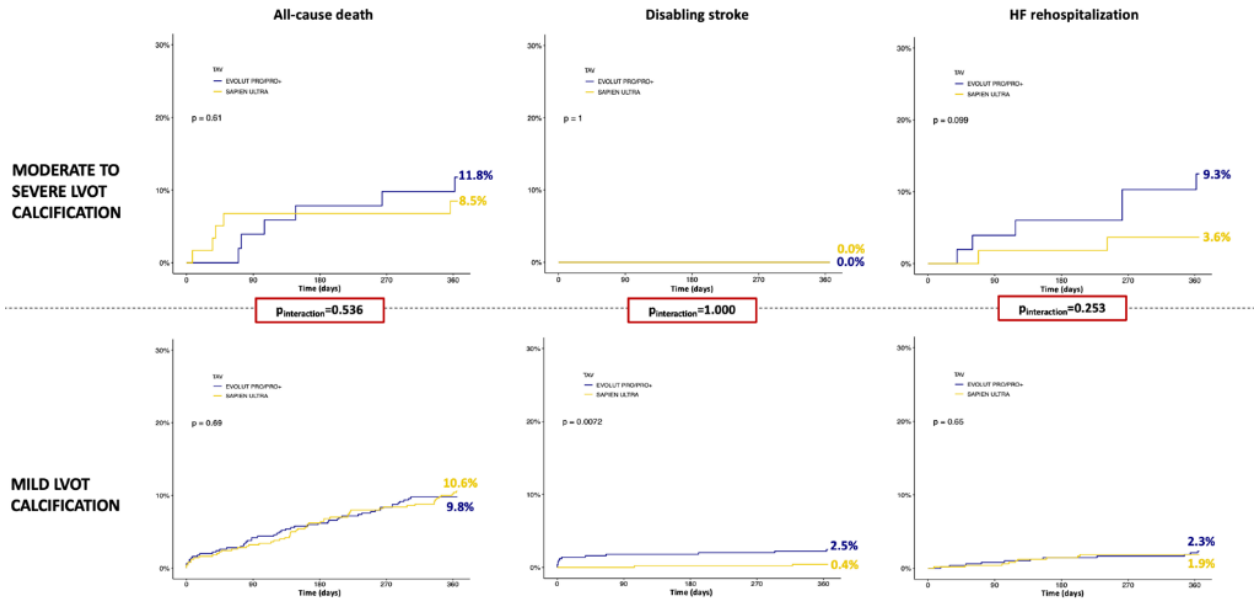
Abbreviations: EOA, Effective Orifice Area; PPM, Prosthesis-Patient Mismatch; PVR, ParaValvular Regurgitation.



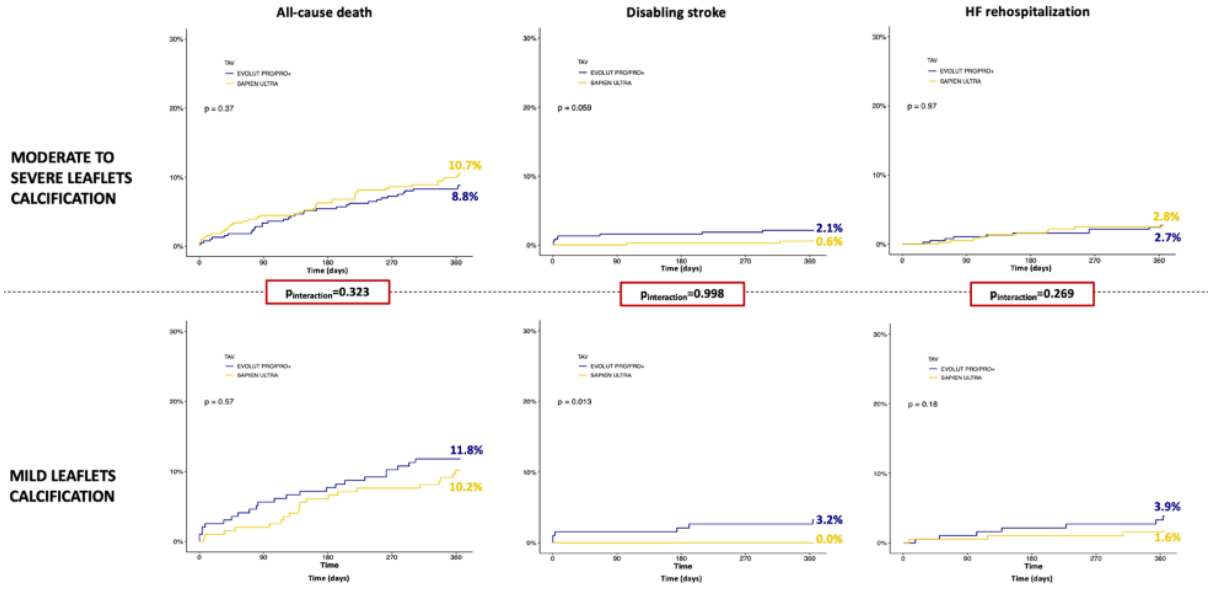
Supplementary Figure 1. One-year Kaplan-Meier curves for secondary outcomes in patients according to aortic leaflet morphology.



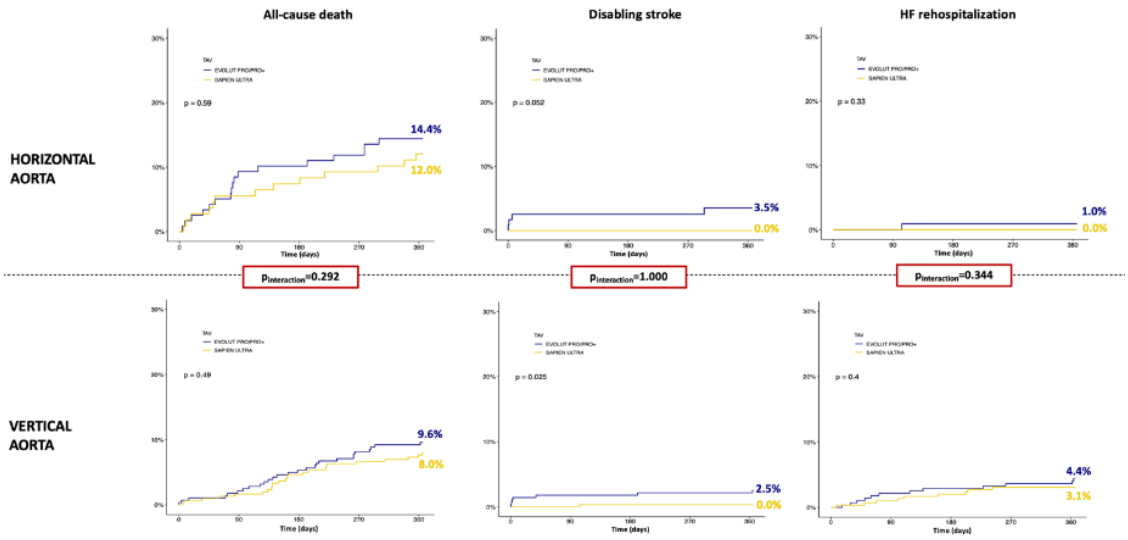
Supplementary Figure 2. One-year Kaplan-Meier curves for secondary outcomes in patients according to aortic annuli dimensions.



Supplementary Figure 3. One-year Kaplan-Meier curves for secondary outcomes in patients according to left ventricular outflow tract calcification grades.



Supplementary Figure 4. One-year Kaplan-Meier curves for secondary outcomes in patients according to leaflet calcification grades.



Supplementary Figure 5. One-year Kaplan-Meier curves for secondary outcomes in patients according to aortic annulus angulation.