SUPPLEMENTARY DATA

Table 1 of the supplementary data

Baseline characteristics of the matched study population and comparison between different devices

	S3U n = 80	MYVAL n = 80	EP+ n = 80	*P* value S3U vs Myval	*P* value S3U vs EP+	*P* value Myval vs EP+	*P* value global
Clinical characteristics							
Age, y	77.61 ± 6.28	77.04 ± 5.66	76.92 ± 6.30	.856	.827	.998	.716
Female sex	19 (23.8)	22 (27.5)	24 (30.0)	.700	.441	.845	.622
BMI, kg/m^2	25.00 ± 3.57	25.48 ± 3.72	25.34 ± 3.22	.775	.883	.988	.683
BSA, m^2	1.82 ± 0.17	1.84 ± 0.22	1.80 ± 0.16	.840	.688	.840	.354
Diabetes mellitus	20 (25.0)	29 (36.3)	21 (26.3)	.151	.999	.216	.212
Hypertension	56 (70.0)	59 (73.8)	61 (76.3)	.719	.499	.850	.667
Hyperlipidaemia	29 (36.3)	22 (27.5)	36 (45.0)	.310	.371	.045*	.090
CAD	36 (45.0)	33 (41.3)	31 (38.8)	.755	.532	.885	.747
Prior stroke/TIA	3 (3.8)	3 (3.8)	0 (0)	.999	.250	.250	.223
PAD	6 (7.7)	9 (11.5)	11 (14.1)	.607	.332	.815	.468
Porcelain aorta	14 (17.9)	0 (0)	7 (9.0)	< .001*	.143	.016*	< .001*
CKD	12 (15.0)	14 (17.5)	21 (26.3)	.824	.164	.248	.187
Hemodialysis	2 (2.5)	0 (0)	3 (3.8)	.500	.999	.250	.174
COPD	12 (15.2)	10 (12.7)	19 (24.1)	.824	.230	.124	.155
Prior heart surgery	2 (3.1)	9 (14.1)	7 (10.9)	.065	.180	.804	.115
Prior CABG	1 (1.3)	10 (12.5)	3 (3.8)	.012*	.625	.092	.008*
Prior pacemaker	2 (2.5)	10 (12.5)	4 (5.0)	.039*	.687	.146	.031*
Prior valvular surgery	1 (1.6)	1 (1.6)	5 (7.8)	.999	.219	.219	.102
Prior AF	17 (21.3)	18 (22.5)	17 (21.3)	.999	.999	.999	.974
NYHA III-IV	39 (48.8)	34 (42.5)	44 (55.0)	.551	.522	.165	.304
STS score, %	2.20 ± 0.86	3.67 ± 2.26	2.02 ± 1.48	.403	.989	.372	.355
EuroSCORE II, %	2.94 ± 2.34	4.38 ± 4.80	3.44 ± 2.25	.091	.455	.420	.071
Electrocardiographic characteristics							
Sinus rhythm	64 (80)	63 (78.8)	63 (78.8)	.999	.999	.999	.974
AF	7 (8.8)	8 (10.0)	7 (8.8)	.999	.999	.999	.953
Pacemaker	9 (11.2)	9 (11.2)	10 (12.4)	.999	.999	.999	.962
LBBB	7 (8.8)	7 (8.8)	9 (11.3)	.999	.804	.791	.834
RBBB	12 (15.0)	0 (0)	5 (6.3)	< .001*	.143	.063	.002*
First-degree AVB	19 (23.8)	20 (25.0)	7 (8.8)	.999	.031*	.011*	.020*
Echocardiographic parameters							
LVEF, %	59.44 ± 10.24	56.29 ± 11.86	56.54 ± 12.67	.116	.186	.998	.074
AVA, cm^2	0.66 ± 0.17	0.66 ± 0.16	0.66 ± 0.16	.990	.996	.999	.957
Mean aortic gradient, mmHg	51.84 ± 14.56	52.33 ± 12.72	50.78 ± 14.48	.994	.967	.874	.796
Peak aortic gradient, mmHg	78.76 ± 24.30	80.35 ± 19.57	82.60 ± 22.80	.973	.817	.941	.736
≥ Moderate AR	0 (0)	1 (1.3)	0 (0)	.999	.999	.999	.999
≥ Moderate MR	0 (0)	1 (1.3)	1 (1.3)	.999	.999	.999	.999
≥ Moderate TR	3 (3.8)	3 (3.8)	0 (0)	.999	.250	.250	.165
CT findings							
Maximal AA diameter, mm	28.55 ± 3.10	28.76 ± 4.00	28.16 ± 3.09	.954	0.752	.541	.468
Minimal AA diameter, mm	22.71 ± 2.59	22.86 ± 2.69	21.97 ± 2.64	.964	0.163	.087	.072
AA perimeter, mm	81.31 ± 8.54	82.26 ± 8.90	78.95 ± 8.87	.941	0.471	.295	.248
Eccentricity index	0.20 ± 0.06	0.20 ± 0.05	0.22 ± 0.07	.999	0.341	.217	.199
AA area, mm^2	531 ± 114	540 ± 112	501 ± 100	.976	0.454	.313	.234
Agatston score, HU	5011 ± 2442	4936 ± 2611	4158 ± 2199	.911	0.090	.999	.981
LVOT calcification	1 (1.3)	2 (2.6)	2 (2.6)	.999	0.999	.999	.779
LM height, mm	14.60 ± 4.82	18.39 ± 4.66	14.75 ± 3.00	.079	0.999	.083	.054
RCA height, mm	15.94 ± 4.49	19.96 ± 3.39	17.08 ± 3.56	.026*	0.8000	.067	.020*
BAV morphology							
Type 0	3 (3.8)	9 (11.3)	5 (6.3)	.146	0.727	.344	.155
Type 1	77 (96.3)	70 (87.5)	74 (92.5)	.092	0.508	.344	.099
Type 2	0 (0)	1 (1.3)	1 (1.3)	.999	0.999	.999	.607

AA, aortic annulus; AF, atrial fibrillation; AR, aortic regurgitation; AVB, atrio-ventricular block; AVA, aortic valve area; BAV, bicuspid aortic valve; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; CT, computed tomography; EP+, Evolut Pro+; EuroScore, European System for Cardiac Operative Risk Evaluation; LBBB, left bundle branch block; LM, left main; LVEF, left ventricular ejection fraction; LVOT, left ventricle outflow tract; MR, mitral regurgitation, NYHA, New York Heart Association; PAD, peripheral artery disease; RCA, right coronary artery; RBBB, right bundle branch block; S3U, Sapien-3 Ultra; STS, Society of Thoracic Surgeons; TIA, transient ischemic attack; TR, tricuspid regurgitation.

The data are expressed as No. (%) or mean ± standard deviation.

*Significant p-values.

Table 2 of the supplementary data
Main procedural characteristics of the global study population

	S3U (n = 129)	Myval (n = 122)	EP+ (n = 109)	*P* value Myval vs S3U	*P* value Myval vs EP+	*P* value S3U vs EP+
Transfemoral approach	128 (99.2)	122 (100)	107 (99.1)	.999	.472	.999
Predilation	41 (31.8)	84 (69.4)	93 (85.3)	< .001*	.004*	<.001
Postdilation	17 (13.2)	21 (17.2)	43 (40.2)	.373	< .001*	< .001*
Valve size, mm				-	-	-
20	2 (1.6)	10 (8.2)		.999	.999	.999
21.5		2 (1.6)				
23	19 (14.7)	38 (31.1)	10 (9.2)			
24.5		6 (4.9)				
26	65 (50.4)	30 (24.6)	29 (26.6)			
27.5		8 (6.5)				
29	43 (33.3)	22 (18)	39 (35.8)			
30.5		1 (0.8)				
32		5 (4.1)				
34			21 (32.8)			
> 1 prosthesis required	1 (0.8)	0 (0)	4 (3.7)	.999	.048*	.999
Valve embolization	1 (0.8)	0 (0)	4 (3.7)	.999	.033*	.182
Coronary artery occlusion	0 (0)	0 (0)	0 (0)	.999	.999	.999
Annulus rupture	0 (0)	0 (0)	0 (0)	.999	.999	.999
Aortic dissection	0 (0)	0 (0)	0 (0)	.999	.999	.999
Conversion to surgery	0 (0)	0 (0)	1 (0.9)	.999	.472	.458
Hemodynamic instability	2 (1.6)	0 (0)	2 (1.9)	. 498	.010*	.999
Successful procedure	123 (95.3)	121 (99.2)	104 (95.4)	.121	.103	.981
Procedural death	0 (0)	0 (0)	0 (0)	.999	.999	.999
Technical success[a]	122 (94.6)	121 (99.2)	103 (94.5)	.067	.054	.979

AR, aortic regurgitation; PPI, permanent pacemaker implantation; TF, transfemoral.
Unless otherwise stated, the data are expressed as No. (%).
[a] Technical success was measured at the time of leaving the procedure room and described according to VARC-3 criteria as freedom from mortality, successful access, delivery of the device and retrieval of the delivery system, correct positioning of a single THV and freedom from surgery or intervention related to device.
*Significant *P* values.

Table 3 of the supplementary data
Outcomes at 30-days follow-up of the global study population

	S3U (n = 129)	Myval (n = 122)	EP+ (n = 109)	*P* value S3U vs Myval	*P* value Myval vs EP+	*P* value S3U vs EP+
PPI	14 (10.9)	12 (9.9)	20 (18.3)	.721	.092	.306
AKI	17 (13.2)	1 (0.8)	6 (5.5)	< .001*	.054	.046*
All-cause mortality	7 (5.4)	2 (1.6)	3 (2.8)	.235	.999	.209
Minor vascular complications	8 (6.2)	1 (0.8)	5 (4.6)	.036*	.103	.585
Major vascular complications	7 (5.4)	5 (4.1)	0 (0)	.622	.062	.017*
Bleeding > BARC 1	19 (14.7)	3 (2.5)	5 (4.6)	.001*	.481	.010*
Stroke	6 (4.7)	1 (0.8)	1 (0.9)	.121	.999	.129
LVEF, %	56.4 ± 12.3	55.1 ± 10	54.8 ± 11.9	.321	.932	.370
AVA, cm^2	1.6 ± 0.4	1.8 ± 0.5	1.9 ± 0.5	< .001*	.422	.002*
Mean aortic gradient, mmHg	13.1 ± 4.8	9.9 ± 4.4	8.5 ± 4.4	< .001*	.021*	< .001*
Peak aortic gradient, mmHg	21.3 ± 8.3	15.4 ± 5.3	14.5 ± 8.2	.011*	.539	.004*
≥Moderate AR	1 (0.8)	3 (3.4)	38 (28)	.307	.004*	<.001*
Prosthetic valve thrombosis	4 (3.1)	0 (0)	0 (0)	.303	.999	.129
Prosthetic valve endocarditis	0 (0)	0 (0)	2 (1.9)	.999	.488	.198
≥ Moderate prosthetic mismatch	18 (14.8)	1 (1.7)	1 (1)	.470	.435	< .001*
Device success[a]	102 (79.1)	116 (95.1)	96 (88.1)	<.001*	.053	.064
Early safety[b]	91 (70.5)	104 (85.2)	83 (76.1)	.005*	.079	.331

ACI, acute kidney injury; AR, aortic regurgitation; AVA, aortic valve area; LVEF, left ventricle ejection fraction; PPI, permanent pacemaker implantation; VARC, Valve Academic Research Consortium.
The values are expressed as No. (%) or mean ± standard deviation.

[a] Device success was described according to VARC-3 criteria as a composite endpoint including technical success, freedom from mortality, surgery or intervention related to the device or to a major vascular or access-related or cardiac structural complication and the intended performance of the valve (mean gradient < 20 mmHg and less than moderate AR).

[b] Early safety was described according to VARC-3 criteria as a composite endpoint including freedom from all-cause mortality, all stroke, VARC type 2-4 bleeding, major vascular, access-related or cardiac structural complication, AKI stage 3 to 4, more than moderate AR, new PPI and surgery or intervention related to the device.

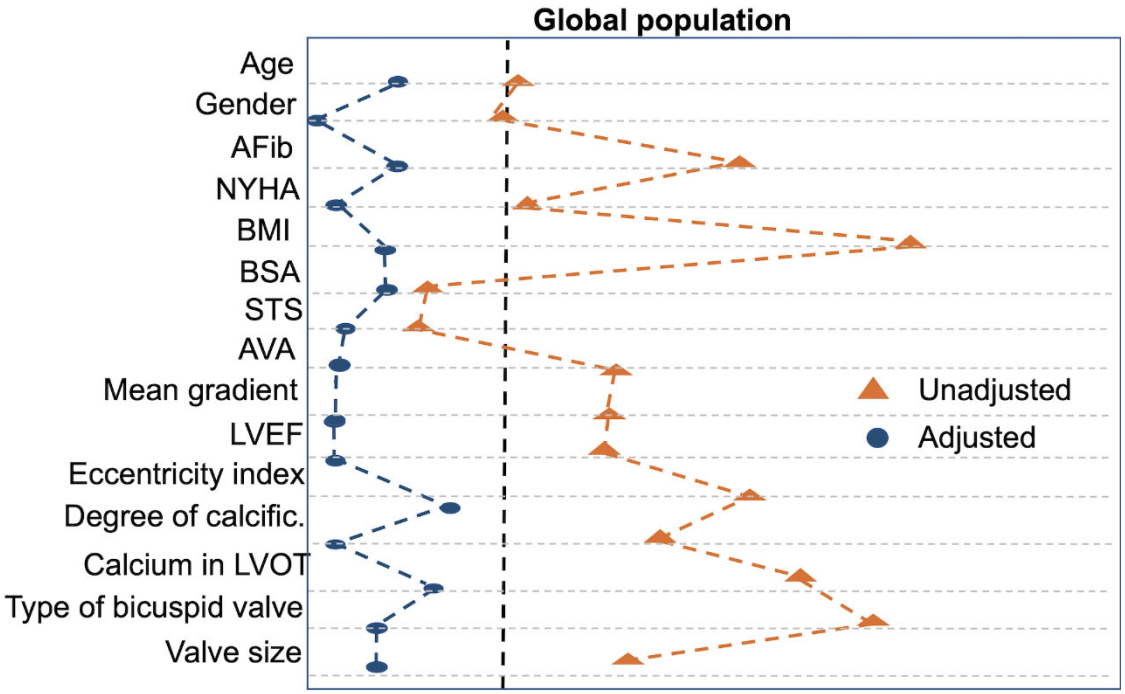
*Significant *P* values.

Table 4 of the supplementary data
Reasons for lack of technical success, device success, or early safety in the global study population

No technical success	Reason	Frequency
	Conversion to open surgery	1
	Failed implant due to poor result	10
	Need for second valve	3
No device success		
	Central aortic regurgitation (moderate)	2
	In-hospital death	12
	Peak aortic velocity > 3 m/s; mean gradient ≥ 20	22
	Other technical aspects	10
No early safety		
	Acute kidney injury	10
	Bleeding type ≥ 2	2
	Bleeding type ≥ 2, acute kidney injury	3
	Bleeding type ≥ 2, acute kidney injury, PPMI	4
	Bleeding type ≥ 2, major vascular complication	3
	Bleeding type ≥ 2, major vascular complication, Acute kidney injury	3
	Bleeding type ≥ 2, major vascular complication, PPMI	1
	Central aortic regurgitation (moderate)	1
	In-hospital death	5
	In-hospital death, bleeding type ≥ 2	1
	In-hospital death, bleeding type ≥ 2, PPMI	1
	In-hospital death, PPMI	2
	In-hospital death, stroke	1
	In-hospital death, stroke, acute kidney injury	1
	In-hospital death, stroke, bleeding type ≥ 2, acute kidney injury, PPMI	2
	Major vascular complication	3
	Major vascular complication, acute kidney injury	1
	PPMI	33
	Stroke	5

PPMI, permanent pacemaker implantation.

Figure 1 of the supplementary data. Variables included in TriMatch analysis through propensity scores.



AFib, Atrial fibrillation; AVA, Aortic vavle area; BMI, body mass index; BSA, body surface area; Calcific, calcification; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

Figure 2 of the supplementary data. Study design.

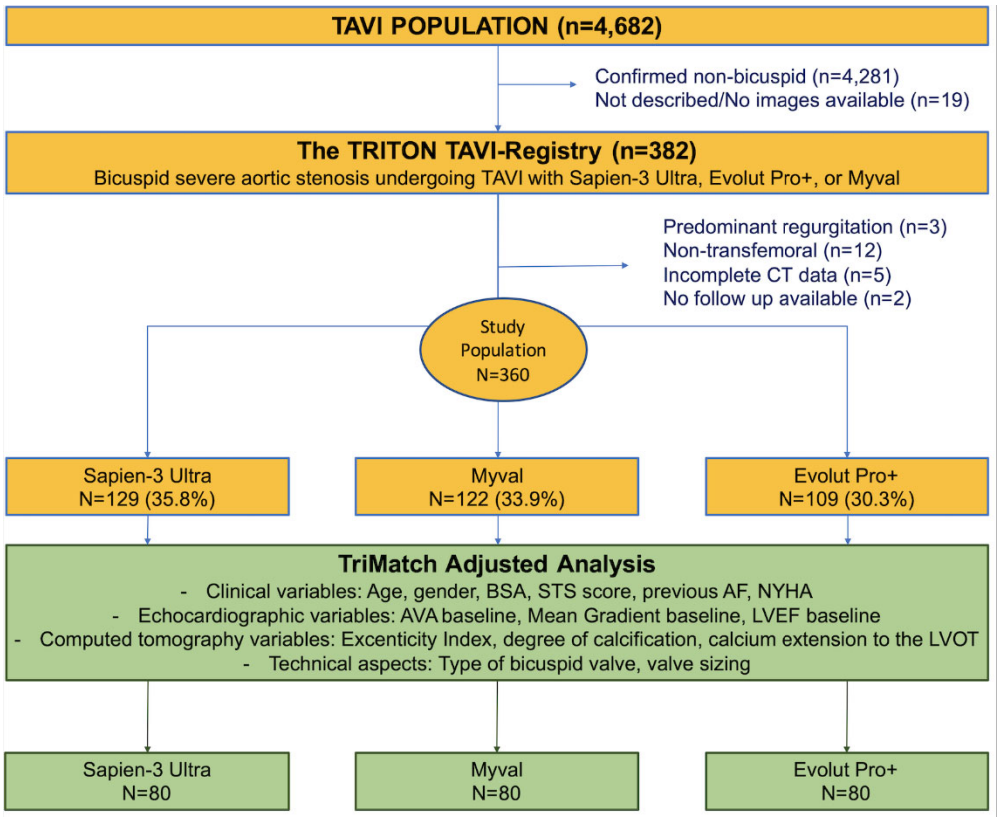
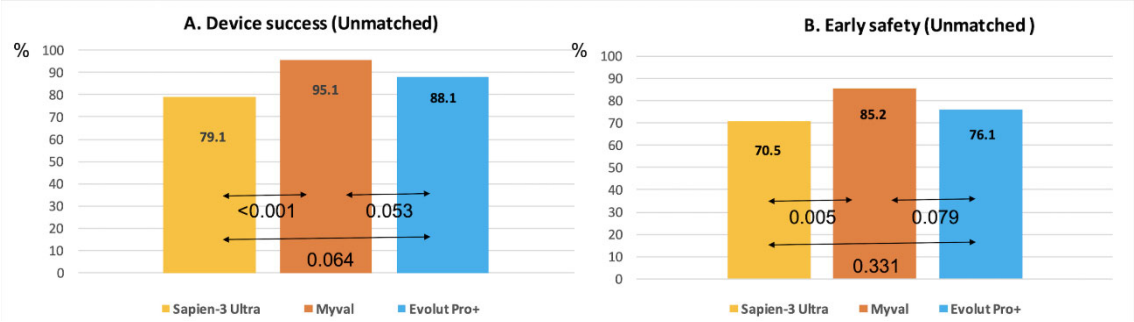


Figure 3 of the supplementary data. Primary and secondary endpoints at 30 days of follow-up in the global population.



Device success was described according to VARC-3 criteria as a composite endpoint including technical success, freedom from mortality, surgery or intervention related to the device or to a major vascular or access-related or cardiac structural complication and the intended performance of the valve (mean gradient < 20 mmHg and less than moderate AR).

Early safety was described according to VARC-3 criteria as a composite endpoint including freedom from all-cause mortality, all stroke, VARC type 2-4 bleeding, major vascular, access-related or cardiac structural complication, AKI stage 3-4, more than moderate AR, new PPI and surgery or intervention related to the device.