

Self-expandable transcatheter heart valves for aortic stenosis. Short-term outcome and matched hemodynamic performance

SUPPLEMENTARY DATA

Table 1 of the supplementary data. Main predictors of 1-year mortality in the global population

	Univariate analysis		
	Death at 1-y FU (n = 33)	Alive at 1-y FU (n = 481)	P
BASELINE CHARACTERISTICS			
Male sex	19 (57.6)	214 (44.5)	.14
Age, y	81.3 ± 6.4	81.5 ± 6.8	.64
STS score, %	6.2 ± 3.6	5.8 ± 4.5	.65
Logistic EuroSCORE, %	15.7 ± 12.5	15.4 ± 10.7	.92
Chronic kidney disease	15 (45.5)	166 (34.5)	.20
Hemodialysis	4 (12.1)	1 (0.2)	< .001
COPD	7 (21.2)	71 (14.8)	.32
Atrial fibrillation	21 (63.6)	184 (38.3)	.004
Prior pacemaker	4 (12.1)	63 (13.1)	> .99
NYHA III-IV	25 (78.1)	233 (49.4)	.002
PROCEDURAL CHARACTERISTICS			
Cardiac tamponade	3 (9.1)	1 (0.2)	.001
Valve embolization	4 (12.5)	12 (2.5)	.01
Need for permanent pacemaker	2 (6.9)	82 (17.4)	.20
Life-threatening bleeding	2 (6.5)	5 (1.1)	.07
Major vascular complication	4 (12.9)	33 (6.9)	.27
Cerebrovascular events	1 (3.2)	12 (2.5)	.57
Aortic regurgitation III-IV post-TAVI	4 (12.9)	14 (2.9)	.02

COPD, chronic obstructive pulmonary disease; FU, follow-up; NYHA, New York Heart Association; STS, Society of Thoracic Surgeons.

Table 2 of the supplementary data. Baseline, procedural, and in-hospital characteristics of Evolut R/Pro vs ACURATE neo in the matched population

	Evolut R/Pro	ACURATE neo	P
Baseline clinical characteristics			
Age, y	82.6 ± 5.6	82 ± 5.7	.49
Female sex, %	46 (63.9)	45 (62.5)	> .99
Body surface area, m ²	1.7 ± 0.18	1.72 ± 0.17	.47
Permanent pacemaker, %	8 (11.1)	5 (6.9)	.58
STS score, %	7.7 ± 3.3	7.1 ± 3.6	.73
Logistic EuroSCORE, %	17.1 ± 8.5	15.8 ± 8.8	.59
Baseline computed tomography			
Eccentricity index	0.18 ± 0.09	0.18 ± 0.08	.99
Mean aortic annulus diameter, mm	22.6 ± 2.9	23.2 ± 1.9	.16
Aortic annulus area, mm ²	400.9 ± 122.6	416 ± 66.8	.32
Aortic annulus perimeter, mm	72 ± 12.9	73.9 ± 6.2	.29
Baseline echocardiography			
LVEF, %	60.8 ± 9.7	59.2 ± 10.5	.37
Mean aortic gradient, mmHg	45.3 ± 14.6	44 ± 15	.60
Aortic valve area, cm ²	0.79 ± 0.36	0.73 ± 0.16	.26
Aortic regurgitation (3-4), %	7 (11.7)	5 (8.3)	.77
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	24 (36.9)	57 (87.7)	< .001
Post-TAVI aortic regurgitation (3-4)	1 (1.4)	3 (4.3)	.63
Procedural complications			
Valve embolization, %	2 (2.8)	1 (1.4)	> .99
Annulus rupture, %	1 (1.4)	0	> .99
Coronary artery occlusion, %	2 (2.9)	1 (1.4)	> .99
Tamponade, %	0	0	> .99
Procedural death, %	0	0	> .99
Procedural success, %	70 (100)	69 (98.6)	> .99
Permanent pacemaker implantation, %	9 (13.2)	4 (5.9)	.27
Cerebrovascular events, %	1 (1.4)	2 (2.9)	> .99
Acute kidney injury, %	4 (5.6)	1 (1.4)	.38
Major vascular complication, %	6 (8.6)	1 (1.4)	.13
Major or life-threatening bleeding, %	3 (4.3)	2 (2.9)	> .99
In-hospital death, %	1 (1.4)	1 (1.4)	> .99
Left ventricular ejection fraction, %	59.5 ± 7.4	57.4 ± 7.9	.15
Aortic valve area, cm ²	1.8 ± 0.5	1.8 ± 0.5	.87
Indexed aortic valve area, cm ²	1.1 ± 0.3	1.1 ± 0.3	> .99
Mean aortic gradient, mmHg	8.4 ± 5.5	8.3 ± 4.3	.93
Aortic regurgitation 2-3-4, %	16 (22.5)	17 (23.9)	> .99
Aortic regurgitation 3-4, %	1 (1.4)	1 (1.4)	> .99

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.

Table 3 of the supplementary data. Baseline, procedural, and in-hospital characteristics of Evolut R/Pro vs Allegra in the matched population

	Evolut R/Pro	Allegra	P
Baseline clinical characteristics			
Age, y	81.4 ± 7.4	81.2 ± 6.8	.90
Female sex, %	29 (44.6)	41 (63.1)	.07
Body surface area, m ²	1.7 ± 0.18	1.72 ± 0.17	.52
Permanent pacemaker, %	7 (10.8)	6 (9.2)	> .99
STS score, %	4.2 ± 1.3	2.6 ± 0.73	.02
Logistic EuroSCORE, %	15 ± 13	16.8 ± 11.7	.81
Baseline computed tomography			
Eccentricity index	0.17 ± 0.1	0.18 ± 0.1	.77
Mean aortic annulus diameter, mm	23.9 ± 3.07	23.7 ± 2.2	.65
Aortic annulus area, mm ²	442 ± 113	425 ± 79.9	.34
Aortic annulus perimeter, mm	74.7 ± 13.8	79 ± 8	.12
Baseline echocardiography			
LVEF, %	58.1 ± 12.9	57.3 ± 11.1	.43
Mean aortic gradient, mmHg	45.16 ± 15.6	43.9 ± 11.7	.60
Aortic valve area, cm ²	0.79 ± 0.36	0.73 ± 0.16	.60
Aortic regurgitation (3-4), %	7 (12.1)	5 (8.6)	.77
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	25 (44.6)	38 (67.9)	.02
Post-TAVI aortic regurgitation (3-4)	2 (3.2)	1 (1.6)	> .99
Procedural complications			
Valve embolization, %	3 (4.8)	3 (4.8)	> .99
Annulus rupture, %	1 (1.5)	1 (1.5)	> .99
Coronary artery occlusion, %	3 (5.1)	3 (5.1)	> .99
Tamponade, %	1 (1.6)	1 (1.6)	> .99
Procedural death, %	1 (1.6)	1 (1.6)	> .99
Procedural success, %	60 (93.8)	62 (96.9)	> .99
Permanent pacemaker implantation, %	9 (15.3)	9 (15.3)	> .99
Cerebrovascular events, %	1 (1.6)	3 (4.8)	.63
Acute kidney injury, %	5 (7.7)	5 (7.7)	> .99
Major vascular complication, %	9 (14.5)	8 (12.9)	> .99
Major or life-threatening bleeding, %	4 (6.3)	3 (4.8)	> .99
In-hospital death, %	3 (4.7)	2 (3.1)	> .99
Left ventricular ejection fraction, %	57.4 ± 10.3	56.5 ± 7.3	.63
Aortic valve area, cm ²	1.9 ± 0.5	2.0 ± 0.6	.78
Indexed aortic valve area, cm ²	1.1 ± 0.3	1.1 ± 0.3	.78
Mean aortic gradient, mmHg	7.7 ± 4.3	6.6 ± 2.9	.13
Aortic regurgitation 2-3-4, %	13 (20.3)	15 (23.4)	.84
Aortic regurgitation 3-4, %	2 (3.1)	4 (6.3)	.69

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.

Table 4 of the supplementary data. Baseline, procedural, and in-hospital characteristics of Evolut R/Pro vs Portico in the matched population

	Evolut R/Pro	Portico	P
Baseline clinical characteristics			
Age, y	82.9 ± 5.7	82.98 ± 5.1	.94
Female sex, %	34 (60.7)	33 (58.9)	> .99
Body surface area, m ²	1.74 ± 0.19	1.72 ± 0.19	.43
Permanent pacemaker, %	6 (10.7)	12 (21.4)	.21
STS score, %	7.57 ± 4.49	6.6 ± 3.3	.55
Logistic EuroSCORE, %	17.62 ± 12	16 ± 0.18	.55
Baseline Computed tomography			
Eccentricity index	0.17 ± 0.0	0.18 ± 0.1	.89
Mean aortic annulus diameter, mm	22.7 ± 3.43	23.09 ± 2.12	.50
Aortic annulus area, mm ²	407.17 ± 126.68	415 ± 74.2	.60
Aortic annulus perimeter, mm	71.2 ± 12.9	68.78 ± 14	.30
Baseline echocardiography			
LVEF, %	57.9 ± 13	59.5 ± 11.08	.51
Mean aortic gradient, mmHg	43.04 ± 13.3	44.2 ± 11.39	.58
Aortic valve area, cm ²	0.74 ± 0.4	0.67 ± 0.18	.30
Aortic regurgitation (3-4), %	8 (15.7)	1 (2.0)	.04
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	12 (24)	12 (24)	> .99
Post-TAVI aortic regurgitation (3-4)	1 (1.8)	5 (8.9)	.22
Procedural complications			
Valve embolization, %	1 (1.8)	1 (1.8)	> .99
Annulus rupture, %	1 (1.8)	1 (1.8)	> .99
Coronary artery occlusion, %	2 (3.8)	2 (3.8)	> .99
Tamponade, %	1 (1.8)	1 (1.8)	> .99
Procedural death, %	0	0	> .99
Procedural success, %	54 (96.4)	54 (96.4)	> .99
Permanent pacemaker implantation, %	6 (11.5)	14 (26.9)	.10
Cerebrovascular events, %	1 (1.9)	0	> .99
Acute kidney injury, %	3 (5.4)	3 (5.4)	> .99
Major vascular complication, %	5 (9.3)	2 (3.7)	.45
Major or life-threatening bleeding, %	3 (5.6)	2 (3.7)	> .99
In-hospital death, %	1 (1.8)	1 (1.8)	> .99
Left ventricular ejection fraction, %	57.22 ± 10.378	60 ± 9.8	.15
Aortic valve area, cm ²	1.9 ± 0.5	1.77 ± 0.4	.40
Indexed aortic valve area, cm ²	1.12 ± 0.35	1.02 ± 0.248	.26
Mean aortic gradient, mmHg	8.1 ± 6	6.9 ± 3.7	.30
Aortic regurgitation 2-3-4, %	13 (23.6)	13 (23.6)	> .99
Aortic regurgitation 3-4, %	1 (1.8)	1 (1.8)	> .99

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.

Table 5 of the supplementary data. Baseline, procedural, and in-hospital characteristics of ACURATE neo vs Allegra in the matched population

	ACURATE neo	Allegra	P
Baseline clinical characteristics			
Age, y	81.91 ± 6.2	80 ± 7.9	> .99
Female sex, %	42 (56.8)	39 (52.7)	.78
Body surface area, m ²	1.77 ± 0.17	1.76 ± 0.17	.59
Permanent pacemaker, %	5 (6.8)	6 (8.1)	> .99
STS score, %	3.7 ± 1.0	3.3 ± 1.2	.18
Logistic EuroSCORE, %	12.68 ± 5.3	16.9 ± 8.821	.69
Baseline computed tomography			
Eccentricity index	0.18 ± 0.1	0.18 ± 0.1	> .99
Mean aortic annulus diameter, mm	23.8 ± 1.8	23.8 ± 2.1	.81
Aortic annulus area, mm ²	432.35 ± 54.65	433.9 ± 81.8	.88
Aortic annulus perimeter, mm	76.65 ± 4	80.24 ± 9	.09
Baseline echocardiography			
LVEF, %	59.87 ± 10.55	57.27 ± 10.5	.001
Mean aortic gradient, mmHg	43.87 ± 14.32	45 ± 11.9	.31
Aortic valve area, cm ²	0.74 ± 0.17	0.68 ± 0.16	.09
Aortic regurgitation (3-4), %	6 (8.5)	4 (5.6)	.73
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	65 (87.8)	48 (64.9)	.002
Post-TAVI aortic regurgitation (3-4)	3 (4.2)	1 (1.4)	.63
Procedural complications			
Valve embolization, %	1 (1.4)	4 (5.4)	.38
Annulus rupture, %			
Coronary artery occlusion, %	1 (1.4)	1 (1.4)	> .99
Tamponade, %	1 (1.4)	1 (1.4)	NS
Procedural death, %	1 (1.4)	1 (1.4)	NS
Procedural success, %	68 (94.4)	70 (97.2)	> .99
Permanent pacemaker implantation, %	7 (9.9)	12 (16.9)	.33
Cerebrovascular events, %	1 (1.4)	5 (6.8)	.38
Acute kidney injury, %	1 (1.4)	5 (6.8)	.22
Major vascular complication, %	2 (2.7)	8 (10.8)	.07
Major or life-threatening bleeding, %	1 (1.4)	1 (1.4)	NS
In-hospital death, %	1 (1.4)	2 (2.8)	> .99
Left ventricular ejection fraction, %	57.53 ± 6.3	55.9 ± 8	.19
Aortic valve area, cm ²	1.8 ± 0.56	2.0 ± 0.64	.13
Indexed aortic valve area, cm ²	1.04 ± 0.34	1.18 ± 0.38	.16
Mean aortic gradient, mmHg	8.5 ± 3.9	6.6 ± 2.7	.001
Aortic regurgitation 2-3-4, %	21 (28.4)	18 (24.3)	.69
Aortic regurgitation 3-4, %	1 (1.4)	4 (5.4)	.38

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.

Table 6 of the supplementary data. Baseline, procedural, and in-hospital characteristics of ACURATE neo vs Portico in the matched population

	ACURATE neo	Portico	P
Baseline clinical characteristics			
Age, y	81.7 ± 6.1	82.8 ± 5.3	.27
Female sex, %	49 (69)	45 (63.4)	.56
Body surface area, m ²	1.7 ± 0.18	1.72 ± 0.17	.64
Permanent pacemaker, %	7 (9.9)	6 (8.5)	.24
STS score, %	5.3 ± 3.3	6.1 ± 3.0	.43
Logistic EuroSCORE, %	14.06 ± 7.2	15.3 ± 5.9	.11
Baseline computed tomography			
Eccentricity index	0.17 ± 0.0	0.17 ± 0.1	.90
Mean aortic annulus diameter, mm	23.36 ± 1.9	22.99 ± 1.9	.22
Aortic annulus area, mm ²	418.10 ± 63.14	412 ± 71.2	.52
Aortic annulus perimeter, mm	75 ± 5.2	71.7 ± 9.25	.02
Baseline echocardiography			
LVEF, %	58.9 ± 9.13	58.67 ± 11.3	.85
Mean aortic gradient, mmHg	44.98 ± 15.4	44.18 ± 13.7	.73
Aortic valve area, cm ²	0.71 ± 0.18	0.69 ± 0.18	.61
Aortic regurgitation (3-4), %	6 (8.5)	1 (1.4)	.13
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	63 (88.7)	69 (97.2)	.11
Post-TAVI aortic regurgitation (3-4)	3 (4.3)	5 (7.1)	.73
Procedural complications			
Valve embolization, %	1 (1.4)	1 (1.4)	> .99
Annulus rupture, %			> .99
Coronary artery occlusion, %	1 (1.4)	1 (1.4)	> .99
Tamponade, %	1 (1.4)	1 (1.4)	> .99
Procedural death, %	0	0	> .99
Procedural success, %	68 (97.1)	69 (98.6)	> .99
Permanent pacemaker implantation, %	5 (7)	18 (25.4)	.007
Cerebrovascular events, %	2 (3.6)	0	.48
Acute kidney injury, %	1 (1.4)	3 (4.2)	.63
Major vascular complication, %	2 (2.8)	3 (4.2)	> .99
Major or life-threatening bleeding, %	3 (4.3)	3 (4.3)	> .99
In-hospital death, %	1 (1.4)	1 (1.4)	> .99
Left ventricular ejection fraction, %	59.5 ± 7.4	57.4 ± 7.9	.15
Aortic valve area, cm ²	1.9 ± 0.5	1.8 ± 0.5	.43
Indexed aortic valve area, cm ²	1.1 ± 0.33	1.07 ± 0.31	.58
Mean aortic gradient, mmHg	8.4 ± 5.0	5.0 ± 4.9	.15
Aortic regurgitation 2-3-4, %	14 (19.7)	15 (21.1)	> .99
Aortic regurgitation 3-4, %	1 (1.4)	2 (2.8)	> .99

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.

Table 7 of the supplementary data. Baseline, procedural, and in-hospital characteristics of Portico vs Allegra in the matched population

	Portico	Allegra	P
Baseline clinical characteristics			
Age, y	82.8 ± 5.3	80 ± 8.6	.08
Female sex, %	30 (53.6)	33 (58.9)	.70
Body surface area, m ²	1.73 ± 0.21	1.73 ± 0.16	.89
Permanent pacemaker, %	11 (19.6)	5 (8.9)	.21
STS score, %	3.7 ± 1.5	2.2 ± 0.42	.48
Logistic EuroSCORE, %	18.7 ± 11.9	18.2 ± 15.7	.90
Baseline computed tomography			
Eccentricity index	0.18 ± 0.2	0.18 ± 0.1	> .99
Mean aortic annulus diameter, mm	23.78 ± 1.6	23.68 ± 1.86	.70
Aortic annulus area, mm ²	441.68 ± 57	429.16 ± 56	.18
Aortic annulus perimeter, mm	73.14 ± 10.7	78.8 ± 8.5	.07
Baseline echocardiography			
LVEF, %	58.7 ± 11.67	57 ± 10.17	.22
Mean aortic gradient, mmHg	43.3 ± 12.8	44.5 ± 11.7	.63
Aortic valve area, cm ²	0.71 ± 0.19	0.71 ± 0.17	.96
Aortic regurgitation (3-4), %	7 (11.7)	5 (8.3)	.77
Procedural and in-hospital outcomes			
Balloon valvuloplasty, %	54 (96.4)	37 (66.1)	< .001
Post-TAVI aortic regurgitation (3-4)	5 (8.9)	1 (1.8)	.22
Procedural complications			
Valve embolization, %	1 (1.8)	2 (3.6)	> .99
Annulus rupture, %			
Coronary artery occlusion, %	1 (1.9)	1 (1.9)	NS
Tamponade, %	0	0	NS
Procedural death, %	0	0	NS
Procedural success, %	55 (98.2)	54 (96.4)	> .99
Permanent pacemaker implantation, %	11 (20.8)	12 (22.6)	> .99
Cerebrovascular events, %	3 (5.5)	2 (3.6)	> .99
Acute kidney injury, %	3 (5.3)	4 (7.3)	> .99
Major vascular complication, %	5 (9.1)	5 (9.1)	NS
Major or life-threatening bleeding, %			
In-hospital death, %	1 (1.8)	1 (1.8)	> .99
Left ventricular ejection fraction, %	59.5 ± 7.4	57.4 ± 7.9	.18
Aortic valve area, cm ²	1.98 ± 0.66	1.88 ± 0.50	.56
Indexed aortic valve area, cm ²	1.1 ± 0.36	1.11 ± 0.31	.05
Mean aortic gradient, mmHg	7.5 ± 3.9	6.5 ± 2.9	.11
Aortic regurgitation 2-3-4, %	15 (26.8)	18 (32.1)	.69
Aortic regurgitation 3-4, %	2 (3.6)	3 (5.4)	> .99

LVEF, left ventricular ejection fraction; STS, Society of Thoracic Surgeons; TAVI, transcatheter aortic valve implantation.