Rev Esp Cardiol. 2021;74(12):1032–1041

Original article

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

Silvio Vera Vera,[a,b] Luis Nombela-Franco,[c] Sandra Santos-Martínez,[a,b] Raúl Moreno,[d] Victor A. Jiménez-Díaz,[b,e] Tania Rodríguez-Gabella,[a,b] Pablo Catalá,[a,b] Alex F. Castro-Mejía,[c] Guillermo Galeote,[d] José Antonio Baz,[b,e] Hipólito Gutiérrez,[a,b] Ana Serrador,[a,b] Mario García-Gómez,[a,b] Alfredo Redondo,[a,b] Carlos Baladrón,[a,b] Roman Arnold,[a,b] Pilar Jiménez-Quevedo,[c] Manuel Carrasco-Moraleja,[a,b] Itziar Gómez Salvador,[a,b] J. Alberto San Román,[a,b] and Ignacio J. Amat-Santos[a,b,*]

[a] *Servicio de Cardiología, Hospital Clínico Universitario, Valladolid, Spain*
[b] *Centro de Investigación Biomédica en Red de Enfermedades Cardiovasculares (CIBERCV), Spain*
[c] *Servicio de Cardiología, Hospital Clínico San Carlos, Madrid, Spain*
[d] *Servicio de Cardiología, Hospital Universitario La Paz, Madrid, Spain*
[e] *Servicio de Cardiología, Hospital Álvaro Cunqueiro, Vigo, Spain*

Article history:
Received 7 April 2020
Accepted 15 September 2020
Available online 4 November 2020

Keywords:
TAVI
Self-expandable valves
Pacemaker
Aortic stenosis

ABSTRACT

Introduction and objectives: Aortic self-expandable (SE) transcatheter aortic valve implantation (TAVI) devices are particularly useful for patients with aortic stenosis and small/tortuous vessels, small aortic annuli, or low coronary ostia. However, it is unclear whether the growing range of SE devices shows comparable hemodynamic and clinical outcomes. We aimed to determine the differential hemodynamic (residual valve area and regurgitation) and clinical outcomes of these devices in comparable scenarios.
Methods: All patients were enrolled from 4 institutions and were managed with 4 different SE TAVI devices. Baseline and follow-up clinical data were collected and echocardiographic tests blindly and centrally analyzed. Patients were compared according to valve type and a 1:1 matched comparison was performed according to degree of calcification, aortic annulus dimensions, left ventricular ejection fraction, and body surface area.
Results: In total, 514 patients were included (Evolut R/PRO, 217; ACURATE neo, 107; ALLEGRA, 102; Portico, 88). Surgical risk scores were comparable in the unmatched population. No differences were observed in the post-TAVI regurgitation rate and in in-hospital mortality (2.7%). The rate of pacemaker implantation at discharge was significantly different among devices ($P = .049$), with Portico showing the highest rate (23%) and ACURATE neo the lowest (9.5%); Evolut R/PRO and ALLEGRA had rates of 15.9% and 21.2%, respectively. The adjusted comparison showed worse residual TAVI gradients and aortic valve area with ACURATE neo vs ALLEGRA ($P = .001$) but the latter had higher risk of valve embolization and a tendency for more cerebrovascular events.
Conclusions: A matched comparison of 4 SE TAVI devices showed no differences regarding residual aortic regurgitation and in-hospital mortality.
© 2020 Sociedad Española de Cardiología. Published by Elsevier España, S.L.U. All rights reserved.

Prótesis percutáneas autoexpandibles para la estenosis aórtica: resultados a corto plazo y comparación hemodinámica tras emparejamiento

Palabras clave:
TAVI
Válvulas autoexpandibles
Marcapasos
Estenosis aórtica

RESUMEN

Introducción y objetivos: El implante percutáneo de válvula aórtica (TAVI) autoexpandible (AE) es particularmente útil para pacientes con estenosis aórtica y accesos vasculares pequeños, anillo pequeño y *ostium* coronario bajo. Sin embargo, aún no está claro si el resultado clínico y hemodinámico es comparable entre los distintos dispositivos AE. Nuestro objetivo es determinar diferencias clínicas y hemodinámicas entre dispositivos, ajustando por características basales.
Métodos: Se analizaron los casos tratados con TAVI-AE en 4 instituciones. Se incluyeron características basales y al seguimiento, y el análisis de los ecocardiogramas fue centralizado y ciego. Se compararon los 4 dispositivos tras emparejar 1:1 por grado de calcificación, dimensiones del anillo, superficie corporal y función ventricular.

* Corresponding author: Servicio de Cardiología, Hospital Clínico Universitario de Valladolid, Avda. Ramón y Cajal 3, 47003 Valladolid, Spain.
E-mail address: ijamat@gmail.com (I.J. Amat-Santos).

https://doi.org/10.1016/j.rec.2020.09.014
1885-5857/© 2020 Sociedad Española de Cardiología. Published by Elsevier España, S.L.U. All rights reserved.

Resultados: Se incluyó a 514 pacientes (Evolut R/PRO, 217; ACURATE neo, 107; ALLEGRA, 102; Portico: 88). No hubo diferencias en las escalas de riesgo. No se detectaron diferencias en insuficiencia aórtica tras el TAVI ni en las tasas de mortalidad hospitalaria (2,7%). La tasa de implante de marcapasos mostró diferencias significativas (p = 0,049), con la mayor tasa tras Portico (23%) y la menor tras ACURATE neo (9,5%). La Evolut R/PRO y la ALLEGRA presentaron tasas del 15,9 y el 21,2%. Tras el ajuste, la comparación mostró mayor gradiente residual y menor área valvular aórtica indexada con ACURATE neo que con ALLEGRA (p = 0,001), pero con esta se produjo la mayor tasa de embolización del dispositivo y una tendencia estadística a mayor tasa de eventos cerebrovasculares.
Conclusiones: La comparación de 4 TAVI-AE tras ajustar por diferencias basales no demostró diferencias en las tasas de insuficiencia aórtica periprotésica ni en la mortalidad hospitalaria.
© 2020 Sociedad Española de Cardiología. Publicado por Elsevier España, S.L.U. Todos los derechos reservados.

Abbreviations

AR: aortic regurgitation
PVL: paravalvular leak
SE: self-expandable
TAVI: transcatheter aortic valve implantation

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) is a prominent therapeutic alternative for patients with severe aortic stenosis at high, intermediate, or low surgical risk.[1–4] The design of the most widespread commercially available percutaneous devices includes balloon- and self-expandable (SE) prostheses. In particular, SE valves are the preferred alternative in certain scenarios, including those involving a high degree of calcification,[5] small annuli,[6] low coronary ostia,[7] marked tortuosity of the ascending aorta,[8] nontransfemoral transvascular access,[9] and a smaller vessel size. However, SE devices have been linked to a higher rate of moderate-to-severe paravalvular leak (PVL) that might result in up to a 3-fold increase in mortality at 1-year follow-up.[10,11] Although post-dilatation of the prosthesis might reduce the incidence of PVL, this approach is not without risks because it has been associated with a higher rate of new conduction disorders (which are also a major concern with most SE devices), valve migration, annular rupture, and stroke.[12]

Several measures have been implemented to reduce these complications, including adoption of sealing skirts, more homogeneous radial force expansion, and repositionable properties.[13] It remains unclear if the growing range of newer iteration SE devices behaves equally in terms of hemodynamics, conduction abnormalities, and clinical outcomes. Accordingly, we compared the main clinical outcomes and hemodynamic performance—as assessed through blinded central echocardiographic analysis—of the 4 SE devices available in our setting: Evolut R/PRO (Medtronic, United States), ACURATE neo (Boston Scientific, United States), ALLEGRA (New Valve Technology AG, Switzerland), and Portico (Abbott, United States).

METHODS

Study population

This retrospective study included 514 consecutive symptomatic patients with severe aortic stenosis of the native valve who received SE TAVI devices in any of 4 centers. The data and images of all procedures performed between January 2017 and January 2019 were collected in a dedicated database after signed informed consent was provided by the patients and approval obtained from the local ethics committees.

In all cases, the Heart Team of each institution determined patient suitability and eligibility for the procedure and the valve type. To be included in the study, patients were required to have baseline, in-hospital, and 30-day echocardiographic images. Also required were multidetector computed tomography data and the main clinical, procedural, and long-term outcomes.

The primary endpoint was valve hemodynamic performance based on echocardiographic parameters, and therefore matched comparisons were performed by matching alternative pairs of devices. Secondary endpoints were based on the VARC-2 consensus and included cardiovascular mortality, myocardial infarction, cerebrovascular events, bleeding complications, acute kidney injury, vascular complications, conduction abnormalities and arrhythmia, repeat hospitalization, and New York Heart Association (NYHA) functional class.

Imaging analysis

Echocardiographic examinations were performed according to the guidelines of the American Society of Echocardiography before the procedure, at discharge, and at 30-day follow-up. The following measurements were obtained: left ventricular outflow tract diameter, left ventricular ejection fraction using the biplane Simpson method, mean and peak transvalvular gradients, area by continuity equation, and the presence, degree, and type (transvalvular, paravalvular, global) of aortic regurgitation (AR). AR severity was evaluated using a multiparametric approach and classified following VARC-2 recommendations[14] as follows: 0, none/trace; 1, mild; 2, mild-to-moderate; 3, moderate; and 4, severe. Grades 3 and 4 were considered significant AR. Location and circumferential extent were also assessed for paravalvular AR. The circumferential extent of the paravalvular jets was measured in parasternal short-axis views using color Doppler imaging.[15] Images were centrally analyzed[16] by 2 independent operators (SVV and SSM) blinded to the type of prosthesis and a lack of significant differences was assessed in 10% of the studies. The initial quality of the images was assessed to determine the proportion of patients with information on the main imaging endpoints, including baseline left ventricular ejection fraction (available in 91.6%), peak and mean aortic gradients (92.8%), estimated aortic valve area (83.3%), presence and global degree of AR (90.6%), mitral regurgitation degree (93.6%), and tricuspid regurgitation (69.2%). At the 30-day follow-up, left ventricular ejection fraction was available in 91.6% of the studies, peak and mean aortic gradient in 88%, aortic valve area in 81.5%, indexed aortic valve area in 81.3%, and the presence, global degree, and location of AR—peri- or intraprosthetic—in 99.2%.

Multidetector computed tomography examinations were performed according to the guidelines of the Society of Cardiovascular

Computed Tomography[17] and good-quality examinations were available in 479 patients (93.5% of the global study population). The main parameters were aortic annulus dimensions (diameters, perimeter, and area), perimeter and area-derived diameters, eccentricity index, and aortic valve calcification graded according to the calcium score (Agatston units).

Statistical analysis

Categorical variables are presented as frequencies, and comparisons between groups were performed using the chi-square or Fisher exact test. Continuous variables are expressed as mean (± standard deviation) or median [25th-75th interquartile range] and were analyzed for normal distribution with the Kolmogorov-Smirnov test. Comparisons between groups were performed using the *t* test or Mann-Whitney *U* test according to variable distribution. ANOVA was used for comparisons between multiple groups. Differences were considered statistically significant at $P < .05$.

Seven propensity scores were used for a 1-to-1 comparison of the 4 types of valves and included the following variables: left ventricular ejection fraction (within 10%, as assessed by transthoracic echocardiography), aortic annulus diameter (within 0.5 mm) and area (within 50 mm^2) (measured using computed tomography), body surface area (within 0.4 m^2), body mass index (within 5 kg/m^2), and degree of calcification (within 500 AU), despite the lack of baseline differences. Pairs of patients were derived using the greedy nearest neighbor method 1:1 with one-fifth of the standard deviation of the logit of the propensity score as caliper with the MatchIt package.[18] After matching, comparisons between groups were performed using McNemar test for categorical variables and paired *t* test for continuous variables. Kaplan-Meier analysis was performed using the log-rank test to compare survival rates between groups.

All analyses were conducted using IBM SPSS Statistics version 24 (IBM, United States).

RESULTS

Of a total of 826 patients who underwent TAVI within the study period, 514 (62.2%) received 1 of the 4 SE devices: 42.2% (n = 217) received an Evolut R/PRO valve, 20.8% (n = 107) an ACURATE neo valve, 19.8% (n = 102) an ALLEGRA Valve, and 17.1% (n = 88) a Portico valve. All 4 participating institutions used the 4 devices compared in this research and did not show significant differences in main outcomes.

Baseline clinical and imaging characteristics

The main baseline characteristics of the patients are summarized in table 1. The mean age of the population was 81.4 ± 6.8 years and 54.7% were women; higher proportion of women were treated with ACURATE neo and Portico valves (64.5% and 65.9%, respectively; $P = .003$). At baseline, more patients who were deemed candidates for Evolut R/PRO (16.2%) and Portico (17%) had a permanent pacemaker vs less than 10% of those treated with alternative SE devices ($P = .049$). Regarding the baseline risk, no differences were found in the STS score or EuroSCORE, but patients in the Portico group had a higher frailty score (2.18 ± 1.3) than those in the other groups ($P = .001$).

Echocardiographic and multidetector computed tomography findings at baseline according to valve type are presented in table 2. There were no differences between the groups in aortic stenosis severity ($P > .50$ for mean transvalvular gradient) or in left ventricular ejection fraction. As shown in table 2, the mean size of the aortic annulus as assessed by computed tomography was significantly larger in patients treated with the Evolut R/PRO device, but the degree of calcification was comparable among the device groups.

Procedural results and main clinical outcomes

The main procedural and in-hospital events after TAVI are summarized in table 3. The transfemoral approach was the most common route of implantation (93%) in all groups, followed by a transsubclavian approach. Although there were no differences in the preimplantation invasive mean aortic gradient, it was significantly lower with the ALLEGRA valve than with the other devices ($P = .049$). The rate of predilatation varied widely among devices, from 43% with Evolut R/PRO to 95.5% with Portico ($P \leq .001$). In addition, postdilatation was less common after Evolut R/PRO (24.9%) and ACURATE neo (24.3%) than after ALLEGRA (41.2%) and Portico (42.4%) ($P = .001$). In the unmatched population, no differences were found in the degree of AR after valve implantation. Major and minor vascular complications were similar in all of the groups and no significant differences were observed.

The rate of pacemaker implantation at discharge was significantly different among the device groups (global $P = .049$), with Portico showing the highest rate (23%) and ACURATE neo the lowest (9.5%); Evolut R/PRO and ALLEGRA had rates of 15.9% and 21.2%, respectively. The need for permanent pacemaker implantation was not related to the degree of aortic valve calcification because there were no differences in calcification among the device groups, even before matching. No differences were found in 30-day mortality among the groups ($P = .096$), with a global rate of 2.7%, but unadjusted 1-year mortality (6.4%) differed significantly for patients treated with each device: 9.7% for Evolut R/PRO, 1.9% for ACURATE neo, 3.9% for ALLEGRA, and 6.8% for Portico ($P = .035$), as shown in the survival curves depicted in figure 1. A similar trend was found for 1-year cardiovascular mortality: 4.7% for Evolut R/PRO, 0.7% for ACURATE neo, 1.9% for ALLEGRA, and 3.8% for Portico ($P = .079$). The main factors associated with 1-year mortality are summarized in table 1 of the supplementary data and included prior hemodialysis, previous atrial fibrillation, worse baseline NYHA class, valve embolization, cardiac tamponade, and residual moderate or severe AR. The need for permanent pacemaker was not associated with higher mortality.

The specific rates of main complications in patients treated with each device are summarized in table 4, and procedural and in-hospital outcomes in the matched population are specifically reported in tables 2 to 7 of the supplementary data. Briefly, the ALLEGRA valve had a better transvalvular mean gradient than ACURATE neo, Evolut, and Portico but the absolute rate of valve embolization was higher with ALLEGRA than with the other valves and this device was associated with more cerebrovascular events vs Portico ($P = .032$) and Evolut ($P = .083$).

TAVI hemodynamics at 30-day follow-up

Echocardiographic assessment of the unmatched population is summarized in table 3. A trend to a better valve area and transaortic gradients was found in the ALLEGRA group (figure 2) without significant differences in left ventricular ejection fraction. After matching (table 5), no differences were found in AR presence or degree after valve implantation in any of the pairs (figure 3). However, patients treated with the ACURATE neo valve had a higher mean aortic gradient (8.5 ± 4 mmHg) than those treated with the ALLEGRA valve (6.7 ± 2.8, $P = .001$). Mean gradients and

Table 1
Main baseline characteristics of the global study population and according to valve type

	Global study population N = 514	Evolut R/PRO n = 217 (42.2%)	ACURATE neo n = 107 (20.8%)	ALLEGRA n = 102 (19.8%)	Portico n = 88 (17.1%)	*P*
Age, y	81.4 ± 6.8	81.4 ± 6.9	81.5 ± 6.2	80.7 ± 7.5	82.4 ± 5.87	.426
Female sex	281/514 (54.7)	105/217 (48.4)	69/107 (64.5)	49/102 (48)	58/88 (65.9)	.003*
BSA, m^2	1.75 ± .19	1.75 ± 0.19	1.75 ± 0.18	1.76 ± 0.18	1.72 ± 0.21	.67
BMI, kg/m^2	27.91 ± 4.56	27.35 ± 4.4	28.34 ± 4.4	28.7 ± 4.9	27.7 ± 4.5	.051
Diabetes mellitus	190/514 (37)	83/217 (38.2)	37/107 (34.6)	39/102 (38.2)	31/88 (35.2)	.897
Hypertension	409/514 (79.6)	165/217 (76)	87/107 (81.3)	80/102 (78.4)	77/88 (87.5)	.148
Dyslipidemia	310/514 (60.3)	120/217 (55.3)	66/107 (61.7)	64/102 (62.7)	60/88 (68.2)	.180
Smoking	99/514 (19.3)	46/217 (21.2)	14/107 (13)	22/102 (21.6)	17/88 (19.3)	.001*
Permanent pacemaker	67/513 (13)	35/216 (16.2)	10/107 (9.3)	7/102 (6.9)	15/88 (17)	.049*
Chronic kidney disease	181/514 (35.2)	73/217 (33.6)	39/107 (36.4)	43/102 (42.2)	26/88 (29.5)	.296
Hemodialysis	5/513 (1.0)	3/217 (1.4)	1/106 (0.9)	1/102 (1)	0/88 (0)	.743
COPD	78/513 (15.2)	46/217 (21.2)	11/106 (10.4)	15/102 (14.7)	6/88 (6.8)	.005*
Peripheral artery disease	36/506 (7.0)	22/214 (10.3)	4/106 (3.8)	7/102 (6.9)	3/84 (3.6)	.084
Previous stroke/TIA	45/514 (8.8)	16/217 (7.4)	10/107 (9.3)	9/102 (8.8)	10/88 (11.4)	.725
Porcelain aorta, %	22/513 (4.3)	13/216 (6)	1/107 (0.9)	3/102 (2.9)	5/88 (5.7)	.146
Coronary artery disease	182/514 (35.4)	98/217 (45.2)	34/107 (31.8)	26/102 (25.5)	24/88 (27.3)	.001*
Prior heart surgery	55/436 (12.6)	32/217 (14.7)	9/73 (12.3)	7/58 (12.1)	7/88 (8)	.449
Prior CABG	29/510 (5.6)	18/213 (8.5)	4/107 (3.7)	4/102 (3.9)	3/88 (3.4)	.155
Prior valvular surgery	39/510 (7.6)	22/213 (10.3)	6/107 (5.6)	6/102 (5.9)	5/88 (5.7)	.292
Atrial fibrillation	205/514 (39.9)	90/217 (41.5)	34/107 (31.8)	38/102 (37.3)	43/88 (48.9)	.093
Medication, % (N = 506)						
Aspirin	242/506 (47.8)	104/212 (49.1)	54/105 (51.4)	44/101 (43.6)	40/88 (45.5)	.658
Clopidogrel	151/506 (29.8)	64/212 (30.2)	30/105 (28.6)	23/101 (22.8)	34/88 (38.6)	.124
VKAs	165/506 (32.6)	76/212 (35.8)	20/105 (19)	32/101 (31.7)	37/88 (42)	.004*
NOACs	37/406	8/116 (6.9)	13/102 (12.7)	8/100 (8)	8/88 (9.1)	.482
NYHA III-IV, %	258/504 (51.2)	122/213 (57.3)	42/102 (41.2)	53/102 (52)	41/87 (57.1)	.049*
Frailty score	0.95 ± 1.2 (N = 500)	0.75 ± 1.1 (n = 216)	0.81 ± 1 (n = 99)	0.42 ± 0.6 (n = 102)	2.18 ± 1.3 (n = 88)	.001*
TAVI score (from ACC)	4.1 ± 3.2	4.2 ± 3.9	4 ± 3.5	4.6 ± 4.2	4.3 ± 3.8	.999
STS score	4.9 ± 4.33	5 ± 4.1	4.4 ± 1.4	5 ± 5.5	4.9 ± 2.7	.920
Logistic EuroSCORE	15.5 ± 10.84	15.9 ± 11.4	13.4 ± 8.3	16.1 ± 14.1	15.2 ± 9.0	.71

ACC, American College of Cardiology; BMI, body mass index; BSA, body surface area; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; NOACs, new oral anticoagulants; STS, Society of Thoracic Surgeons; NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation; TIA, transient ischemic attack; VKAs, vitamin K antagonists.
Data are expressed as No. (%) or mean ± standard deviation.
* Indicates significant *P* values.

aortic valve areas for each pair are reported in tables 2 to 7 of the supplementary data. The center treating the patient was not included in the matched analysis, but univariate analysis showed no impact of this variable on in-hospital mortality (*P* = .37) or on the rate of AR of any degree (*P* = .54).

DISCUSSION

Although recent comparisons of balloon- and self-expandable devices have reported better global outcomes, mainly driven by a lower PVL rate with balloon-expandable devices,[19–22] the current clinical practice does not follow this "all-comers" schema, but a personalized indication of what seems best for each patient. SE TAVI devices are usually preferred in patients with smaller or more tortuous vessels and specifically when these characteristics lead to a need for transsubclavian access, due to the better profile of their delivery systems. Moreover, they are also more often used in small aortic annuli and when there is higher risk of coronary occlusion, aortic annulus rupture, or valve embolization for any reason. The price to pay seems to be a higher risk of PVL and need for pacemaker implantation.[23] However, not all SE devices behave similarly in terms of conduction abnormalities and, in particular, no systematic comparison has examined their critical effect on paravalvular regurgitation and residual gradients. Evolut R/PRO and Portico are partially resheathable, unlike ALLEGRA and ACURATE neo. The Portico valve is the only intra-annular valve, and ACURATE neo is the only device that is released from top to bottom. All of these technical differences might have a major clinical impact on patients' outcomes.

The main findings of our research were as follows. *a*) There were no differences in terms of residual AR at 30-day follow-up among the 4 SE devices after a careful central echocardiographic analysis and a matched process that considered anatomical features, with a low global rate (2.7%) of more-than-moderate AR. *b*) Despite a similar degree of valve calcification and after matched paired analysis, the ACURATE neo valve had a higher mean gradient than the ALLEGRA TAVI—not when compared with the others—but half the permanent pacemaker rate of any other device, which, despite being unrelated to the mortality rate, has important implications for patients and the cost-effectiveness of the intervention. *c*) Valve embolization occurred more often with the ALLEGRA valve, which might partially explain the tendency for a higher rate of cerebrovascular events. *d*) Although no adjustment according to

Table 2
Main baseline echocardiographic and computed tomography findings of the global study population and according to valve type

	Global study population N = 514	Evolut R/PRO n = 217 (42.2%)	ACURATE neo n = 107 (20.8%)	ALLEGRA n = 102 (19.8%)	Portico n = 88 (17.1%)	*P*
Computed tomography data						
Maximal aortic annulus diameter, mm	26 ± 3.1	26.6 ± 3.6	25.8 ± 2.3	26.7 ± 2.6	25.6 ± 2.6	.003[b]
Minimal aortic annulus diameter, mm	21.3 ± 2.9	21.8 ± 3.2	20.9 ± 2.4	21.3 ± 2.7	20.4 ± 2.4	.002[b]
Eccentricity index[a]	0.182 ± 0.093	0.174 ± 0.098	1.184 ± 0.089	0.202 ± 0.087	0.189 ± 0.086	.203
Mean aortic annulus diameter, mm	23.7 ± 2.6	24.1 ± 3.2	23.3 ± 2.0	23.8 ± 2.3	22.8 ± 1.9	.001[b]
Aortic annulus area, mm^2	432.71 ± 92	451 ± 113	417 ± 64	431 ± 82	410 ± 68	.001[b]
Aortic annulus perimeter, mm	75.3 ± 11.7	76.8 ± 11.7	73.3 ± 10	80.1 ± 9.7	69.4 ± 11	.001[b]
Calcium score, Agatston units	2285 (1531-3216)	2402 (1474-3276)	2145 (1650-3114)	2313 (1604-3435)	2148 (1581-2811)	.553
Echocardiographic data						
LVEF	57 ± 12	56 ± 12	59 ± 10	56 ± 11	58 ± 11	.198
Peak aortic gradient, mmHg	74.4 ± 22	74 ± 23	74.5 ± 23	80 ± 21	74 ± 21	.190
Mean aortic gradient, mmHg	44.4 ± 15	44.5 ± 15	45.1 ± 14	44.6 ± 12	45.3 ± 13	.970
Aortic valve area, cm^2	0.7 ± 0.2	0.74 ± 0.2	0.72 ± 0.2	0.71 ± 0.2	0.68 ± 0.1	.271
Aortic regurgitation						
None/trace (grade 0)	182/466 (39.1)	62/182 (34.1)	41/97 (42.3)	48/99 (48.5)	31/88 (35.2)	
Mild (grade 1)	170/466 (36.5)	71/182 (39)	34/97 (38.1)	34/99 (34.3)	28/88 (31.8)	
Moderate (grade 2)	84/466 (18)	32/182 (17.6)	13/97 (13.4)	12/99 (12)	27/88 (30.7)	
Moderate-to-severe (grade 3)	23/466 (4.9)	13/182 (7.1)	5/97 (5.2)	3/99 (3.0)	2/88 (2.3)	
Severe (grade 4)	7/466 (1.5)	4/182 (2.2)	1/97 (1)	2/99 (2)	0	
Aortic regurgitation (3-4)	30/466 (6.4)	17/182 (9.3)	6/97 (6.2)	5/99 (5.1)	2/88 (2.3)	.144
Mitral regurgitation						
None/trace (grade 0)	152/483 (31.5)	50/199 (25.1)	39/98 (39.8)	42/98 (42.9)	21/88 (23.9)	
Mild (grade 1)	216/483 (44.7)	87/199 (43.7)	39/98 (39.8)	39/98 (39.8)	51/88 (58)	
Moderate (grade 2)	98/483 (20.3)	53/199 (26.6)	19/98 (19.4)	15/98 (15.3)	11/88 (12.5)	
Moderate-to-severe (grade 3)	15/483 (3.1)	7/199 (3.5)	1/98 (1)	2/98 (2)	5/88 (5.7)	
Severe (grade 4)	2/483 (0.4)	2/199 (1)	0	0	0	
Mitral regurgitation (3-4)	17/483 (3.5)	9/199 (4.5)	1/98 (1)	2/98 (2)	5/88 (5.7)	.237
Tricuspid regurgitation (3-4)	18/356 (5.1)	7/104 (6.7)	1/64 (1.6)	5/100 (5)	5/88 (5.7)	.419

LVEF, left ventricular ejection fraction. Data are expressed as no./N (%) or mean ± standard deviation.
[a] 1− (Minimal diameter of aortic annulus /Maximal diameter of aortic annulus).
[b] Indicates significant *P* values.

baseline risk was performed, procedural and 30-day mortality rates were comparable.

Previous comparisons among self-expandable devices

In the meta-analysis by Barbanti et al.,[24] which compared Sapien-3, Lotus, Portico, JenaValve, ACURATE neo, and Evolut R devices, the 30-day mortality (2.2%) and residual more-than-mild AR (1.6%) were comparable to that reported here. However, the authors also highlighted the unresolved issue of the high need for permanent pacemaker implantation (16.2%). Similar findings were reported in the more recent NEOPRO registry[25] (Evolut PrO vs ACURATE neo), except for a much lower and comparable rate of pacemaker implantation (12.8% vs 11.0%, $P = .565$) that is inconsistent with contemporary reports. Costa et al.[26] identified pacemaker rates of 8.3% for SAPIEN 3, 16.7% for Evolut R, and 2.1% for ACURATE neo ($P < .05$). The same registry reported lower gradients with Evolut R than with ACURATE neo (6.1 ± 2.4 mmHg vs 8.4 ± 3.5 mmHg, $P < .01$) but comparable residual AR and mortality. In addition, an Italian registry[27] reinforced the lower pacemaker rate after the ACURATE neo valve in a matched comparison with Evolut, Portico, Lotus, and Sapien-3. Regarding the Portico valve, its matched comparison vs Sapien-3[28] suggested a comparable 30-day mortality and similar (> 20%) need for permanent pacemaker implantation and PVL, but a comparison with Evolut-R[29] revealed a lower rate of significant PVL with Portico (0%) than with Evolut R (15.2%) in patients with elliptic annulus ($P = .034$).

Despite the variability in these important outcomes, at least some comparative studies have been performed among Evolut, Portico, and ACURATE neo devices. In contrast, only case series exist for the ALLEGRA valve.[30] The hemodynamic outcomes of this newest device showed a mean gradient of 7.2 ± 3.5 mmHg with an effective orifice area of 2.06 ± 0.3 cm^2. More-than-mild PVL was present in 5.1% of patients before discharge and the pacemaker implantation rate was 13.5% at 30 days, which is in agreement with our findings. The positive post-TAVI gradients reported with the ALLEGRA valve suggest that the supra-annular leaflet position and the radial strength of this device might be particularly useful for small calcified aortic annuli. However, the current inability to resheath the device increases risk and might offset its benefits because it showed the highest rate of valve embolization in our analysis and a high rate of cerebrovascular events. The underlying mechanisms merit deeper insight in future research.

Clinical implication for patient-specific device selection

When a SE device is selected to treat a patient with aortic stenosis, not all options are optimal, and they depend on patients' characteristics. Partially resheathable devices (Evolut/Portico) should probably be selected for patients with high risk of coronary

Table 3
Main procedural and in-hospital outcomes of the global study population and according to valve type

	Global study population N = 514	Evolut R/PRO n = 217 (42.2%)	ACURATE neo n = 107 (20.8%)	ALLEGRA n = 102 (19.8%)	Portico n = 88 (17.1%)	*P*
Procedural outcomes						
Transfemoral approach	478/514 (93)	195/217 (89.9)	102/107 (95.3)	93/102 (91.2)	(88/88) 100	.01*
More than 1 prosthesis required	12/481 (2.5)	7/217 (3.3)	0	4/102 (3.9)	1/88 (1.1)	.273
Balloon valvuloplasty	318/481 (66.1)	80/186 (43)	92/105 (87.6)	62/102 (60.8)	84/88 (95.5)	≤.001*
Postdilatation	157/507 (30.5)	53/213 (24.9)	26/107 (24.3)	42/102 (41.2)	36/85 (42.4)	.001*
Aortic regurgitation at discharge (2-3-4)	127/510 (24.9)	57/215 (26.5)	24/107 (22.4)	27/100 (27)	19/88 (21.6)	.706
Aortic regurgitation at discharge (3-4)	14/510 (2.7)	5/215 (2.3)	2/107 (1.9)	4/100 (4)	3/88 (3.4)	.757
Procedural complications, %						
Valve embolization	16/512 (3.1)	9/215 (4.2)	1/107 (0.9)	5/102 (4.9)	1/87 (1.1)	.194
Annulus rupture	1/514 (0.2)	1/217 (0.5)	0	0	0	.712
Coronary artery occlusion	9/502 (1.8)	7/209 (3.3)	1/107 (0.9)	0	1/88 (1.1)	.149
Tamponade	4/512 (0.8)	0	1/107 (0.9)	1/101 (1)	2/88 (2.3)	.229
Procedural death	4/512 (0.8)	3/217 (1.4)	0	1/101 (1)	0	.458
Procedural success	495/510 (97.1)	210/217 (96.8)	102/105 (97.1)	97/100 (97)	86/88 (97.7)	.977
In-hospital clinical outcomes						
Permanent pacemaker implantation	84/499 (16.8)	33/208 (15.9)	10/105 (9.5)	21/99 (21.2)	20/87 (23)	.049*
New-onset atrial fibrillation	34/506 (6.6)	16/212 (7.5)	6/105 (5.7)	8/102 (7.8)	4/87 (4.6)	.745
Cerebrovascular events	13/506 (2.6)	4/212 (1.9)	3/105 (2.9)	6/102 (5.9)	0	.066
Acute kidney injury	21/510 (4.1)	8/216 (3.7)	2/105 (1.9)	8/102 (7.8)	3/87 (3.4)	.166
Minor vascular complication	56/508 (11)	23/212 (10.8)	12/107 (11.2)	10/102 (9.8)	11/87 (12.6)	.941
Major vascular complication	37/508 (7.3)	18/212 (8.5)	5/107 (4.7)	11/102 (10.8)	3/87 (3.4)	.152
Minor bleeding	42/507 (8.3)	24/213 (11.3)	5/107 (4.7)	7/102 (6.9)	6/85 (7.1)	.189
Major bleeding	23/507 (4.5)	12/213 (5.6)	2/107 (1.9)	7/102 (6.9)	2/85 (2.4)	.207
Life-threatening bleeding	7/505 (1.4)	3/213 (1.4)	1/105 (1)	2/102 (2)	1/85 (1.2)	.936
Days in intensive care unit	1.9 ± 1.9	2.2 ± 2 (199)	1.3 ± 0.8 (72)	2.6 ± 2.7 (46)	1.4 ± 1.2 (86)	≤.001*
Length of stay, d	10 ± 9.8 (512)	10.8 ± 9.4 (217)	9.5 ± 10.5 (106)	12 ± 12 (101)	8 ± 5.7 (88)	.028
In-hospital death, %	14/511 (2.7)	7/217 (3.2)	2/105 (1.9)	3/101 (3.0)	2/88 (2.3)	.096
30-day echocardiographic findings						
Left ventricular ejection fraction	57.3 ± 9.2 (471)	56.7 ± 10 (193)	57 ± 7.3 (98)	55 ± 7.3 (92)	59 ± 9.8 (88)	.077
Aortic valve area, cm^2	1.9 ± 0.57 (265)	1.9 ± 0.56 (85)	1.8 ± 0.54 (60)	2.1 ± 0.57 (63)	1.9 ± 0.57 (57)	.052
Indexed aortic valve area, cm^2	1.1 ± 0.34 (264)	1.1 ± 0.3 (85)	1 ± 0.3 (60)	1.2 ± 0.36 (62)	1.1 ± 0.33 (57)	.070
Peak aortic gradient, mmHg	15 ± 9.6 (455)	15 ± 8 (181)	18 ± 13 (97)	14 ± 6.5 (93)	15 ± 8.6 (84)	.009*
Mean aortic gradient, mmHg	8 ± 6 (455)	7.8 ± 4.4 (182)	9.9 ± 9.6 (96)	6.9 ± 3 (94)	7.9 ± 5.5 (83)	.004*
Aortic regurgitation (periprosthetic)						
None/trace (grade 0)	132/496 (26.6)	55/217 (25.3)	27/106 (25.5)	24/97 (24.7)	26/76 (34.2)	
Mild (grade 1)	236/496 (47.6)	102/217 (47)	57/106 (53.8)	46/97 (47.4)	31/76 (40.8)	
Moderate (grade 2)	112/496 (22.6)	50/217 (23)	20/106 (18.9)	25/97 (25.8)	17/76 (22.4)	
Moderate-to-severe (grade 3)	14/496 (2.8)	10/217 (4.6)	1/106 (0.9)	2/97 (2.1)	1/76 (1.3)	
Severe (grade 4)	2/496 (0.4)	0	1/106 (0.9)	0	1/76 (1.3)	
Aortic regurgitation (intraprosthetic)						
None/trace (grade 0)	466/496 (94)	209/217 (96.3)	95/106 (89.6)	90/97 (92.8)	72/76 (94.7)	
Mild (grade 1)	28/496 (5.6)	8/217 (3.7)	11/106 (10.4)	5/97 (5.2)	4/76 (5.3)	
Moderate (grade 2)	1/496 (0.2)	0	0	1/97 (1)	0	
Moderate-to-severe (grade 3)	1/496 (0.2)	0	0	1/97 (1)	0	
Severe (grade 4)	0	0	0	0	0	
Aortic regurgitation (global)						
None/trace (grade 0)	150/510 (29.4)	63/215 (29.3)	28/107 (26.2)	27/100 (27)	32/88 (36.4)	
Mild (grade 1)	233/510 (45.7)	95/215 (44.2)	55/107 (51.4)	46/100 (46)	37/88 (42)	
Moderate (grade 2)	113/510 (22.2)	52/215 (24.2)	22/107 (20.6)	23/100 (23)	16/88 (18.2)	
Moderate-to-severe (grade 3)	12/510 (2.3)	5/215 (2.3)	1/107 (0.9)	4/100 (4)	2/88 (2.3)	
Severe (grade 4)	2/510 (0.4)	0	1/107 (0.9)	0	1/88 (1.1)	
Aortic regurgitation (global) grades 2-3-4	127/510 (24.9)	57/215 (26.5)	24/107 (22.4)	27/100 (27)	19/88 (21.6)	.706
Aortic regurgitation (global) grades 3-4	14/510 (2.7)	5/215 (2.3)	2/107 (1.9)	4/100 (4)	3/88 (3.4)	.757

Data are expressed as no./N (%) or mean ± standard deviation.
* Indicates significant *P* values.

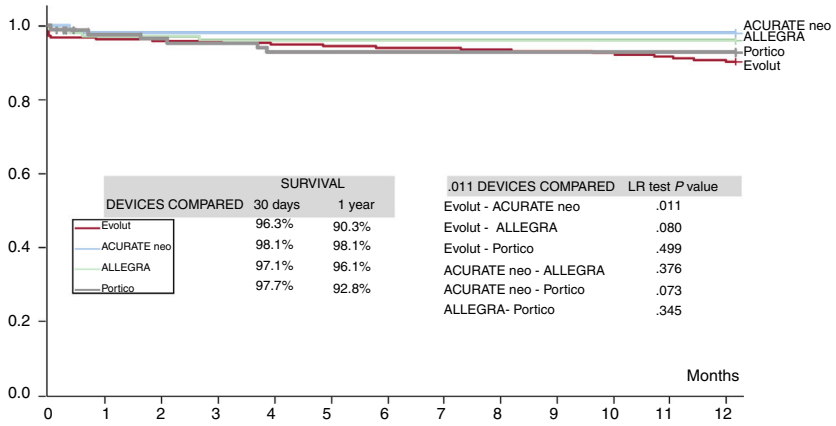

Figure 1. Thirty-day and 1-year survival curves according to self-expandable transcatheter heart valve in the global study population. LR, log-rank.

Table 4
Main clinical and hemodynamic outcomes between different self-expandable TAVI devices in the unmatched population

Main characteristics	Evolut/ACURATE N = 217/107	Evolut/ALLEGRA N = 217/102	Evolut/Portico N = 217/88	ACURATE/ALLEGRA N = 107/102	ACURATE/Portico N = 107/88	ALLEGRA/Portico N = 102/88
AR ≥ 3	2.3%/1.9% *P* = .999	2.3%/4.0% *P* = .472	2.3%/3.4% *P* = .695	1.9%/4.0% *P* = .432	1.9%/3.4% *P* = .659	4.0%/3.4% *P* = .999
AR ≥ 2	26.5%/22.4% *P* = .427	26.5%/27.0% *P* = .927	26.5%/21.6% *P* = .370	22.4%/27.0% *P* = .446	22.4%/21.6% *P* = .888	27.0%/21.6% *P* = .389
Mean aortic gradient at discharge	7.8 ± 4.4/9.9 ± 9.7 *P* = .041*	7.8 ± 4.4/6.9 ± 3.1 *P* = .083	7.8 ± 4.4/7.9 ± 5.5 *P* = .846	9.9 ± 9.7/6.9 ± 3.1 *P* = .004*	9.9 ± 9.7/7.9 ± 5.5 *P* = .093	6.9 ± 3.1/7.9 ± 5.5 *P* = .142
Permanent pacemaker implantation	15.9%/9.5% *P* = .124	15.9%/21.2% *P* = .250	15.9%/23% *P* = .146	9.5%/21.2% *P* = .020*	9.5%/23% *P* = .011*	21.2%/23% *P* = .771
Valve embolization	4.5%/0.9% *P* = .113	4.5%/4.9% *P* = .772	4.5%/1.1% *P* = .182	0.9%/4.9% *P* = .086	0.9%/1.1% *P* = .883	4.9%/1.1% *P* = .142
Cerebrovascular event	1.9%/2.9% *P* = .689	1.9%/5.9% *P* = .083	1.9%/0% *P* = .326	2.9%/5.9% *P* = .253	2.9%/3.4% *P* = .999	5.9%/0% *P* = .032*
In-hospital mortality	3.2%/1.9% *P* = .723	3.2%/3.0% *P* = .999	3.2%/2.3% *P* = .999	1.9%/3.0% *P* = .678	1.9%/2.3% *P* = .999	3.0%/2.3% *P* = .999

AR, aortic regurgitation; TAVI, transcatheter aortic valve implantation.
* Indicates significant *P* values.

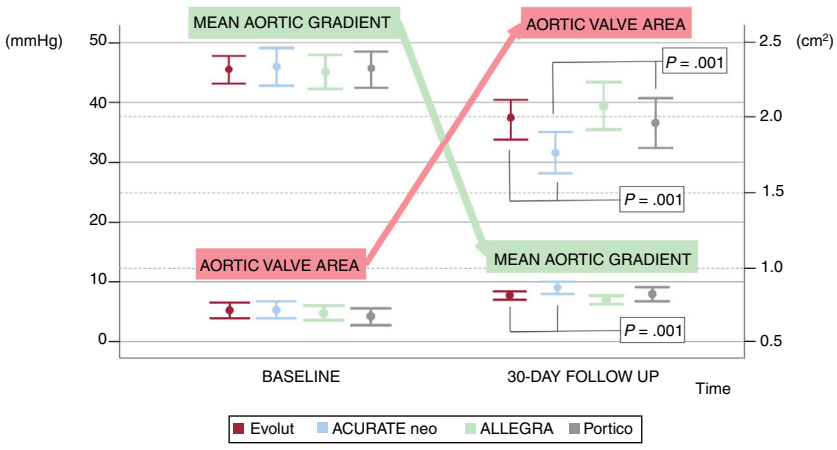

Figure 2. Baseline and 30-day mean aortic gradients and aortic valve area according to self-expandable transcatheter heart valve in the global study population.

obstruction. On the other hand, these devices should be avoided in patients with high risk of conduction abnormalities, particularly those with a long life-expectancy, in order to reduce permanent pacemaker need, and ACURATE neo probably represents the best alternative. In contrast, the current generation of the Portico valve exhibits the highest rate of conduction abnormalities, despite its appropriate hemodynamic behavior. The new FlexNav delivery system that has been implemented in the newer iteration of the Portico valve probably increases the stability of the device and likely reduces the rate of permanent pacemaker implantation. Moreover, the development of new implantation techniques as the "cusp overlap view" might alter the current scenario regarding post-TAVI conduction abnormalities.[31] Finally, ALLEGRA could be useful for patients undergoing a valve-in-valve procedure with a small bioprosthesis because the valve deployment is usually very stable and it might provide better residual gradients than alternative devices such as ACURATE neo,[32] with a low risk of valve embolization.

Table 5
Hemodynamic outcomes and need for permanent pacemaker implantation among different pairs of self-expandable TAVI devices after matching[a]

	Evolut	ACURATE neo	Portico
ACURATE neo	72 PAIRS AR ≥ 3: 1.4% vs 1.4%, *P* = .999 AR ≥ 2: 22.5% vs 23.9%, *P* = .999 MeanGrdt.: 8.4 ± 5.5 vs 8.3 ± 4.3, *P* = .926 Pacemaker rate: 13.2% vs 5.9%, *P* = .267		
Portico	56 PAIRS AR ≥ 3: 1.8% vs 1.8%, *P* = .999 AR ≥ 2: 23.6% vs 23.6%, *P* = .999 MeanGrdt.: 8.2 ± 6.1 vs 7 ± 3.8, *P* = .299 Pacemaker rate: 11.5% vs 26.9%, *P* = .096	71 PAIRS AR ≥ 3: 1.4% vs 2.8%, *P* = .999 AR ≥ 2: 19.7% vs 21.1%, *P* = .999 MeanGrdt.: 8.8 ± 5 vs 7.5 ± 5, *P* = .151 Pacemaker rate: 7% vs 25.4%, *P* = .007[b]	
ALLEGRA	65 PAIRS AR ≥ 3: 3.1% vs 6.3%, *P* = .687 AR ≥ 2: 20.3% vs 23.4%, *P* = .839 MeanGrdt.: 7.7 ± 4.3 vs 6.7 ± 2.9, *P* = .130 Pacemaker rate: 15.3% vs 15.3%, *P* = .999	74 PAIRS AR ≥ 3: 1.4% vs 5.4%, *P* = .375 AR ≥ 2: 28.4% vs 24.3%, *P* = .690 MeanGrdt.: 8.5 ± 4 vs 6.7 ± 2.8, *P* = .001[b] Pacemaker rate: 9.9% vs 16.9%, *P* = .332	56 PAIRS AR ≥ 3: 5.4% vs 3.6%, *P* = .999 AR ≥ 2: 32.1% vs 26.6%, *P* = .690 MeanGrdt.: 7.6 ± 4 vs 6.6 ± 2.9, *P* = .114 Pacemaker rate: 22.6% vs 20.8%, *P* = .999

AR, aortic regurgitation; MeanGrdt, mean gradient; TAVI, transcatheter aortic valve implantation.
Results show first the values for devices in the first line and then the values for devices in the first column.
[a] Matched variables included: left ventricular ejection fraction (within 10%, as assessed by transthoracic echocardiography), aortic annulus diameter (within 0.5 mm) and area (within 50 mm^2) (measured using computed tomography), body surface area (within 0.4 m^2), body mass index (within 5 kg/m^2), and the degree of calcification (within 500 Agatston units, measured using computed tomography).
[b] Indicates significant *P* values.

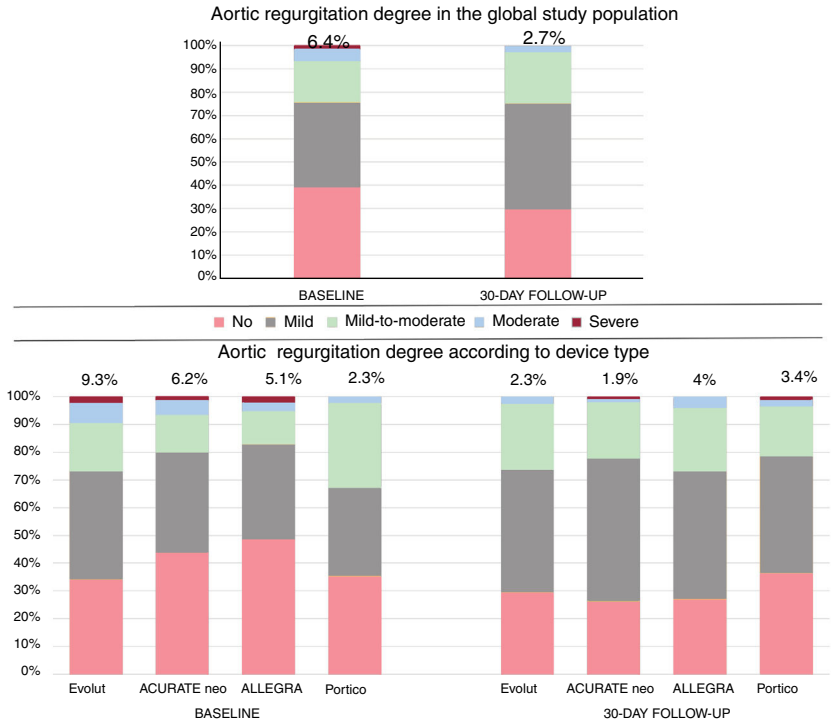

Figure 3. Degree of aortic regurgitation after valve implantation in the global study population and according to valve type in the unmatched population. The percentage of moderate or severe postprocedural aortic regurgitation is presented for the global population and for patients treated with each device.

Limitations

This is a retrospective study; this limitation was addressed through a prospective collection of the data in a similar database in all institutions and through an anonymized core laboratory echocardiographic analysis. The lower number of patients receiving certain devices may reflect an earlier stage in the learning curve and might have affected outcomes. However, the lack of differences in terms of main clinical outcomes or AR degree suggests a potential "class effect" with all SE devices, with a positive impact on the learning curve of newer SE devices in centers already experienced with alternative SE TAVI devices. On the other hand, the higher 1-year mortality rate shown by the patients treated with Evolut R/PRO probably indicates that these patients have anatomical or clinical conditions—not reflected in surgical risk scores—that affect the mid-term prognosis and that this valve may be the preferred TAVI device in more challenging scenarios, given the greater experience of the participating institutions with this system. The 2 iterations of the Evolut valve were analyzed together and they exhibited no differences in term

of outcomes. Finally, the slightly lower number of pairs in the matched comparison limits the power of the analysis but, given the concordant finding with the unmatched sample, still confirms the reduced risk of bias in the global study population.

CONCLUSIONS

A matched comparison of 4 SE TAVI devices showed no differences in residual AR or 30-day mortality, with a low rate of significant residual AR (2.7%). ACURATE neo was associated with worse residual transvalvular gradients vs ALLEGRA but offered the lowest rate of permanent pacemaker implantation.

FUNDING

None to declare.

CONFLICTS OF INTEREST

L. Nombela-Franco is proctor for Abbott; R. Moreno is proctor for Boston and NVT; J.A. Baz is proctor for NVT; and I.J. Amat-Santos is proctor for Boston. There are no other conflicts of interest regarding this manuscript.

WHAT IS KNOWN ABOUT THE TOPIC?

- Aortic self-expandable (SE) transcatheter aortic valve implantation (TAVI) devices are particularly useful for patients with aortic stenosis and small/tortuous vessels, small aortic annuli, or low coronary ostia.
- However, the growing range of SE devices raises questions about the comparability of their hemodynamic and clinical outcomes.

WHAT DOES THIS STUDY ADD?

- A matched comparison of 4 SE TAVI devices showed no differences regarding residual AR and in-hospital mortality.
- ACURATE neo was superior in terms of the absolute need for permanent pacemaker implantation.
- New iterations of current self-expandable TAVI devices should address the excessive pacemaker rate currently presented by most SE TAVI devices through more accurate positioning without increasing the risk of paravalvular leak.

APPENDIX. SUPPLEMENTARY DATA

Supplementary data associated with this article can be found in the online version available at https://doi.org/10.1016/j.rec.2020.09.014

REFERENCES

1. Leon MB, Smith CR, Mack M, et al. Transcatheter aortic-valve implantation for aortic stenosis in patients who cannot undergo surgery. *N Engl J Med.* 2010;363:1597–1607.
2. Leon MB, Smith CR, Mack MJ, et al. Transcatheter or surgical aortic-valve replacement in intermediate-risk patients. *N Engl J Med.* 2016;374:1609–1620.
3. Mack MJ, Leon MB, Thouran VH, et al. Transcatheter aortic-valve replacement with a balloon-expandable valve in low-risk patients. *N Engl J Med.* 2019;380:1695–1705.
4. Popma JJ, Deeb GM, Yakubov SJ, et al. Transcatheter aortic-valve replacement with a self-expanding valve in low-risk patients. *N Engl J Med.* 2019;380:1706–1715.
5. Dworakowski R, Wendler O, Halliday B, et al. Device-dependent association between paravalvar aortic regurgitation and outcome after TAVI. *Heart.* 2014;100:1939–1945.
6. Regazzoli D, Chiarito M, Cannata F, et al. Transcatheter self-expandable valve implantation for aortic stenosis in small aortic annuli: the TAVI-SMALL registry. *JACC Cardiovasc Interv.* 2020;13:196–206.
7. Barbanti M. Avoiding coronary occlusion and root rupture in TAVI - the role of pre-procedural imaging and prosthesis selection. *Interv Cardiol.* 2015;10:94–97.
8. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve replacement: part 1: basic anatomy, imaging, sheaths, wires, and access routes. *JACC Cardiovasc Interv.* 2013;6:643–653.
9. Toggweiler S, Leipsic J, Binder RK, et al. Management of vascular access in transcatheter aortic valve implantation: part 2: vascular complications. *JACC Cardiovasc Interv.* 2013;6:767–776.
10. Abdel-Wahab M, Comberg T, Büttner HJ, et al. Aortic regurgitation after transcatheter aortic valve implantation with balloon- and self-expandable prostheses: a pooled analysis from a 2-center experience. *JACC Cardiovasc Interv.* 2014;7:284–292.
11. Athappan G, Patvardhan E, Tuzcu EM, et al. Incidence, predictors, and outcomes of aortic regurgitation after transcatheter aortic valve implantation: meta-analysis and systematic review of literature. *J Am Coll Cardiol.* 2013;61:1585–1595.
12. Wang N, Lal S. Post-dilation in transcatheter aortic valve implantation: a systematic review and meta-analysis. *J Interv Cardiol.* 2017;30:204–211.
13. Jose J, Richardt G, Abdel-Wahab M. Balloon- or self-expandable TAVI: clinical equipoise? *Interv Cardiol.* 2015;10:103–108.
14. Kappetein AP, Head SJ, Généreux P, et al. Updated standardized endpoint definitions for transcatheter aortic valve implantation: the Valve Academic Research Consortium-2 consensus document. *J Thorac Cardiovasc Surg.* 2013;145:6–23.
15. Zoghbi WA, Asch FM, Bruce C, et al.Guidelines for the evaluation of valvular regurgitation after percutaneous valve repair or replacement: a report from the American Society of Echocardiography developed in collaboration with the Society for Cardiovascular Angiography and Interventions, Japanese Society of Echocardiography, and Society for Cardiovascular Magnetic Resonance. *J Am Soc Echocardiogr.* 2019;32:431–475.
16. Department of Cardiology of the Institute of Heart Sciences (ICICOR) at the Clinical University Hospital of Valladolid. Imaging Unit ICICORELAB. Available at: http://www.icicorelab.es. Accessed 15 Sep 2020.
17. Achenbach S, Delgado V, Hausleiter J, Schoenhagen P, Min JK, Leipsic JA. SCCT expert consensus document on computed tomography imaging before transcatheter aortic valve implantation (TAVI)/transcatheter aortic valve replacement (TAVR). *J Cardiovasc Comput Tomogr.* 2012;6:366–380.
18. Ho D, Imai K, King G, Stuart EA. Matching as nonparametric preprocessing for reducing model dependence in parametric causal inference. *Polit Anal.* 2007;15:199–236.
19. Chieffo A, Buchanan GL, Van Mieghem NM, et al.Transcatheter aortic valve implantation with the Edwards SAPIEN versus the Medtronic CoreValve Revalving system devices: a multicenter collaborative study: the PRAGMATIC Plus Initiative (Pooled-RotterdAm-Milano-Toulouse In Collaboration). *J Am Coll Cardiol.* 2013;61:830–836.
20. Nombela-Franco L, Ruel M, Radhakrishnan S, et al. Comparison of hemodynamic performance of self-expandable CoreValve versus balloon-expandable Edwards SAPIEN aortic valves inserted by catheter for aortic stenosis. *Am J Cardiol.* 2013;111:1026–1033.
21. Abdel-Wahab M, Mehilli J, Frerker C, et al. Comparison of balloon-expandable vs self-expandable valves in patients undergoing transcatheter aortic valve replacement: the CHOICE randomized clinical trial. *JAMA.* 2014;311:1503–1514.
22. Ribeiro HB, Urena M, Allende R, Amat-Santos IJ, Rodés-Cabau J. Balloon-expandable prostheses for transcatheter aortic valve replacement. *Prog Cardiovasc Dis.* 2014;56:583–595.
23. Kumar R, Latib A, Colombo A, Ruiz CE. Self-expanding prostheses for transcatheter aortic valve replacement. *Prog Cardiovasc Dis.* 2014;56:596–609.
24. Barbanti M, Buccheri S, Rodés-Cabau J, et al. Transcatheter aortic valve replacement with new-generation devices: a systematic review and meta-analysis. *Int J Cardiol.* 2017;245:83–89.
25. Pagnesi M, Kim WK, Conradi L, et al. Transcatheter aortic valve implantation with next-generation self-expanding devices: a multicenter, retrospective, propensity-matched comparison of Evolut PRO versus ACURATE neo transcatheter heart valves. *JACC Cardiovasc Interv.* 2019;12:433–443.
26. Costa G, Buccheri S, Barbanti M, et al. Outcomes of three different new generation transcatheter aortic valve prostheses. *Catheter Cardiovasc Interv.* 2020;95:398–407.
27. Giordano A, Corcione N, Ferraro P, et al. Comparative one-month safety and effectiveness of five leading new-generation devices for transcatheter aortic valve implantation. *Sci Rep.* 2019;9:17098.
28. Mas-Peiro S, Seppelt PC, Weiler H, et al. A direct comparison of self-expandable Portico versus balloon-expandable Sapien 3 devices for transcatheter aortic valve replacement: a case-matched cohort study. *J Invasive Cardiol.* 2019;31:E199–E204.

29. Gorla R, De Marco F, Morganti S, et al. Transcatheter aortic valve implantation with the Portico and Evolut R bioprostheses in patients with elliptic aortic annulus. *EuroIntervention.* 2020;15:e1588–e1591.
30. Cuevas O, Moreno R, Pascual-Tejerina V, et al. The Allegra transcatheter heart valve: European multicentre experience with a novel self-expanding transcatheter aortic valve. *EuroIntervention.* 2019;15:71–73.
31. Tang GHL, Zaid S, Michev I, et al. Cusp-Overlap" view simplifies fluoroscopy-guided implantation of self-expanding valve in transcatheter aortic valve replacement. *JACC Cardiovasc Interv.* 2018;11:1663–1665.
32. Schäfer U, Butter C, Landt M, et al. Thirty-day outcomes of a novel transcatheter heart valve to treat degenerated surgical valves: the VIVALL multicentre, single-arm, pilot study. *EuroIntervention.* 2019;15:e757–e763.