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Impact of aortic landing zone geometry on TAVI implantation depth: comparison between ACURATE *neo2* and Portico/Evolut

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ABSTRACT

Background During transcatheter aortic valve implantation (TAVI), increased aortic angulation can affect the final implantation depth of self-expandable (SE) devices due to the interaction between the high stent frame and the targeted aortic landing zone (LZ). We herein sought to investigate the behaviour of the ACURATE *neo2*, a SE device with a unique release mechanism, in relation to patient-specific angulation and curvature of the aortic LZ.

Methods The mismatch between the intended and the final implantation depth (ΔH) was compared between patients treated with ACURATE *neo2* (Acurate, n=106) and Evolut/Portico (n=101) SE devices. To do so, curvature ($\kappa_{LZ,tot}$) and angulation ($\alpha_{LZ,Dist}$) were calculated based on the three-dimensional aortic LZ centerline available from pre-TAVI CT.

Results The Acurate and Evolut/Portico groups showed a negligible difference (p=0.09) for ΔH averaged between non-coronary (NCC) and left coronary cusp (LCC). However, when splitting both ΔH_{NCC} and ΔH_{LCC} values into two subgroups based on $\kappa_{LZ,tot}$ and $\alpha_{LZ,Dist}$ median values, ΔH significantly increased on LCC compared with NCC in Evolut/Portico patients with high LZ curvature ($\kappa_{LZ,tot}$ >0.123/mm, p=0.016) and high LZ distal angulation ($\alpha_{LZ,Dist}$ >28.5°, p=0.012). No statistically significant differences arose within the Acurate group.

Conclusions Among SE devices, the ACURATE *neo2* was the least affected by the curvature and angulation of the LZ anatomy, leading to a more predictable and symmetrical implantation depth. The clinical impact of this finding on TAVI outcomes in patients with an angulated aortic LZ warrants further investigation in larger studies.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ During transcatheter aortic valve implantation (TAVI), increased aortic angulation at the targeted landing zone (LZ) can influence the final implantation depth of self-expandable (SE) devices.

WHAT THIS STUDY ADDS

⇒ The study examined the impact of the patient-specific aortic LZ on the final implantation depth of ACURATE *neo2*. Among SE devices, ACURATE *neo2* showed the least sensitivity to LZ anatomy, achieving a symmetrical depth closely matching the intended target on full release, even in patients with an angulated aortic LZ.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The ACURATE *neo2* unique release mechanism enables a more predictable, symmetrical implantation depth during TAVI. This may help reduce postprocedural permanent pacemaker implantation and paravalvular leakage, warranting further investigation in patients with angulated aortic LZ.

INTRODUCTION

Transcatheter aortic valve implantation (TAVI) has become the preferred treatment for patients with severe aortic stenosis across different surgical risk levels.[1–3] Greater aortic angulation, commonly referred to as a horizontal aorta, is recognised as an anatomical factor that can complicate TAVI procedures. Some studies suggest it may also impact procedural success, although the evidence remains inconclusive.[4–8] We have recently reported that the interaction between the transcatheter heart valve (THV) and the aorta, namely the angulation of the aortic landing zone (LZ), may affect the final position of self-expandable (SE) Portico (Abbott, Minneapolis, Minnesota, USA) and Evolut-R/Pro+ (Medtronic, Minneapolis, Minnesota, USA) devices, which have a high stent frame, as compared with balloon-expandable (BE) Sapien 3 (Edwards Lifesciences, Irvine, California, USA) and Myval (Meril Life Sciences Pvt, Vapi, Gujarat, India) devices with a short stent frame.[9]

ACURATE *neo2* (Boston Scientific, Marlborough, Massachusetts, USA) is a SE device with a high stent frame around 50 mm comparable to that of Evolut-R/Pro+ and Portico, but the THV frame is complemented by top-down deployment and stabilisation arches.[10] Phase 1 of valve release consists of the opening of the upper crown and stabilisation arches which facilitate coaxial alignment between the THV and aortic root (AR) as well as the capping of the aortic leaflets. During phase 2, the distal part of the stent crown is released, providing valve anchoring to aortic leaflets to prevent asymmetric THV sliding in the left ventricle. However, the performance of this device according to the anatomy of the aortic LZ has been poorly explored.[11]

Hence, we herein sought to investigate the impact of angulation and curvature of the aortic LZ on the final implantation depth of ACURATE *neo2*, as compared with both Portico and Evolut-R/Pro+ SE devices.

METHODS

This study originated from a retrospective, single-centre registry enrolling consecutive patients with severe aortic stenosis, available preoperative CT scan and measurements of implantation depth treated up to March 2023 at IRCCS Policlinico San Donato (San Donato Milanese, Italy). The study protocol was approved by the local ethics committee of IRCCS Ospedale San Raffaele (protocol code 'AI4TAVI', No. 33/INT/2023, approved on 15 March 2023) and conducted in accordance with the principles of the Declaration of Helsinki. Due to the retrospective nature of the study and use of anonymised data, informed consent was waived.

Data analysis

Data were retrieved from TAVI recipients treated between December 2016 and September 2021 with one of the following THVs: Evolut-R/Pro+ (Medtronic, Minneapolis, Minnesota, USA), Portico (Abbott, Minneapolis, Minnesota, USA), ACURATE *neo2*™ (Boston Scientific, Marlborough, Massachusetts, USA). Patients were excluded in case of valve-in-valve TAVI or bicuspid aortic valve. Patients were subsequently divided into two groups based on the implanted THV: (i) ACURATE *neo2* (Acurate) and (ii) Portico or Evolut-R/Pro+ (Portico/Evolut).

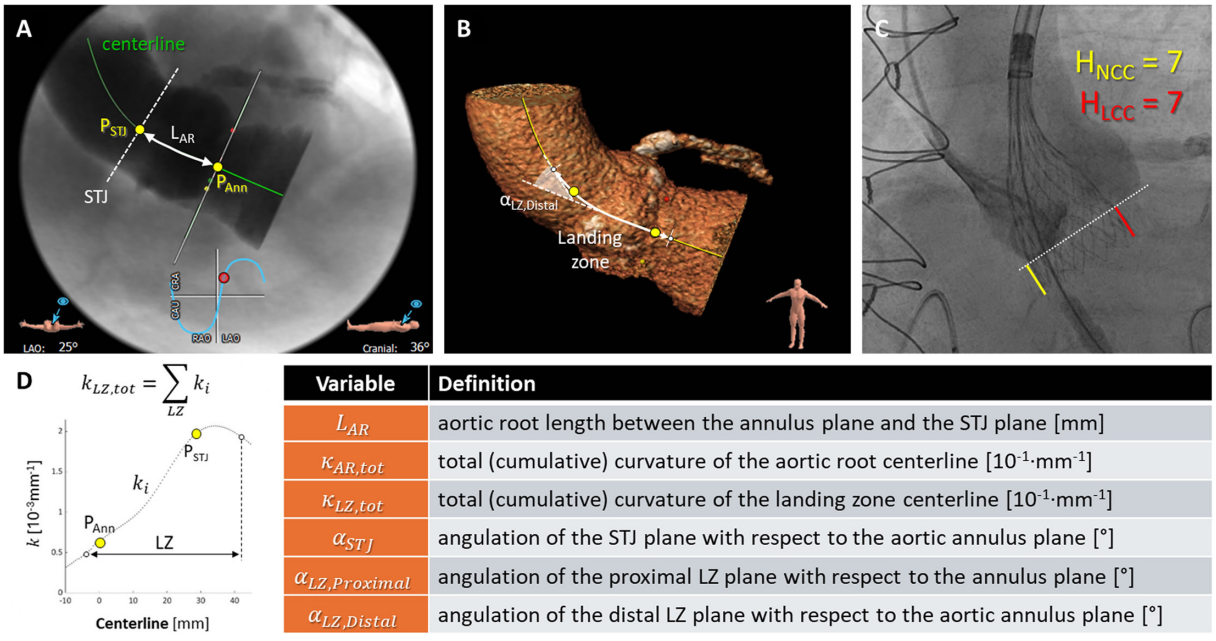
A comprehensive description of the methods used in this study has been published and is freely accessible in our previous work.[9] Briefly, the following procedure was employed (figure 1):

Pre-TAVI imaging

CT angiography was acquired on a 256-row multidetector scanner (Siemens Healthineers, Erlangen, Germany), and optimal systolic reconstruction (BestSyst) was considered from ECG-gated image sequential acquisition.

Image post-processing

A trained operator imported and postprocessed each dataset in 3mensio Structural Heart (V.8.2, Pie Medical Imaging BV, Maastricht, The Netherlands) to extract three-dimensional aortic centerline. This process involved verifying the automatically generated centerline through multiplanar reconstruction views and adjusting the position of the centerline control points as needed. Both positions of the annulus plane (P_{Ann}) and sinotubular junction (P_{STJ}), which delimit the AR unit, were



Variable	Definition
L_{AR}	aortic root length between the annulus plane and the STJ plane [mm]
$\kappa_{AR,tot}$	total (cumulative) curvature of the aortic root centerline [10^{-1}·mm^{-1}]
$\kappa_{LZ,tot}$	total (cumulative) curvature of the landing zone centerline [10^{-1}·mm^{-1}]
α_{STJ}	angulation of the STJ plane with respect to the aortic annulus plane [°]
$\alpha_{LZ,Proximal}$	angulation of the proximal LZ plane with respect to the annulus plane [°]
$\alpha_{LZ,Distal}$	angulation of the distal LZ plane with respect to the aortic annulus plane [°]

Figure 1 Pipeline of landing zone (LZ) analysis based on aortic centerline extracted from pre-TAVI CT imaging (A,B), intraprocedural evaluation of the implantation depth (C) and extraction of geometric features from the aortic LZ centerline (D). LCC, left coronary cusp; NCC, non-coronary cusp; TAVI, transcatheter aortic valve implantation.

annotated along the centerline. Aortic angulation, defined as the angle between the horizontal plane and the annulus,[6] was measured on CT angiography using the implantation projection in which the three coronary cusps were aligned.

LZ analysis

A purposely-defined code written in Matlab (The MathWorks, Natick, Massachusetts, USA) was used to extract LZ geometric features from its centerline, as detailed in figure 1. Accordingly, each LZ length was determined based on the nominal height of the corresponding implanted THV and taking its label size into account: 50÷53 mm for Portico, 45÷46 mm for Evolut-R/Pro+ and 50 mm for ACURATE THVs. For all the THVs, a theoretical implant depth of 4 mm was assumed; further details available in theonline supplemental material 1 .

Procedure endpoint

The mismatch (ΔH) between the intended (H_{Pre}) and the final (H_{Post}) implantation depth ($\Delta H = H_{Post} - H_{Pre}$) was calculated for each THV. The implantation depth was defined by averaging the maximal distance (expressed in millimetres) between the intraventricular end of the bioprosthesis and the aortic annulus at the level of both the non-coronary cusp (NCC) and the left coronary cusp (LCC). This measurement was extracted from the implantation projection where the inflow edges are aligned.[12] The choice of implantation projection was left to the operator's discretion, allowing the use of either the three-cusps or cusp overlap views, guided by projection angulations predicted from CT angiography using 3mensio. Since 2019, the cusp overlap view has been more commonly employed. ΔH was computed at both cusps, yielding ΔH_{NCC} and ΔH_{LCC}, which were finally averaged to obtain the mean value ΔH_{mean}. The intended implantation depth was measured with the valve opened up to the non-recapture point for Portico/Evolut and with the valve capping the aortic leaflets and opened stabilisation arches for Acurate, prior to complete release. Also, device success after TAVI was defined according to the Valve Academic Research Consortium 3 (VARC-3) definition.[13]

Statistical analysis

The normality of data distribution was assessed using the Kolmogorov-Smirnov and Shapiro-Wilk tests. Continuous variables with a normal distribution are presented as mean±SD, while those not following a normal distribution are reported as median and IQR. Variables with a normal distribution were compared using the unpaired student's t-test, whereas the Mann-Whitney U test was applied for skewed distributions. Categorical and dichotomous variables are expressed as counts and percentages and were compared using Pearson's χ^2 or Fisher's exact tests, as appropriate. All p values were two-sided, with values <0.05 considered statistically significant. Statistical analyses were conducted using SPSS V.28.0 (IBM Italia, Milano, Italy).

RESULTS

The study population included 106 patients treated with ACURATE, 22 with Evolut Pro+, 53 with Evolut-R and 26 with Portico THVs.

Baseline characteristics and LZ features

Baseline characteristics, including echocardiographic and CT-based measurements, are summarised in table 1. Patients in the Acurate group were older (p=0.003) and females were more represented (p<0.001). Differences between the two groups were not statistically significant in terms of most cardiovascular risk factors, specifically Society of Thoracic Surgeons score, creatinine clearance and aortic valve calcium score. Regarding echocardiographic features, the Acurate group showed higher left ventricle ejection fraction (p=0.04); on CT angiography, Acurate patients also reported greater aortic angulation (p<0.001) than Portico/Evolut patients as well as smaller diameters of aortic annulus (p<0.001), left ventricle outflow trunk (p=0.02) and sinuses of Valsalva (p<0.001) diameters. Focusing on LZ-specific baseline features (figure 2), the Acurate group showed a significantly higher $\kappa_{LZ,tot}$ compared with the Portico/Evolut group (p=0.008), with median values equal to 0.137/mm and 0.123/mm, respectively. Additionally, $\alpha_{LZ,Dist}$ was also significantly higher in the Acurate group (p<0.001), with a median value of 40.0° compared with 28.5° in the Portico/Evolut group.

Further comparison between the Portico and Evolut subgroups revealed that, based on baseline anatomical characteristics (online supplemental material 1), the Portico platform was preferred over Evolut for patients with smaller aortic dimensions. Notably, there were no significant differences between the Portico and Evolut THVs in terms of baseline curvature ($k_{LZ,tot}$) or angulations ($\alpha_{LZ,Proximal}$ and $\alpha_{LZ,Distal}$).

Procedural data and in-hospital outcome

Procedural data and in-hospital outcome are detailed in table 2. Transfemoral access was used in the majority of patients (93.7%), while the subclavian access route was more frequent in the Portico/Evolut group (p=0.001), which also reported lower rates of predilatation (p<0.001) with respect to the Acurate group. Negligible differences were detected between the two groups in terms of vascular complications and stenting of the access site; of note, PCI with stenting during TAVI was more frequent in the Portico/Evolut group (p=0.03).

Overall device success was satisfying and equal to 94.7%; though without reaching statistical significance, it was higher for Accurate than Portico/Evolut group (96.2% *vs* 93.1%). Permanent pacemaker implantation (PPI) was more frequent in the Portico/Evolut group (p=0.004); post-TAVI mean gradient, though statistically different (p<0.001) between the two groups, reported median values of 9.0 mm Hg and 7.0 mm Hg in the Acurate and Portico/Evolut groups, respectively.

Table 1 Baseline patient characteristics

Variables	Overall (n=207)	Acurate (n=106)	Portico/Evolut (n=101)	P value*
Age (years)	82 (79, 86)	84 (80, 87)	81 (77, 85)	**0.003**
Female sex	107 (51.7)	69 (65.1)	38 (37.6)	**<0.001**
BSA (m^2)	1.83±0.20	1.80±0.19	1.86±0.20	**0.03**
Hypertension	163 (78.7)	91 (85.9)	73 (72.3)	**0.02**
Diabetes	54 (26.1)	27 (25.5)	27 (26.7)	0.86
Dyslipidaemia	94 (45.4)	51 (48.1)	43 (42.6)	0.49
COPD	23 (11.1)	8 (7.6)	15 (14.9)	0.12
CAD	44 (21.3)	16 (15.1)	28 (27.7)	**0.03**
Prior AF	64 (30.9)	37 (34.9)	27 (26.7)	0.23
Prior CABG	22 (10.6)	7 (6.6)	15 (14.9)	0.07
Prior AMI	16 (7.7)	10 (9.4)	6 (5.9)	0.44
STS score (%)	2.7 (2.0, 4.3)	2.5 (2.0, 3.2)	3.2 (2.0, 5.3)	0.06
Creatinine clearance (mL/min/1.73 m^2)	61 (44, 77)	65 (46, 79)	57 (43, 73)	0.08
Haemoglobin (g/dL)	12.7±1.7	12.9±1.6	12.4±1.8	0.08
Ejection fraction (%)	60.0 (54.0, 66.0)	61 (55.0, 67.0)	58.5 (50.0, 65.0)	**0.04**
Mean AV gradient (mm Hg)	44.6±13.6	43.5±12.2	45.7±14.8	0.24
Aortic regurgitation≥moderate	32 (15.5)	15 (14.2)	17 (16.8)	0.70
LM height (mm)	14.3±3.6	13.1±2.9	15.5±3.8	**<0.001**
RCA height (mm)	17.9±3.6	16.8±3.0	19.2±3.9	**<0.001**
Annulus minimal diameter (mm)	21.1±2.5	20.7±1.9	21.5±2.9	**0.02**
Annulus maximal diameter (mm)	26.6±2.4	25.8±1.9	27.4±2.6	**<0.001**
Annulus mean diameter (mm)	23.9±2.1	23.3±1.6	24.5±2.4	**<0.001**
Annulus perimeter (mm)	75.3±6.5	73.5±5.0	77.2±7.4	**<0.001**
Annulus area (mm^2)	439.6±80.5	418.5±59.5	461.7±93.2	**<0.001**
LVOT diameter (mm)	23.5±2.6	23.1±1.9	23.9±3.1	**0.02**
Valsalva diameter (mm)	32.4±3.6	31.5±3.2	33.4±3.7	**<0.001**
Calcium volume 800 HU (mm^3)	214 (118, 453)	223 (119, 384)	184 (112, 470)	0.66
Aortic angulation (°)	50.5±10.4	53.1±10.8	47.8±9.3	**<0.001**
Index of eccentricity	0.20 (0.17, 0.25)	0.19 (0.16, 0.23)	0.21 (0.17, 0.26)	0.07
L_{AR} (mm)	20.8±3.5	20.0±3.3	21.7±3.6	**<0.001**
$k_{AR,tot}$ (/10/mm)	0.33 (0.21, 0.43)	0.30 (0.21, 0.40)	0.35 (0.25, 0.45)	**0.03**
$k_{LZ,tot}$ (/10/mm)	1.31 (1.09, 1.52)	1.37 (1.22, 1.59)	1.23 (1.01, 1.48)	**<0.001**
α_{STJ} (°)	8.6 (5.3, 12.6)	9.1 (5.4, 12.7)	8.3 (5.1, 12.1)	0.54
$\alpha_{LZ,Proximal}$ (°)	2.1 (1.1, 3.1)	1.7 (1.1, 2.8)	2.5 (1.3, 3.9)	**0.006**
$\alpha_{LZ,Distal}$ (°)	34.0 (25.9, 42.9)	40.0 (31.1, 45.7)	28.5 (21.5, 37.1)	**<0.001**

Values expressed as mean±SD, median (IQR) or n (% of column total).
Significant values (p<0.05) are in bold.
*Acurate versus Portico+Evolut.
AF, atrial fibrillation; AMI, acute myocardial infarction; BSA, body surface area; CABG, coronary artery bypass grafting; CAD, coronary artery disease; COPD, chronic obstructive pulmonary disease; HU, Hounsfield units; $k_{AR,tot}$, total (cumulative) curvature of the aortic root centerline; $k_{LZ,tot}$, total (cumulative) curvature of the landing zone centerline; L_{AR}, aortic root length; LM, left main; LVOT, left ventricle outflow trunk; LZ, landing zone; RCA, right coronary artery; STJ, sinotubular junction; STS, Society of Thoracic Surgeons; $\alpha_{LZ,Distal}$, angulation of the distal LZ plane with respect to the aortic annulus plane; $\alpha_{LZ,Proximal}$, angulation of the proximal LZ plane with respect to the aortic annulus plane; α_{STJ}, angulation of the STJ plane with respect to the aortic annulus plane.

Ejection fraction remained higher in the Acurate group (p=0.02), as already noticed at baseline. Rate of at least moderate paravalvular leak (PVL>moderate) remained comparable among the two groups (p=0.09), although it was higher in the Portico/Evolut group with a percentage rate of 6.9% against 1.9% in the Acurate group.

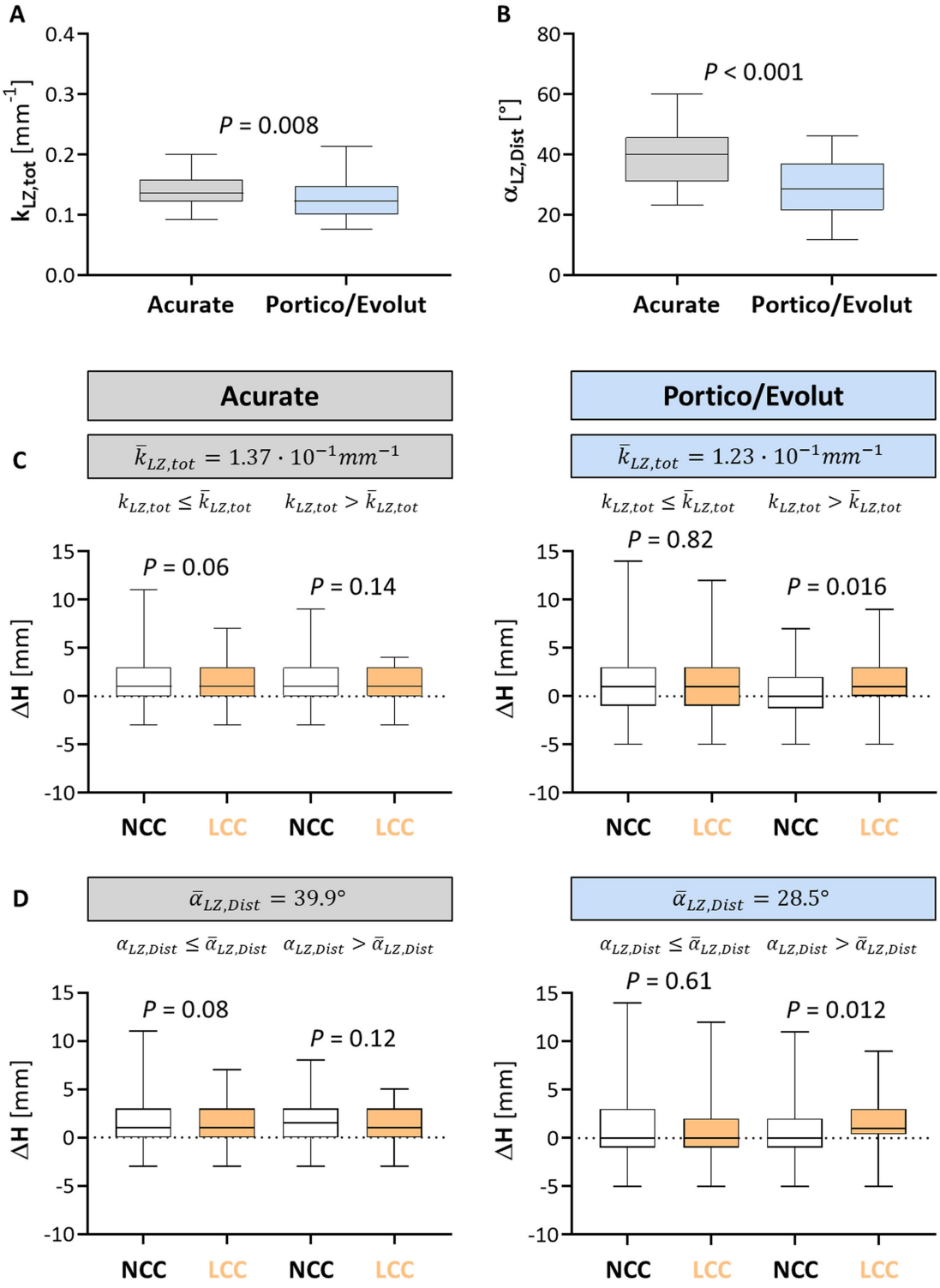


Figure 2 Box and whisker plots of (A) $\kappa_{LZ,tot}$ and (B) $\alpha_{LZ,Dist}$ distributions along the aortic LZ centerline. Box and whisker plots of ΔH values clustered within the Acurate and the Portico/Evolut groups according to the median value of (C) $\kappa_{LZ,tot}$ and (D) $\alpha_{LZ,Dist}$, respectively. LZ, landing zone; LCC, left coronary cusp; NCC, non-coronary cusp.

Implantation depth

The Acurate and Portico/Evolut groups showed a negligible difference in terms of ΔH_{mean}, when averaged across both aortic cusps (p=0.09). When examining individual cusps, ΔH_{NCC} was significantly higher in the Acurate group compared with Portico/Evolut (p=0.009), while ΔH_{LCC} remained comparable between the two groups. Differences were statistically negligible also when comparing ΔH values between NCC and LCC cusps within the same group (p=0.20 for Acurate and p=0.12 for Portico/Evolut). The Evolut platform reported a deeper intended implantation depth (H_{Pre}) at the LCC level compared with the Portico platform with median values of 7.0 mm and 5.0 mm, respectively (p=0.003 at posthoc analysis,).

Table 2 Procedural and in-hospital outcome

Variables	Overall (n=207)	Acurate (n=106)	Portico/Evolut (n=101)	P value*
Femoral route	194 (93.7)	106 (100)	88 (87.1)	**<0.001**
Subclavian route	9 (4.3)	0 (0.0)	9 (8.9)	**0.001**
EPS	2 (1.0)	0 (0.0)	2 (2.0)	0.24
Any vascular complications	14 (6.7)	10 (9.4)	4 (4.0)	0.17
PTA with stenting of access site	8 (3.8)	5 (4.7)	3 (3.0)	0.72
PCI with stenting	8 (3.8)	1 (0.9)	7 (6.9)	**0.03**
Predilatation	154 (74.4)	104 (98.1)	50 (49.5)	**<0.001**
Implantation depth				
NCC H_{Pre} (mm)	5.0 (4.2, 6.0)	5.1 (4.3, 5.7)	5.0 (4.0, 7.0)	0.13
LCC H_{Pre} (mm)	6.3 (5.0, 7.5)	6.2 (5.3, 7.2)	7.0 (5.0, 8.0)	0.15
NCC H_{Post} (mm)	6.6 (4.8, 8.2)	6.5 (4.8, 8.3)	7.0 (4.6, 8.0)	0.56
LCC H_{Post} (mm)	7.5 (6.0, 9.0)	7.2 (6.2, 8.8)	8.0 (6.0, 10.0)	0.29
ΔH_{NCC} (mm)	1.0 (-0.3, 3.0)	1.3 (0.1, 3.0)	0.0 (-1.0, 2.5)	**0.009**
ΔH_{LCC} (mm)	1.0 (-0.1, 3.0)	1.0 (–0.1, 2.8)	1.0 (0.0, 3.0)	0.88
ΔH_{mean} (mm)	1.0 (-0.3, 2.7)	1.6 (0.2, 2.8)	0.5 (-0.5, 2.5)	0.09
Postdilatation	98 (47.3)	48 (45.3)	52 (51.5)	0.41
Emergent cardiac surgery	0 (0.0)	0 (0.0)	0 (0.0)	–
Need for second valve	0 (0.0)	0 (0.0)	0 (0.0)	–
Contrast volume (mL)	151 (130, 200)	157 (130, 200)	150 (125, 184)	0.30
Radiation time (min)	22.0 (17.1, 27.5)	21.4 (17.5, 26.9)	22.2 (16.1, 28.5)	0.79
In-hospital outcome				
Ejection fraction (%)	60.0 (55.0, 66.0)	62.0 (56.0, 67.0)	58.5 (52.3, 65.0)	**0.02**
Mean gradient (mm Hg)	8.0 (6.0, 11.0)	9.0 (7.0, 12.0)	7.0 (5.0, 10.0)	**<0.001**
PVL≥moderate	9 (4.3)	2 (1.9)	7 (6.9)	0.09
Device success	196 (94.7)	102 (96.2)	94 (93.1)	0.36
PPI	20 (9.7)	4 (3.8)	16 (15.8)	**0.004**
Stroke	5 (2.4)	2 (1.9)	3 (3.0)	0.67
In-hospital mortality	0 (0.0)	0 (0.0)	0 (0.0)	–

Values expressed as mean±SD, median (IQR) or n (% of column total). Mismatch in implantation depth (ΔH) calculated as $H_{Post} - H_{Pre}$.
Significant values (p<0.05) are in bold.
*Acurate versus Portico+Evolut.
EPS, embolic protection system; H_{Post}, final implantation depth; H_{Pre}, preimplantation intended depth; LCC, left coronary cusp; NCC, non-coronary cusp; PCI, percutaneous coronary intervention; PPI, permanent pacemaker implantation; PTA, percutaneous transluminal angioplasty; PVL, paravalvular leak; ΔH, variation of implantation depth.

When splitting both ΔH_{NCC} and ΔH_{LCC} values into two subgroups according to the median value of $\kappa_{LZ,tot}$ (figure 2C) and $\alpha_{LZ,Dist}$ (figure 2D), differences arose between ΔH_{NCC} and ΔH_{LCC} in the Portico/Evolut group only. Indeed, ΔH significantly increased on the LCC cusp compared with the NCC one in Portico/Evolut patients associated with high LZ curvature ($\kappa_{LZ,tot}$ above 0.123/mm median value, p=0.016) and high LZ distal angulation ($\alpha_{LZ,Dist}$ above 28.5° median value, p=0.012).

Specifically, as shown by the Bland-Altman analysis of the differences between ΔH_{LCC} and ΔH_{NCC} (), the Acurate group exhibited a consistent bias of –0.6mm with comparable limits of agreement, regardless of both LZ curvature ($\kappa_{LZ,tot}$) and distal angulation ($\alpha_{LZ,Dist}$). Conversely, in the Portico/Evolut group, the bias markedly changed from –0.3mm in patients with low $\kappa_{LZ,tot}$ (and low $\alpha_{LZ,Dist}$) to 1.2mm in patients with high $\kappa_{LZ,tot}$ (and high $\alpha_{LZ,Dist}$).

DISCUSSION

The main finding of the present study is that ACURATE *neo2*, despite being a high-frame SE valve, is less sensitive to the curvature and angulation of the LZ anatomy compared with Portico/Evolut THVs. This results in a symmetrical implantation depth, closely matching the intended depth on complete release, even in patients

with an angulated aortic LZ. Indeed, when aortic LZ curvature and angulation increase, Portico/Evolut THVs exhibited significant sliding of the distal valve frame on LCC on complete release, due to the interaction between the upper part of the THV and ascending aorta.

Historically, the so-called horizontal aorta, defined by an aortic angulation ≥48◦, has been associated with lower rates of device success with SE as compared with BE valves,[5 7] whereas other groups demonstrated no significant differences.[8 14]

In a previous study, we investigated additional factors that may explain the discrepancies observed in the literature.[9] We found that the geometry of the entire aortic LZ, including both the AR and the proximal portion of the ascending aorta during SE valve implantation, progressively interacts with the THV during release and ultimately affects its final position, particularly when the LZ centerline has significant curvature and angulation. Indeed, our previous analysis demonstrated that increased angulation of the distal THV portion of the LZ significantly affects the final release of the device, resulting in a mismatch, i.e., ΔH, between the actual and intended implantation depth. Specifically, the final implantation depth of SE devices like Evolut-R, Evolut Pro+ and Portico tends to be deeper than intended, particularly on LCC due to the interaction between the high THV frame and the inner wall of the aortic lumen, especially during the final THV release.

In the context of horizontal aorta, the first iteration of the ACURATE *neo* THV demonstrated higher device success compared with Evolut R/Pro+,[5] although it was also associated with a higher rate of moderate or greater PVL.[15] Recently, in patients with horizontal aorta, ACURATE *neo*2 has been associated with a lower incidence of moderate or greater PVL compared with its predecessor, while maintaining comparable procedural success.[11]

To the best of our knowledge, this is the first attempt to evaluate the behaviour of the Acurate *neo*2 in relation to patient-specific geometrical features of the aortic LZ. According to our data, the ACURATE *neo2* exhibited a comparable and symmetrical implantation depth between NCC and LCC, regardless of the LZ curvature and angulation; in contrast, significant ΔH differences were observed between NCC and LCC with other self-expanding valves, such as Evolut-R, Evolut Pro+ and Portico.

Our findings can be attributed to the synergistic action of the stabilisation arches and the top-down release mechanism of the ACURATE *neo2* during phase 1, as illustrated in figure 3. We can hypothesise that the conformability of the stabilisation arches to the shape of the ascending aorta helps maintain the coaxial alignment between the THV and the AR during the capping of aortic leaflets by the upper crown. Similarly, the top-down release mechanism allows the operator to evaluate pre-emptively, before complete release, the potential impact of ascending aorta geometry on THV position. For instance, if coaxiality is lost at the end of phase 1, further advancement of the delivery system is required

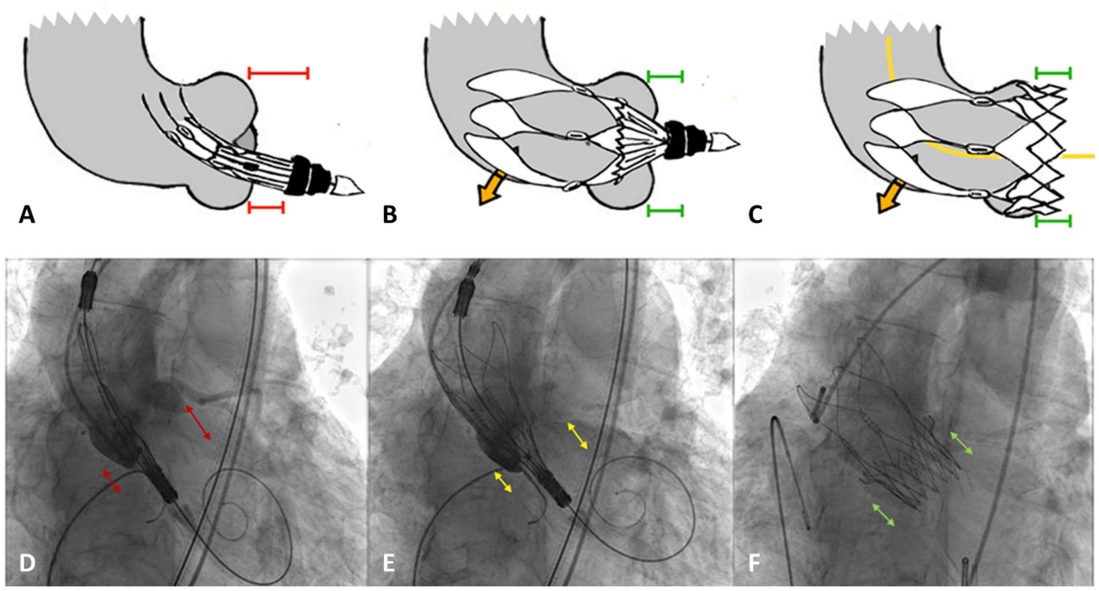


Figure 3 Mechanism of aortic landing zone interaction with ACURATE *neo2* valve. (A–D) Initial positioning of the device with the black marker on the nadir of NCC. Due to the high curvature of the landing zone, the aortic root is not coaxial to the delivery system, leading to asymmetric implantation depth (red arrows). (B–E) During phase 1, the upper stent crown caps the aortic leaflets, and the stabilisation arches are gradually opened. The conformability of stabilisation arches to the curvature of the ascending aorta helps to improve the coaxiality of the whole system during the capping of aortic leaflets; implantation depth gets more symmetrical (yellow arrows). (C–F) During phase 2, the distal part of the stent frame is quickly opened. The valve is free from the tension of the delivery system and achieves its final position in the aortic root, maintaining a symmetrical implantation depth on both NCC and LCC. LCC, left coronary cusp; NCC, non-coronary cusp.

to realign the THV; this can be performed safely with the ACURATE *neo2*, without the risk of the THV sliding into the left ventricle thanks to the capping of aortic leaflets by the upper crown.

The clinical significance of our findings may be relevant in terms of reduction of postprocedural PPI and PVL, both of which have a prognostic impact.[15–17] In this context, the symmetrical implantation depth observed in our analysis for the ACURATE *neo*2 may explain both the low single-digit PPI rate and the lack of correlation between increased aortic angulation and at least moderate PVL, as reported for ACURATE *neo*2 in the ITAL-neo registry.[11]

Finally, as the number of younger and low-risk patients undergoing TAVI will steadily increase in the future,[3 18–20] the need for PPI and the occurrence of PVL will become less and less acceptable. Therefore, enhanced understanding of the strengths and weaknesses of each TAVI system applied in different cohorts of patients is crucial to improve procedural outcomes.

Limitations

The present study has several limitations that need to be taken into consideration.

First, this is a single-centre retrospective study with a relatively small sample size, and therefore possible bias in the selected population could be presumed. Significant differences in baseline characteristics, for example, age, gender and some CT-based features, were noticed between the Acurate and Portico/Evolut groups, with the former also showing a greater median value of aortic LZ angulation and curvature. Nonetheless, these less favourable baseline conditions in the Acurate group did not significantly affect THV implantation depth, thus further supporting the strength of our comparative analysis.

Second, the purpose of this study is purely hypothesis-generating. Larger, prospective studies are needed to determine whether symmetric versus asymmetric THV implantation in patients with angulated LZ anatomies will result in higher rates of PPI and PVL.

Third, the calculation of angulation and curvature of the aortic LZ centerline should be automated, for example, by incorporating these metrics into dedicated automatic workflows[21] and made readily accessible to clinicians during routine TAVI planning.

Fourth, the Portico and Evolut platforms were grouped together due to their shared SE design, similar cell-based stent frame and bottom-up deployment mechanism. However, key differences remain, most notably in delivery system flexibility: Portico's FlexNav uses a single-spine design allowing multidirectional flexion, while Evolut's Enveo system employs a dual-spine structure limiting flexion to two directions. Also, the Portico stent is slightly longer (further details available in the). Therefore, a subanalysis of baseline and procedural characteristics stratifying the study population also by Portico and Evolut platforms is available in the .

CONCLUSION

The final position of ACURATE *neo*2 is not affected by the angulation and curvature of the device LZ anatomy, leading in all cases to a symmetrical implantation depth between NCC and LCC, as compared with Evolut-R, Evolut Pro+ and Portico THVs, which showed significant sliding on LCC on complete release in the presence of an angulated LZ.

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Competing interests FB is a proctor for Medtronic, Abbott and Boston Scientific; NB and LT are proctors for Abbott and Boston Scientific. All the remaining authors declare no competing interests.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. The study protocol was approved by the local ethics committee of IRCCS Ospedale San Raffaele (protocol code 'AI4TAVI', No. 33/INT/2023, approved on 15 March 2023). Due to the retrospective nature of the study and use of anonymised data, informed consent was waived.

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REFERENCES

1 Mack MJ, Leon MB, Smith CR, *et al*. 5-year outcomes of transcatheter aortic valve replacement or surgical aortic valve replacement for high surgical risk patients with aortic stenosis (PARTNER 1): a randomised controlled trial. *Lancet* 2015;385:2477–84.

2 Leon MB, Smith CR, Mack MJ, *et al*. Transcatheter or Surgical Aortic-Valve Replacement in Intermediate-Risk Patients. *N Engl J Med* 2016;374:1609–20.

3 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;380:1706–15.
4 Veulemans V, Maier O, Bosbach G, *et al*. Novel insights on outcome in horizontal aorta with self-expandable new-generation transcatheter aortic valve replacement devices. *Cathet Cardio Intervent* 2020;96:1511–9.
5 Gallo F, Gallone G, Kim W-K, *et al*. Horizontal Aorta in Transcatheter Self-Expanding Valves: Insights From the HORSE International Multicentre Registry. *Circ Cardiovasc Interv* 2021;14:e010641.
6 Gorla R, De Marco F, Garatti A, *et al*. Impact of aortic angle on transcatheter aortic valve implantation outcome with Evolut-R, Portico, and Acurate-NEO. *Catheter Cardiovasc Interv* 2021;97:E135–45.
7 Abramowitz Y, Maeno Y, Chakravarty T, *et al*. Aortic Angulation Attenuates Procedural Success Following Self-Expandable But Not Balloon-Expandable TAVR. *JACC Cardiovasc Imaging* 2016;9:964–72.
8 Medranda GA, Musallam A, Zhang C, *et al*. The Impact of Aortic Angulation on Contemporary Transcatheter Aortic Valve Replacement Outcomes. *JACC Cardiovasc Interv* 2021;14:1209–15.
9 Gorla R, Oliva OA, Arzuffi L, *et al*. Angulation and curvature of aortic landing zone affect implantation depth in transcatheter aortic valve implantation. *Sci Rep* 2024;14:10409.
10 Reardon MJ. The ACURATE neo™ and neo2™ Valve Systems. *Heart Int* 2021;15:37–41.
11 Barki M, Ielasi A, Buono A, *et al*. Transcatheter aortic valve replacement with the self-expanding ACURATE Neo2 in patients with horizontal aorta: Insights from the ITAL-neo registry. *Int J Cardiol* 2023;389:131236.
12 Petronio AS, Sinning J-M, Van Mieghem N, *et al*. Optimal Implantation Depth and Adherence to Guidelines on Permanent Pacing to Improve the Results of Transcatheter Aortic Valve Replacement With the Medtronic CoreValve System: The CoreValve Prospective, International, Post-Market ADVANCE-II Study. *JACC Cardiovasc Interv* 2015;8:837–46.
13 Généreux P, Piazza N, VARC-3 WRITING COMMITTEE. Valve Academic Research Consortium 3: Updated Endpoint Definitions for Aortic Valve Clinical Research. *J Am Coll Cardiol* 2021;77:2717–46.
14 Di Stefano D, Colombo A, Mangieri A, *et al*. Impact of horizontal aorta on procedural and clinical outcomes in second-generation transcatheter aortic valve implantation. *EuroIntervention* 2019;15:e749–56.
15 Tamburino C, Bleiziffer S, Thiele H, *et al*. Comparison of Self-Expanding Bioprostheses for Transcatheter Aortic Valve Replacement in Patients With Symptomatic Severe Aortic Stenosis: SCOPE 2 Randomized Clinical Trial. *Circulation* 2020;142:2431–42.
16 Pagnesi M, Kim W-K, Baggio S, *et al*. Incidence, Predictors, and Prognostic Impact of New Permanent Pacemaker Implantation After TAVR With Self-Expanding Valves. *JACC Cardiovasc Interv* 2023;16:2004–17.
17 van Wely M, Rooijakkers M, Stens N, *et al*. Paravalvular regurgitation after transcatheter aortic valve replacement: incidence, quantification, and prognostic impact. *Eur Heart J Imaging Methods Pract* 2024;2:qyae040.
18 Prosperi-Porta G, Nguyen V, Willner N, *et al*. Association of Age and Sex With Use of Transcatheter Aortic Valve Replacement in France. *J Am Coll Cardiol* 2023;82:1889–902.
19 Gad MM, Elgendy IY, Saad AM, *et al*. Outcomes of Transcatheter Versus Surgical Aortic Valve Replacement in Patients <60 Years of Age. *Cardiovasc Revasc Med* 2022;43:7–12.
20 Mack MJ, Leon MB, Thourani VH, *et al*. Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients. *N Engl J Med* 2019;380:1695–705.
21 Saitta S, Sturla F, Gorla R, *et al*. A CT-based deep learning system for automatic assessment of aortic root morphology for TAVI planning. *Comput Biol Med* 2023;163:107147.