ORIGINAL RESEARCH

STRUCTURAL

The Coronary Access After TAVI (CAVEAT) Study



A Prospective Registry of CA After TAVR

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ABSTRACT

BACKGROUND As transcatheter aortic valve replacement (TAVR) is now performed in patients with longer life expectancy, the need for coronary access (CA) after TAVR is expected to rise.

OBJECTIVES The aim of this study was to evaluate the feasibility of CA after TAVR with 4 different types of transcatheter heart valves (THVs).

METHODS In the multicenter, prospective CAVEAT (Coronary Access After TAVI; NCTO4647864) registry, coronary angiography was performed immediately following transfemoral TAVR using short-frame SAPIEN 3 or SAPIEN 3 Ultra (SAPIEN 3/Ultra) and tall-frame ACURATE neo or ACURATE neo2 (ACURATE neo/neo2), Portico or Navitor, and Evolut Pro or Evolut Pro+ (Evolut Pro/Pro+) THVs. The primary endpoint was defined as selective CA of both coronary arteries.

RESULTS In total, 632 patients were enrolled (mean age 82 years, 59% women). Selective CA of both coronary arteries was achieved in 89% of SAPIEN 3/Ultra, 63% of ACURATE neo/neo2, 62% of Portico or Navitor, and 45% of Evolut Pro/Pro+ THVs (P < 0.001). Unfeasible CA of at least 1 coronary artery occurred in 2%, 6%, 6%, and 9% of cases, respectively (P = 0.06). In pairwise comparisons, the incidence of the primary endpoint was significantly higher for the SAPIEN 3/Ultra compared with all tall-frame THVs (P < 0.001). Among tall-frame devices, no significant difference was observed between the ACURATE neo/neo2 and the Portico or Navitor (P = 0.9), but both devices demonstrated higher rates of the primary endpoint than the Evolut Pro/Pro+ (P = 0.005 and P = 0.002, respectively). Multivariate analysis identified implantation depth, moderate or severe commissural misalignment, and use of a tall-frame THV as independent predictors of unfeasible or nonselective CA.

CONCLUSIONS The short-frame SAPIEN 3/Ultra THV demonstrated the highest rate of selective CA following TAVR. Among tall-frame THVs, the large-cell designs of the Portico or Navitor and ACURATE neo/neo2 outperformed the closed-cell Evolut Pro/Pro+ in terms of selective CA. (JACC Cardiovasc Interv. 2025;18:1571–1583) © 2025 The Authors. Published by Elsevier on behalf of the American College of Cardiology Foundation. This is an open access article under the CC BY license (http://creativecommons.org/licenses/by/4.0/).

ABBREVIATIONS AND ACRONYMS

CA = coronary access

CAD = coronary artery disease

CT = computed tomographic

LCA = left coronary artery

PCI = percutaneous coronary intervention

RCA = right coronary artery

STJ = sinotubular junction

TAVR = transcatheter aortic valve replacement

THV = transcatheter heart valve

s transcatheter aortic valve replacement (TAVR) becomes increasingly common in younger patients with longer life expectancy, the demand for coronary angiography and percutaneous coronary intervention (PCI) during follow-up is anticipated to rise. Challenges in coronary access (CA) after TAVR have been well documented, particularly with tall-frame compared with short-frame transcatheter heart valves (THVs). However, the degree of difficulty in coronary cannulation varies among tallframe THVs because of differences in key design elements, such as stent cell configuration, leaflet position, commissural posts, and

sealing skirt height, which can significantly influence CA.^{2,3} To overcome these challenges, modifications in implantation techniques have been developed, with a particular emphasis on aligning the neocommissures of tall-frame THVs with the native aortic valve commissures.⁴ Yet prior studies evaluating the success rates of selective coronary cannulation post-TAVR have been limited by their retrospective designs, single-center settings, and small sample sizes and a lack of data on intra-annular self-expanding THVs.5-7 The CAVEAT (Coronary Access After TAVI; NCT04647864) registry represents the first multicenter, prospective registry specifically designed to assess the feasibility of CA immediately following TAVR with the SAPIEN 3 or SAPIEN 3 Ultra (SAPIEN 3/Ultra; Edwards Lifesciences), ACURATE neo or ACURATE neo2 (ACURATE neo/neo2; Boston Scientific), Evolut Pro or Evolut Pro+ (Evolut Pro/Pro+; Medtronic), and Portico or Navitor (Abbott Laboratories) THVs, with adequate statistical power to identify potential differences across devices.

METHODS

STUDY DESIGN AND PATIENT POPULATION. This study was conducted as a prospective analysis from the investigator-driven, international, multicenter CAvEAT registry, including patients undergoing coronary cannulation of both coronary arteries immediately after TAVR using the SAPIEN 3/Ultra, ACURATE neo/neo2, Evolut Pro/Pro+, and Portico or Navitor THVs. All patients underwent TAVR for the treatment of native severe aortic stenosis. Exclusion criteria included the presence of a bicuspid aortic valve, severe chronic kidney disease (glomerular filtration rate <30 mL/min/m²), or known ostial coronary chronic total occlusion. Additionally, patients in whom TAVR technical success, as defined by Valve Academic Research Consortium-3 criteria,8 was not achieved were excluded from the analysis (Figure 1). The choice of coronary catheter and vascular access for coronary angiography was left to the operator's discretion. A maximum of 3 (diagnostic or guiding) catheters were allowed, while the use of coronary guidewire and guide extension catheters was not permitted. No restriction was set by protocol in terms of time or contrast volume limit. Baseline clinical characteristics, aortic root features assessed on computed tomographic (CT) imaging, procedural details, and follow-up data were collected prospectively by investigators at each participating institution in accordance with Valve Academic Research Consortium-3 definitions.8 Data were anonymized and consolidated into a centralized online case report form for statistical analysis. All enrolling centers were high-volume heart valve clinics, each performing at least 100 TAVR procedures annually. The study protocol was approved by the Institutional Review Board

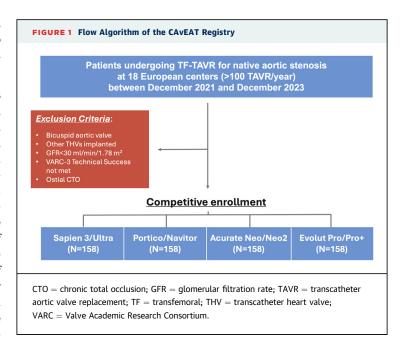
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The authors attest they are in compliance with human studies committees and animal welfare regulations of the authors' institutions and Food and Drug Administration guidelines, including patient consent where appropriate. For more information, visit the Author Center.

or ethics committee at each participating site, and all patients provided written informed consent prior to inclusion. The study adhered to the ethical principles outlined in the Declaration of Helsinki.

DEFINITIONS AND ENDPOINTS. CA was classified as selective if the catheter tip remained stably within the coronary lumen during image acquisition, nonselective if the coronary artery was visualized in its entirety but the catheter tip was positioned outside the coronary ostium, and unfeasible if visualization of the coronary artery could not be achieved. The selectivity of CA was adjudicated by an independent core laboratory. The primary endpoint of the study was defined as the successful achievement of selective CA for both the left coronary artery (LCA) and right coronary artery (RCA). Technical details of coronary cannulation, including the type and number of coronary catheters used, as well as the additional volume of contrast media required to engage the coronary ostia, were systematically recorded. Patients were followed for a 30-day period, and clinical events such as death, stroke, myocardial infarction, acute kidney injury, and need for pacemaker implantation were collected.

THV DESIGN AND COMMISSURAL ALIGNMENT TECHNIQUES. Four different types of THVs were included in the CAvEAT study (Supplemental Figure 1). The intra-annular, short-frame, balloonexpandable SAPIEN 3/Ultra features a frame height ranging from 15.5 to 22.5 mm, depending on valve size. This valve includes an upper row of open cells that are 40% larger than those of its predecessor, the SAPIEN XT.9 Its design incorporates 3 commissural posts positioned approximately 1 mm below the upper edge of the prosthesis frame. The supra-annular, self-expanding Evolut Pro or Evolut Pro+ has a taller frame, with a small diamond-cell design extending above the coronary ostia and a commissural post height of 26 mm.3 Similarly, the supraannular, self-expanding ACURATE neo/neo2 valve also features a tall frame with an open-cell architecture in its upper section, and commissural post heights range from 28 to 31 mm depending on valve size.1 The Portico or Navitor THV has a tall-frame design with intra-annular leaflet positioning, extending up to 21 to 25 mm from the ventricular edge of the valve stent. It incorporates a larger cell design compared with the Evolut Pro/Pro+.10 In accordance with the study protocol, all tall-frame THVs were implanted with the aim of achieving commissural alignment between the THV posts and the native aortic valve commissures. Specific implantation



techniques to optimize commissural alignment for each THV type, except for the SAPIEN 3/Ultra, have been described elsewhere.¹ Postimplantation, fluoroscopic evaluation of commissural misalignment was performed using the ALIGN-TAVR (Alignment of Transcatheter Aortic-Valve Neo-Commissures) Consortium criteria.¹¹

SAMPLE SIZE CALCULATION AND STATISTICAL

ANALYSIS. A sample size of 632 subjects (158 per THV group, with competitive enrollment) was determined through simulations of binomial experiments on the basis of assumed success rates for different valve types reported in previous studies.5-7,12 These simulations evaluated the precision of CIs and the ability to detect significant differences in success rates across valves. The chosen size ensures a maximum CI half width of 7.8% and achieves at least 90% power for detecting significant differences in the comparison between the SAPIEN 3/Ultra valve and the other THVs in the study. Descriptive statistics are reported as median (Q1-Q3) for continuous variables and as absolute number (percentage) for categorical variables. The Wilcoxon rank sum test and Kruskal-Wallis test were used to compare the distributions of continuous variables. The Pearson chi-square test or the Fisher exact test, as appropriate, was used to compare the distributions of categorical variables. When comparing the outcome distribution between valve types taken in pairs, the Benjamini-Hochberg correction was applied to account for multiple testing. Univariable and multivariable logistic

regression models were used to identify predictors of outcomes. Results are reported as ORs with 95% CIs and *P* values. Variables included in the univariable and multivariable models (aortic valve area, coronary ostia height, sinus of Valsalva height, intercommissural distances, ascending aortic mean diameter, implantation depth, relationship of the THV and sinotubular junction [STJ], valve oversizing, mean aortic gradient, moderate or severe misalignment, and THV type) were selected on the basis of clinical relevance. An interaction term was included in the logistic regression models to evaluate the effect of misalignment according to valve type. All analyses were performed using R (R Foundation for Statistical Computing).

RESULTS

BASELINE AND PROCEDURAL CHARACTERISTICS.

A total of 632 patients were enrolled across 18 European centers. The mean age of the study population was 82 years (Q1-Q3: 78-85 years), with a mean Society of Thoracic Surgeons risk score of 3.2% (Q1-Q3: 2.2%-5%). Baseline demographic and CT characteristics stratified by valve type are summarized in Table 1. Patients treated with tall-frame THVs demonstrated significantly smaller native aortic valve dimensions compared with those receiving short-frame devices. Additionally, a lower prevalence of prior coronary artery disease (CAD) was noted in the tall-frame THV group, as evidenced by fewer cases of prior PCI (P = 0.003) and coronary artery bypass grafting (P = 0.018). Procedural characteristics by THV type are presented in Table 2. Rates of pre- and postdilatation, as well as valve oversizing, were significantly higher in the tall-frame THV groups (P < 0.001for all). Median implantation depths varied significantly by valve type, with values of 4.0 mm (Q1-Q3: 3.3-4.5 mm) for the SAPIEN 3/Ultra, 5.0 mm (Q1-Q3: 4.0-6.2 mm) for the Evolut Pro/Pro+, 4.9 mm (Q1-Q3: 4.2-5.6 mm) for the ACURATE neo/neo2, and 6.5 mm (Q1-Q3: 5.6-7.8 mm) for the Portico or Navitor (P < 0.001). Overall, no or mild angiographic commissural misalignment was observed in 71% of cases (337 of 474), while severe misalignment occurred in 6% (28 of 474), with a trend toward a significant difference among the tall-frame devices (P = 0.06).

CA AFTER TAVR. The rates of selective, nonselective, and unfeasible cannulation for both coronary arteries according to valve type are depicted in **Figure 2**. The primary endpoint was achieved in 64% of patients (404 of 632), with a significant difference among the

4 groups (P < 0.001). Overall, rates of unfeasible cannulation were low, predominantly involving the RCA (5.5% [35 of 632] vs 0.5% [3 of 632] for the LCA), with no significant differences among the 4 groups (P = 0.06) (Figure 3). The SAPIEN 3/Ultra THV demonstrated a higher rate of the primary endpoint compared with each tall-frame device (89% [141 of 158] [95% CI: 84%-93%] vs 63% [100 of 158] [95% CI: 55%-70%] for the Portico or Navitor, 62% [98 of 158] [95% CI: 53%-69%] for the ACURATE neo/neo2, and 45% [71 of 158] [95% CI: 37%-53%] for the Evolut Pro/ Pro+; P < 0.001 for each pairwise comparison). Among tall-frame THVs, the Portico or Navitor and ACURATE neo/neo2 THVs showed significantly higher rates of the primary endpoint compared with the Evolut Pro/Pro+ THV (63% and 62% vs 45%; P = 0.002and P = 0.005, respectively). However, differences in selective cannulation rates among tall-frame THVs were less pronounced for the RCA compared with the LCA. Independent predictors of unfeasible or nonselective cannulation of the RCA and/or LCA after TAVR, as detailed in Table 3, included higher implantation depth (OR: 0.83; 95% CI: 0.74-0.94; P = 0.002), the presence of moderate or severe THV misalignment (OR: 5.51; 95% CI: 3.38-9.00; P < 0.001), and the use of tall-frame THVs (OR: 6.24; 95% CI: 3.10-12.6; P < 0.001). Univariable logistic regression is reported in Supplemental Table 1. The impact of moderate or severe misalignment on the primary endpoint was consistent across tall-frame THVs, with no significant interaction detected (P for interaction = 0.14 for the ACURATE neo/neo2 and P for interaction = 0.64 for the Portico or Navitor vs the Evolut Pro/Pro+, respectively) (Supplemental Table 2).

CA DETAILS AND SAFETY OUTCOMES. Procedural details of coronary cannulation after TAVR are summarized in Table 4. CA was attempted via femoral arterial access in 75% of cases. No interaction between access site (femoral vs radial) and the incidence of the primary endpoint was observed among different THV subgroups (P for interaction = 0.45 for the SAPIEN 3/Ultra, P for interaction = 0.40 for the ACURATE neo/neo2, P for interaction = 0.48 for the Evolut Pro/Pro+, and P for interaction = 0.89 for the Portico or Navitor). Among patients implanted with the SAPIEN 3/Ultra THV, coronary cannulation was achieved without interaction with the valve frame (ie, either above or outside the THV stent) in 76% and 82% of cases for the LCA and RCA, respectively. In most cases, CA was successfully performed using a single diagnostic catheter for both the RCA (94% [594 of 632]) and LCA (93.5% [591 of 632]). However, the use of multiple catheters was more frequent in the

 TABLE 1
 Baseline Clinical and Anatomical Characteristics According to Transcatheter Heart Valve Type
 SAPIEN 3/ ACURATE neo/ **Evolut Pro/ Total Population** SAPIEN 3 Ultra ACURATE neo2 Portico/Navitor Evolut Pro-(N = 632)(n = 158)(n = 158)(n = 158)(n = 158)P Value Clinical characteristics Age, y 82 (78-85) 80 (77-85) 81 (78-85) 82 (80-85) 82 (79,85) 0.04 Female 372 (59) 62 (39) 78 (49) 123 (78) 109 (69) < 0.001 BMI, kg/m² 26.5 (23.8-29.4) 27.3 (24.7-31.0) 26.4 (23.9-29.0) 26.2 (22.5-29.4) 25.9 (23.1-28.7) 0.006 < 0.001 STS score, % 3.2 (2.2-5.0) 2.5 (1.9-3.7) 3.1 (2.1-5.3) 3.8 (2.5-6.3) 3.9 (2.4-5.4) Diabetes mellitus 205 (32) 54 (34) 51 (32) 43 (27) 0.3 Hypertension 549 (87) 144 (91) 131 (83) 138 (87) 136 (86) 0.3 Active smoking 443 (70) 95 (60) 104 (66) 133 (84) 111 (70) < 0.001 126 (80) 100 (63) 115 (73) 0.012 Dyslipidemia 456 (72) 115 (73) < 0.001 77 (49) 36 (23) 37 (23) Coronary artery disease 194 (31) 44 (28) Previous AMI 98 (15) 32 (20) 19 (12) 25 (16) 22 (14) 0.2 Previous PCI 122 (19) 43 (27) 21 (13) 22 (14) 36 (23) 0.003 Previous CABG 25 (4) 13 (8.2) 3 (1.9) 4 (2.6) 5 (3.4) 0.018 Previous stroke/TIA 64 (10) 16 (10) 15 (9.5) 17 (11) 16 (10) >0.9 CKD 246 (39) 59 (37) 68 (43) 65 (41) 54 (34) 0.4 COPDa 105 (17) 33 (21) 32 (20) 19 (12) 21 (13) 0.071 Atrial fibrillation 196 (31) 48 (30) 48 (30) 52 (33) 48 (30) >0.9 Prior pacemaker 59 (9.4) 14 (8.9) 18 (11) 11 (7.2) 16 (10) 0.6 NYHA functional class 0.6 47 (7.4) 8 (5.2) 11 (7.1) 18 (11) 10 (6.2) П 242 (38) 61 (39) 58 (37) 55 (35) 68 (43) Ш 318 (50) 81 (51) 74 (47) 82 (58) 81 (51) I۱/ 22 (3.6) 5 (3.3) 8 (5.1) 4 (2.6) 5 (3.3) LVEF, % 60 (55-64) 59 (52-64) 59 (52-63) 62 (56-65) 58 (55-64) 0.006 45 (40-53) 44 (38-52) 47 (41-55) 45 (40-54) 45 (40-55) 0.048 Mean aortic gradient Computed tomography characteristics 23.5 (22.1-25.3) 24.5 (22.6-26.3) 24.2 (22.3-26.2) 23.0 (22.1-24.3) 22.6 (21.5-24.5) < 0.001 Aortic annular mean diameter, mm Aortic annular area, mm2 425 (375-494) 467 (400-534) 451 (379-533) 413 (373-444) 393 (353-456) < 0.001 Aortic annular perimeter, mm 74.9 (70.1-80.5) 77.7 (72.0-83.2) 77.0 (71.0-83.2) 73.7 (70.0-76.5) 71.7 (67.9-77.5) < 0.001 LVOT maximal diameter, mm 27.2 (25.0-29.6) 28.0 (25.1-30.6) 28.2 (25.9-30.3) 26.6 (25.1-28.1) 25.8 (24.0-28.0) < 0.001 LVOT minimal diameter, mm 19.4 (17.4-21.4) 20.7 (18.0-23.0) 20.2 (17.8-22.3) 18.7 (17.0-20.1) 18.6 (16.7-20.0) < 0.001RCA height, mm 15.5 (13.3-17.5) 16.2 (13.6-18.6) 15.5 (13.0-17.5) 15.3 (13.3-17.4) 15.0 (12.8-16.8) 0.033 LCA height, mm 13.4 (11.6-15.3) 13.6 (11.4-15.7) 13.2 (11.5-15.4) 13.1 (11.7-14.9) 13.5 (11.8-15.1) 0.7 Right SoV height, mm 20.8 (18.8-23.3) 21.9 (19.2-24.6) 20.5 (18.8-23.4) 20.7 (19.0-22.9) 19.7 (18.6-21.6) < 0.001 Left SoV height, mm 20.4 (18.6-22.3) 20.9 (19.0-23.0) 20.3 (18.4-22.2) 20.3 (18.6-22.1) 20.1 (18.0-22.0) 0.039 27.5 (25.5-29.8) 28.7 (26.8-30.3) 28.2 (25.6-30.7) 26.9 (25.0-28.6) 26.7 (24.9-28.3) < 0.001 STJ diameter, mm Ascending aorta, mm 31.6 (29.6-33.8) 32.4 (29.9-34.4) 31.6 (29.3-33.8) 31.5 (29.7-33.8) 31.2 (29.0-33.4) 0.06 Intercommissural distance, LCC, mm 31.0 (28.5-33.8) 32.4 (30.0-34.9) 32.2 (29.4-34.7) 29.8 (28.2-31.9) 29.4 (27.3-32.0) < 0.001 Intercommissural distance, RCC, mm 29.3 (26.9-31.8) 30.8 (28.3-32.4) 30.2 (26.3-30.3) 28.5 (26.3-30.3) 28 (25.9-30.1) < 0.001 Intercommissural distance, NCC, mm 31.6 (29.0-34.3) 32.9 (30.3-35.7) 32.6 (29.6-35.0) 30.6 (28.4-32.3) 29.9 (27.8-32.6) < 0.001

Values are median (Q1-Q3) or n (%). Categorical variables were compared using the chi-square test or the Fisher exact test.

AMI = acute myocardial infarction; BMI = body mass index; CABG = coronary artery bypass graft; CKD = chronic kidney disease; COPD = chronic obstructive pulmonary disease; LCA = left coronary artery; LCC = left coronary cusp; LVEF = left ventricular ejection fraction; LVOT = left ventricular outflow tract; NCC = non coronary cusp; PCI = percutaneous coronary intervention; RCA = right coronary artery; RCC = right coronary cusp; SOV = sinus of Valsalva; STJ = sinotubular junction; STS = Society of Thoracic Surgeons; TIA = transient ischemic attack.

Evolut Pro/Pro+ group (16.7% [26 of 158] for the RCA and 12.5% [20 of 158] for the LCA). Judkins right and Judkins left catheters were the most commonly used for RCA (91% [575 of 632]) and LCA (96.2% [608 of 632]) cannulation, respectively. No significant interaction was found between THV size (small vs large) and the incidence of the primary endpoint among short-frame THVs (eg, SAPIEN 3/Ultra; P for interaction = 0.24) or tall-frame THVs with open-cell designs (eg, Portico or Navitor [P] for

interaction = 0.97], ACURATE neo/neo2 [*P* for interaction = 0.18]). In contrast, a significant interaction was observed between THV size and selective coronary cannulation in the Evolut Pro/Pro+ subgroup (*P* for interaction = 0.005), with a markedly higher likelihood of successful cannulation of both coronary arteries following implantation of large vs small THVs (79% vs 21%). Only 1 adverse event, involving embolization of an Evolut Pro THV, was reported during coronary cannulation after TAVR.

TABLE 2 Procedural Characteristics According to THV Type							
	Total Population $(N = 632)$	SAPIEN 3/ SAPIEN 3 Ultra (n = 158)	Evolut Pro/ Evolut Pro+ (n = 158)	ACURATE neo/ ACURATE neo2 (n = 158)	Portico/Navitor (n = 158)	P Value	
Valve type							
SAPIEN 3/SAPIEN 3 Ultra							
23 mm		54 (34)	-	-	-		
26 mm		65 (41)	-	-	-		
29 mm		39 (25)	-	-	-		
Evolut R/Evolute Pro/Evolut Pro+							
23 mm		-	13 (9)	-	-		
26 mm		-	37 (23)	-	-		
29 mm		-	62 (39)	-	-		
34 mm		-	46 (29)	-	-		
ACURATE neo/ACURATE neo2							
Small		-	-	49 (31)	-		
Medium		-	-	81 (51)	-		
Large		_	-	28 (18)	-		
Portico/Navitor					44 (=)		
23 mm		_	-	_	11 (7)		
25 mm		_	-	_	63 (40)		
27 mm 29 mm		-	-	-	55 (35)		
		-	-	-	29 (18)		
Implantation depth, mm	4.9 (4.0 to 6.2)	4.0 (3.3 to 4.5)	5.0 (4.0 to 6.2)	4.9 (4.2 to 5.6)	6.5 (5.6 to 7.8)	< 0.001	
Angiographic misalignment							
None/mild	338 (71)	NA	122 (77)	113 (72)	103 (65)	0.06	
Moderate	107 (23)	NA	27 (17)	37 (23)	43 (27)		
Severe	29 (6)	NA	9 (6)	8 (5)	12 (8)		
Predilation	402 (63)	21 (13)	103 (65)	152 (96)	126 (80)	< 0.001	
Postdilatation	144 (22)	11 (7)	31 (20)	43 (27)	59 (37)	< 0.001	
THV/STJ relation ^a	-3.7 (-10.8 to 2.8)	-11.4 (-16.7 to -4.4)	4.3 (-2.8 to 9.7)	−7.7 (−13.1 to −2.0)	-1.1 (-5.2 to 4.1)	< 0.001	
Valve oversizing, % ^b		10.5 (4.0 to 17.5)	28.6 (19.5 to 39.7)	16.7 (12.2 to 21.1)	26.1 (16.6 to 33.0)	< 0.001	

Values are n (%) or median (Q1-Q3). Categorical variables were compared using the chi-square test or the Fisher exact test. ^aTHV-STJ relation was calculated as (THV diameter/STJ mean diameter – 1) × 100. ^bThe percentage of oversizing was calculated as (nominal THV area/annular area – 1) × 100.

NA = not applicable; STJ = sinotubular junction; THV = transcatheter heart valve.

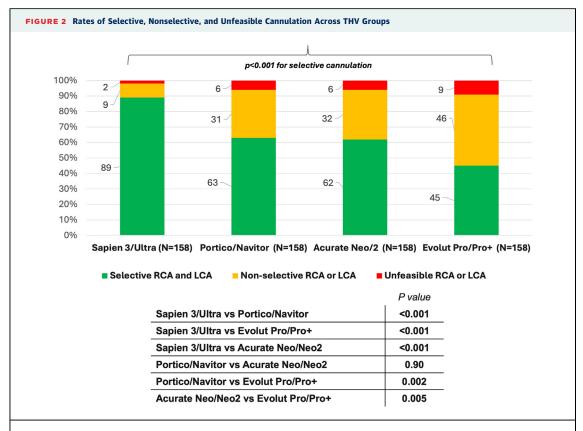
Consistent with prior findings, pacemaker implantation rates were significantly higher for Evolut Pro/Pro+ and Portico or Navitor THVs compared with SAPIEN 3/Ultra and ACURATE neo/neo2 THVs (P < 0.001). As detailed in **Table 5**, safety outcomes at 30 days were comparable among the valve subgroups. Notably, the rates of acute kidney injury at 30 days were low and showed no significant differences across groups, despite significant variation in contrast medium usage (highest in the Evolut Pro/Pro+ group and lowest in the SAPIEN 3/Ultra group) (**Figure 4**).

DISCUSSION

The CAvEAT registry, as the first adequately powered prospective study comparing CA across the 4 most commonly used THVs, highlights key insights into the interplay between THV design and post-TAVR coronary reaccess (Central Illustration). The main findings

can be summarized as follows: 1) selective CA of both coronary arteries was more frequently achieved after implantation of a short-frame THV; 2) among tall-frame THVs, the rate of selective coronary cannulation was higher after TAVR with a large-cell compared with a closed-cell design THV; 3) the overall rate of unfeasible CA was low and consistent across THV types, with the RCA being more commonly affected than the LCA; and 4) moderate or severe THV misalignment, high THV implantation, and the use of a tall-frame THV were independently associated with lower rates of selective CA.

CAD remains a frequent comorbidity in patients undergoing TAVR, with a prevalence exceeding 50% and increasing with age and surgical risk.^{1,13} Previous studies have reported an incidence of unplanned coronary angiography or PCI over 10% at 2 years, with acute coronary syndromes accounting for one-half of these cases.^{7,12,13} The demand for CA post-TAVR is



Rates of selective, nonselective, and unfeasible coronary access of both coronary arteries across transcatheter heart valve (THV) groups. The bottom part of the figure reports the pairwise comparisons in terms of primary endpoint rates among all types of THVs. LCA = left coronary artery; RCA = right coronary artery.

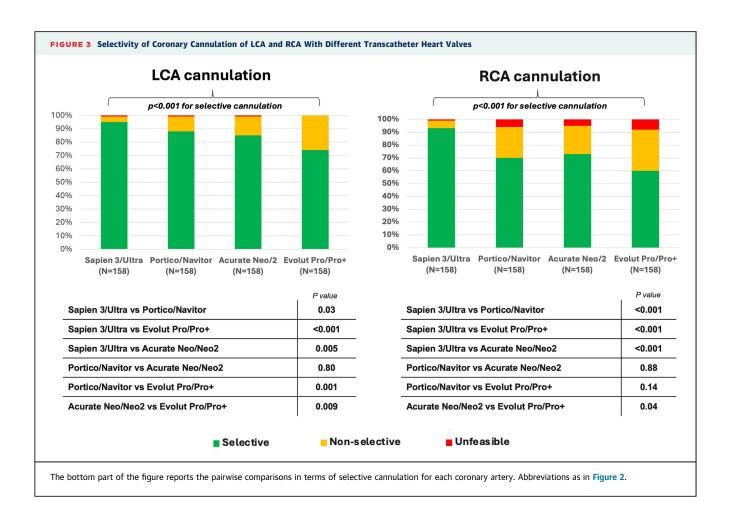
expected to rise, driven by the progressive nature of CAD and the longer life expectancy of contemporary TAVR candidates. ¹⁴

The CAvEAT registry supports and extends previous findings from single-center and retrospective studies, underscoring the technical challenges posed by tall stent-frame THVs with supra-annular leaflet positions in achieving selective CA. The results demonstrated a clear advantage of the SAPIEN 3/Ultra THVs, with their intra-annular, short-frame design minimizing interference with the coronary ostia. This is evident from the higher rates of CA achieved above or outside the stent frame in this subgroup. Notably, the selectivity of coronary cannulation was not influenced by any baseline anatomical characteristic (ie, aortic annular dimensions, STJ diameter, and coronary height), as shown by multivariate analysis.

Challenges in CA with previous-generation tall-frame CoreValve (Medtronic) and Evolut THVs prompted the development of new tall-frame THVs incorporating larger cell designs, such as the ACU-RATE neo/neo2 and Portico or Navitor valves.

However, until now, the actual impact of these larger cell designs on successful coronary cannulation has remained speculative. The present study provides the first robust, adequately powered comparison of the most commonly used tall-frame TAVR devices, demonstrating a significant advantage of open-cell over closed-cell designs in achieving selective CA of both coronary arteries. Interestingly, the benefit of the larger cell design was more pronounced for LCA cannulation compared with the RCA. This discrepancy may be attributed to the unique challenges associated with RCA engagement. Unlike the LCA, RCA cannulation often requires catheter rotation within the aortic root to align with the coronary ostium, a maneuver that frequently results in interaction with the stent frame or commissural posts of a tall-frame THV, regardless of stent cell dimensions. This mechanical interference likely diminishes the relative advantage of an open-cell design when accessing the RCA compared with the LCA.

In addition to advancements in THV design, specific implantation techniques focused on achieving



commissural alignment have been developed to simplify CA following tall-frame THV implantation. Commissural alignment aims to avoid positioning a commissural post directly in front of one or both coronary ostia, which would otherwise require the

TABLE 3 Multivariable Analysis of Predictors of Unfeasible or Nonselective Coronary Access of at Least 1 Coronary Artery

OR (95% CI) P Value

	OR (95% CI)	P Value
Aortic valve area	1.00 (0.99-1.00)	0.75
RCA height	0.99 (0.92-1.07)	0.89
LCA height	0.97 (0.89-1.05)	0.40
STJ diameter	0.99 (0.90-1.09)	0.88
THV/STJ relation	1.01 (0.99-1.04)	0.27
Valve oversizing	1.40 (0.50-3.87)	0.52
Implantation depth	0.83 (0.74-0.94)	0.002
Moderate/severe misalignment	5.51 (3.38-9.00)	< 0.001
Tall-frame THVs	6.24 (3.10-12.6)	< 0.001
Abbreviations as in Tables 1 and 2.		

catheter to navigate around the post, resulting in noncoaxial engagement of the coronary ostium through the stent frame. The ALIGN-ACCESS (TAVR With Commissural Alignment Followed by Coronary Access) study¹⁵ was the first to provide evidence that achieving commissural alignment significantly increases the rate of selective CA after TAVR with supra-annular devices. The findings of the CAvEAT registry confirm and expand upon these results by identifying moderate or severe commissural misalignment as an independent predictor of unfeasible or nonselective CA, regardless of the type of THV implanted. This underscores the critical role of commissural alignment in optimizing post-TAVR coronary reaccess. However, it is important to note that the THV devices included in this study lacked specific fluoroscopic markers designed to facilitate commissural alignment. Despite efforts to align commissures during all tall-frame THV implantations, moderate or severe misalignment was observed in nearly one-third of patients in the CAvEAT registry. These rates of significant misalignment are consistent

TABLE 4 Details of Coronary Cannulation						
	Total Population (N = 632)	SAPIEN 3/ SAPIEN 3 Ultra (n = 158)	Evolut Pro/ Evolut Pro+ (n = 158)	ACURATE neo/ ACURATE neo2 (n = 158)	Portico/Navitor (n = 158)	P Value
Arterial access						
Femoral Radial	475 (75) 157 (25)	133 (84) 25 (16)	93 (59) 65 (41)	126 (80) 32 (20)	123 (78) 35 (22)	<0.001
Number of catheters for RCA CA						
1 2 >2	592 (94) 26 (4) 15 (2)	153 (97) 3 (2) 2 (1)	132 (83.3) 15 (9.6) 11 (7.1)	156 (99) 2 (1) 0 (0)	151 (96) 5 (3) 2 (1)	<0.05
Number of catheters for LCA CA						
1 2 >2	591 (93.5) 32 (5) 9 (1.5)	150 (95) 5 (3) 3 (2)	138 (87,5) 16 (10) 4 (2.5)	150 (95) 6 (4) 2 (1)	153 (97) 5 (3) 0 (0)	<0.05
Type of catheter for RCA CA ^a						
JR AL AR Other	562 (91) 3 (0.5) 17 (2.8) 35 (5.7)	151 (96.8) 1 (0.6) 1 (0.6) 3 (2)	124 (80) 0 (0) 11 (7.1) 20 (12.9)	150 (98) 0 (0) 0 (0) 3 (2)	137 (89.5) 2 (1.3) 5 (3.3) 9 (5.9)	<0.001
Type of catheter for LCA CA ^a						
JL AL XB/EBU	605 (96.2) 4 (0.6) 7 (1.1)	152 (96.8) 0 (0) 1 (0.6)	146 (92.4) 2 (1.3) 3 (1.9)	153 (98.1) 2 (1.3) 1 (0.6)	154 (97.4) 0 (0) 2 (1.3)	0.035
Other	13 (2.1)	4 (2.6)	7 (4.4)	0 (0)	2 (1.3)	

Values are n (%) and were compared using the chi-square test or the Fisher exact test. ^aAfter excluding cases of unfeasible coronary cannulation.

AL = Amplatz left; AR = Amplatz right; CA = coronary access; JL = Judkins left; JR = Judkins right; XB/EBU = extra backup; other abbreviations as in Table 1.

with those reported in previous studies, ^{6,15,16} highlighting the inherent challenges of achieving precise commissural alignment without dedicated markers or delivery systems with active commissural alignment. The latest iterations of TAVR devices, including the Evolut FX, Navitor Vision, and ACURATE Prime, have introduced specific fluoroscopic markers designed to identify the position of the neocommissures. These

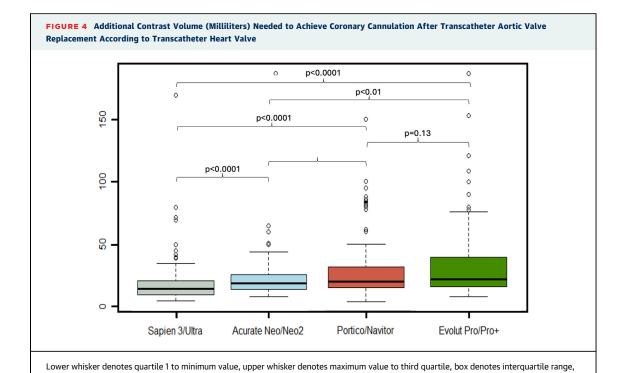
markers guide proper THV orientation during implantation, enhancing the likelihood of achieving commissural alignment. Early data from recent case series¹⁷ suggest that these devices, though not included in this study, have significantly reduced the rates of moderate and severe misalignment compared with earlier generation THVs. However, it remains to be determined whether improved commissural

TABLE 5 Clinical Outcomes According to Transcatheter Heart Valve Type							
	Total Population (N = 632)	SAPIEN 3/ SAPIEN 3 Ultra (n = 158)	Evolut Pro/ Evolut Pro+ (n = 158)	ACURATE neo/ neo2 (n = 158)	Portico/ Navitor (n = 158)	P Value	
30-d mortality	3 (0.6)	2 (1.3)	1 (0.8)	0 (0)	0 (0)	0.7	
30-d stroke	3 (0.6)	1 (0.8)	1 (0.8)	1 (0.8)	0 (0)	>0.9	
30-d MI	2 (0.4)	0 (0)	1 (0.8)	0 (0)	1 (0.8)	0.5	
30-d AKI	8 (1.3)	2 (1.4)	3 (1.8)	3 (1.8)	0 (0)	0.7	
Complications related to coronary cannulation ^a	1 (0.2)	0 (0)	1 (0.8)	0 (0)	0 (0)	0.8	
Pacemaker after TAVR ^a	92 (15)	11 (7)	27 (17)	11 (7)	43 (27)	< 0.001	

Values are n (%) and were compared using the chi-square test or the Fisher exact test. ^aThe only complication related to coronary cannulation was a transcatheter heart valve embolization in the ascending aorta.

 $AKI = acute \ kidney \ injury; \ MI = myocardial \ infarction; \ TAVR = transcatheter \ aortic \ valve \ replacement.$





alignment with these newer devices will mitigate the differences in CA performance observed among different THV designs.

and central line denotes median.

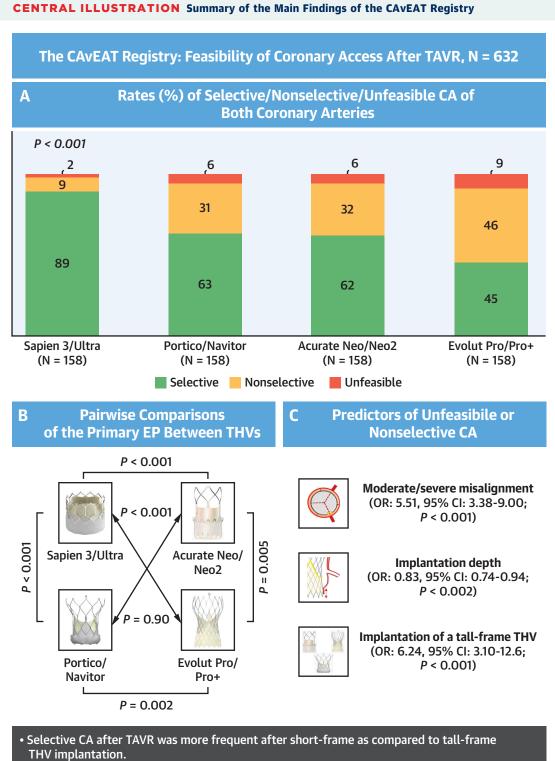
Another independent predictor of unsuccessful CA identified in this study was higher THV implantation position. Although current procedural guidelines advocate for higher implantation to minimize conduction disturbances and reduce the need for permanent pacemaker implantation,18,19 this approach may increase the risk for impaired CA.² In this regard, the lower mean implantation depth of the Portico or Navitor THV group, which is likely the reason behind the higher rate of pacemaker implantation compared with all other devices, may have positively affected CA. These findings highlight the importance of individualized implantation strategies, particularly when balancing the goals of reducing conduction disturbances and ensuring optimal CA in younger patients with concomitant CAD, who are more likely to require future coronary interventions.

Despite the increased contrast medium requirements for CA attempts following tall-frame THV implantation, particularly with the Evolut Pro/Pro+, the low overall rate of acute kidney injury observed in this study is reassuring. However, it is critical to acknowledge that the study excluded patients with severe chronic kidney disease at baseline. As such,

the potential impact of CA challenges on renal function in more fragile populations remains uncertain and warrants further investigation, particularly for patients with pre-existing renal impairment.

Encouragingly, the rate of unfeasible CA was low across all THV subgroups and predominantly involved the RCA. Furthermore, in the vast majority of successful cases, CA was achieved using a single coronary catheter, demonstrating the general feasibility of CA despite technical challenges. Importantly, failure in selective CA does not necessarily preclude the ability to perform PCI, highlighting the adaptability of interventional strategies even in nonoptimal conditions.

The findings of this study provide valuable insights into the pitfalls of CA after TAVR and lay the groundwork for future THV design enhancements. For instance, the next-generation Evolut FX+ features a re-engineered design incorporating 3 larger cells, each 4 times larger than in earlier versions, to facilitate easier CA.²⁰ Similarly, the upcoming SAPIEN X4 is set to include fluoroscopic markers at the level of the commissures and support commissural alignment during implantation.²¹ These advances aim to address 2 key barriers to successful CA: stent frame interference and THV misalignment. Future studies are essential to assess the real-world performance of



- Among tall-frame bioprosthesis, rates of selective CA were higher after TAVR with an open-cell vs closed-cell design THV.

Tarantini et al. JACC Cardiovasc Interv. 2025;18(12):1571-1583.

CA = coronary access; CAvEAT = Coronary Access After TAVI; EP = endpoint; TAVR = transcatheter aortic valve replacement; THV = transcatheter heart valve

these next-generation THVs in terms of their impact on selective CA rates.

Tailored THV selection (considering multiple factors, such as native aortic anatomy, post-TAVR valve gradients, paravalvular leak, conduction disturbances, hypoattenuated leaflet thickening, durability, CA, etc) remains a critical consideration for heart teams, especially for patients with longer life expectancy and a higher likelihood of requiring post-TAVR coronary interventions. The results of the CAVEAT registry offer valuable guidance for prosthesis selection in this patient subset, emphasizing the importance of aligning clinical and anatomical considerations with device-specific attributes to optimize long-term outcomes.

STUDY LIMITATIONS. The nonrandomized design may have introduced selection bias and limits the ability to establish causation. However, the CAvEAT registry represents the first adequately powered study to detect potential differences in CA following TAVR, supported by its prespecified sample size calculations. The protocol restriction prohibiting the use of coronary guidewires, microcatheters, or guide extension catheters may have led to a lower rate of selective CA than could otherwise be achieved in routine practice. Nonetheless, the observed increased use of contrast medium and the greater number of coronary catheters required for CA with tall-frame THVs, especially those with closed-cell designs, highlight the technical challenges associated with these devices.

The study population was derived from highvolume tertiary care centers with significant expertise in structural heart interventions. Therefore, the results may not be generalizable to less experienced centers, at which procedural outcomes could differ. Additionally, post-TAVR CT evaluations were not performed, which might have provided more detailed insights into the anatomical factors influencing CA. However, the study used fluoroscopic evaluation of commissural alignment, which has been previously validated.¹¹

It could be speculated that anatomical differences among groups (ie, the wider use of tall-frame THVs in patients with smaller aortic roots) might have influenced the rate of selective CA. Yet no baseline CT characteristic or THV-STJ relation were found to be independent predictors of nonselective or unfeasible CA on multivariable analysis.

Finally, the findings of this study should not be extrapolated to specific patient subgroups excluded

from it, such as those with bicuspid aortic valve disease or those undergoing valve-in-valve procedures, or to patients implanted with other THV types not included in the registry. These limitations emphasize the need for further studies, particularly randomized trials and investigations incorporating newer THV iterations, to confirm and expand upon these findings.

CONCLUSIONS

The CAVEAT study demonstrated that selective coronary cannulation after TAVR was more frequently achieved with short-frame THVs compared with tall-frame devices, particularly in cases of significant commissural misalignment or high implantation depth. Among tall-frame THVs, those with larger cell designs (eg, Portico or Navitor, ACURATE neo/neo2) outperformed the closed-cell Evolut Pro/Pro+ in facilitating CA. These findings provide valuable guidance for heart team in tailoring THV selection, especially for younger patients and/or those with concomitant CAD who may require future coronary interventions. The results also highlight the need for further evaluation of next-generation THVs designed to enhance CA.

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PERSPECTIVES

WHAT IS KNOWN? Previous retrospective and singlecenter studies have reported difficulties in CA after TAVR with tall-frame compared with short-frame THVs.

WHAT IS NEW? The CAVEAT study, the first prospective, multicenter registry adequately powered to assess differences in CA after TAVR among the 4 most widely implanted THVs, confirmed the superior performance of

short-frame devices in achieving selective CA. Among tall-frame THVs, a large-cell design was associated with a higher rate of selective CA.

WHAT IS NEXT? Future research should focus on whether engineering advancements in next-generation THVs will improve CA rates observed in the CAVEAT study, particularly for tall-frame devices.

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KEY WORDS coronary access, aortic stenosis, coronary artery disease, transcatheter aortic valve replacement

APPENDIX For supplemental tables and a figure, please see the online version of this paper.