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Clinical value of CT-derived simulations of transcatheter-aortic-valve-implantation in challenging anatomies the PRECISE-TAVI trial

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Abstract

Background: Preprocedural computed tomography planning improves procedural safety and efficacy of transcatheter aortic valve implantation (TAVI). However, contemporary imaging modalities do not account for device-host interactions.

Aims: This study evaluates the value of preprocedural computer simulation with FEops HEARTguide™ on overall device success in patients with challenging anatomies undergoing TAVI with a contemporary self-expanding supra-annular transcatheter heart valve.

Methods: This prospective multicenter observational study included patients with a challenging anatomy defined as bicuspid aortic valve, small annulus or severely calcified aortic valve. We compared the heart team's transcatheter heart valve (THV) planning decision based on (1) conventional multislice computed tomography (MSCT) and (2) MSCT imaging with FEops HEARTguide™ simulations. Clinical outcomes and THV performance were followed up to 30 days.

Results: A total of 77 patients were included (median age 79.9 years (IQR 74.2–83.8), 42% male). In 35% of the patients, preprocedural planning changed after FEops HEARTguide™ simulations (change in valve size selection [12%] or target implantation height [23%]). A new permanent pacemaker implantation (PPI) was implanted in 13% and >trace paravalvular leakage (PVL) occurred in 28.5%. The contact pressure index (i.e., simulation output indicating the risk of conduction abnormalities) was significantly higher in patients with a new PPI, compared to those without (16.0% [25th–75th percentile 12.0–21.0] vs. 3.5% [25th–75th percentile

Abbreviations: BAV, bicuspid aortic valve; ECG, electrocardiogram; LVOT, left ventricular outflow tract; MSCT, multislice computed tomography; PPI, permanent pacemaker implantation; PVL, paravalvular leakage; TAVI, transcatheter aortic valve implantation; TTE, transthoracacic echocardiography.

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0–11.3], $p < 0.01$) The predicted PVL was 5.7 mL/s (25th–75th percentile 1.3–11.1) in patients with none-trace PVL, 12.7 (25th–75th percentile 5.5–19.1) in mild PVL and 17.7 (25th–75th percentile 3.6–19.4) in moderate PVL ($p = 0.04$).
Conclusion: FEops HEARTguide™ simulations may provide enhanced insights in the risk for PVL or PPI after TAVI with a self-expanding supra-annular THV in complex anatomies.

KEYWORDS
computer simulations, conduction abnormalities, paravalvular leakage, transcatheter aortic valve implantation

1 | INTRODUCTION

Multislice computed tomography (MSCT) is the recommended imaging modality for obtaining detailed information on aortic valve morphology, calcium burden, and anatomic dimensions in the work up for transcatheter aortic valve implantation (TAVI).[1,2] The CoreValve/Evolut platform is a self-expanding supra-annular transcatheter valve that compared favorably to SAVR in a series of randomized controlled trials with superior hemodynamic valve performance but with more paravalvular leakage (PVL) and a higher need for new pacemaker implantation (PPI).[3–5]

Heavily calcified tricuspid, bicuspid, and small aortic valves may pose specific challenges from a TAVI perspective and are associated with PVL, conduction abnormalities and aortic root injury.[6–8]

Insights in device-host interactions may help to understand and predict such TAVI related complications. FEops HEARTguide™ is a CE marked software package, also regulatory approved in Canada and Australia, for patient-specific simulations for structural heart interventions, which can support to determine the risk for conduction abnormalities and PVL post-TAVI by virtually implanting a transcatheter heart valve in a 3D anatomical computer model. Simulations may enhance insights in how transcatheter heart valves seat in a particular anatomy and may help operators to modify the implant strategy accordingly or to select a different valve platform. The computer simulations has been validated in tricuspid and bicuspid anatomies.[9–12]

The goal of this prospective multi-center observational study (PRECISE-TAVI) is to evaluate the effect of FEops HEARTguide™ on THV sizing and implantation strategy in severe AS patients with challenging aortic anatomy to predict risk of PVL and conduction abnormalities following TAVI with the Evolut Pro(+).

2 | METHODS

2.1 | Study population

The PRECISE-TAVI trial is a prospective multicenter observational study, including patients with a challenging anatomy, eligible for an Evolut Pro valve (Medtronic). A challenging anatomy was defined as (1) a bicuspid aortic valve, (2) a heavily calcified tricuspid valve (with Agatston score >3000 [men] and >1600 [women]) or (3) a small aortic valve (mean annular diameter <20 mm). Therefore, given the fact that there is no worldwide accepted cutoff point, we choose to use a mean diameter <20 mm as, in our opinion, this measurement has the lowest interobserver variability, compared to the annulus area and perimeter. The following centers participated in the trial: Erasmus Medical Center Rotterdam and St. Antonius Hospital Nieuwegein (the Netherlands), University Hospital Cologne and German Heart Center Berlin (Germany), St. George's University of London (United Kingdom), MonashHeart Melbourne (Australia), and Antwerp University Hospital (Belgium). Presence of a permanent pacemaker before TAVI and a failing surgical bio-prosthesis or suboptimal MSCT imaging quality that would preclude accurate computational modeling were exclusion criteria. The study was conducted in accordance with the declaration of Helsinki and did not fall under the scope of the Medical Research Involving Human Subjects Act per Institutional Review Boards' review (MEC-2020-0486).

2.2 | Study procedure

First, multidisciplinary heart teams identified patients with challenging aortic anatomies who were selected for TAVI with the Evolut Pro (+) THV based on MSCT analyses per local standard. THV sizing and implantation strategy were documented. Second, patient-specific computer simulations of device implantation were performed and the derived contact pressure and PVL were obtained. Simulations were then shared with the local heart teams. THV sizing and implantation strategies could be changed accordingly per local heart team's discretion. A dedicated prospective database captured relevant patient demographics, medical history and comorbidities, ECG, Transthoracic Echocardiography (TTE), and MSCT findings including THV sizing and implantation strategies before and after FEops HEARTguide™ simulations, procedural and clinical follow-up data.

2.3 | Computer simulations

MSCT imaging studies were transmitted to FEops (Gent) for HEARTguide computer simulations of device implantation. A detailed description of the computer simulations has been described earlier.[12]

In brief, a 3-dimensional, patient-specific aortic root was reconstructed from the preprocedural ECG-gated contrast-enhanced CT-scan with finite element models. For each patient, Evolut TAVI simulations were performed for the two most appropriate available device sizes and at an implantation depth <3 mm (high implantation) and 5 mm (medium implantation). The THV properties of the models were assessed from micro-CT images and optical microscopy measurements, as well as in-vitro radial compression tests at body temperature.

Computer simulations have been already used to predict the risk of conduction abnormalities and PVL post-TAVI. (central illustration) For the prediction of conduction abnormalities, the contact pressure exerted on the region nearby the membranous septum is extracted from the simulation. More in detail, The region of interest extends from the inferior border of the membranous septum to a depth of 15 mm below the annulus, which should include the area where the HIS bundle pierces the membranous septum, surfaces the LVOT (transition zone between the membranous and muscular part of the interventricular septum) and extends as the proximal part of the left bundle branch. This is the area where the HIS-bundle surfaces in the LVOT and might be subjected to pressure trauma by the valve frame. The relative area of the region of interest that experiences contact pressure is defined as contact pressure index and a contact pressure index of >14% was defined as the cut-off point for conduction abnormalities.[9]

A subsequent computational fluid dynamic simulation of the blood flow in diastole is computed to predict the risk of PVL. A blood flow of >16 mL/s was defined as a cut-off point for moderate PVL.[10]

2.4 | Outcomes and definitions

The primary objective of the study was to evaluate to what extent computer simulations in challenging aortic anatomies may affect TAVI sizing and implantation strategies and identify patients at risk for high degree AV blocks or more than trace PVL. The follow-up period was 30 days. PVL-assessment was performed by TTE.

2.5 | Statistical analysis

Distribution of continuous variables were tested for normality with the Shapiro–Wilk test. Continuous variables were reported as mean ± standard deviation or median (25th–75th percentile) and analyzed with a student's *T* test, ANOVA, Mann–Whitney *U* or Kruskal–Wallis test as appropriate. Categorical variables were reported as percentage and compared with χ^2 or Fishers Exact test. The best-fitted simulation, based on the implantation depth, for each patient was used to evaluate correlation with PVL and new pacemakers. Receiver-operating characteristic (ROC)-curves were generated to find the optimal cut-off values for >trace PVL based on the computer model PVL-measurements and for new PPI post-TAVI based on the computer model contact pressure index. (Youden index criteria). A two-sided $p < 0.05$ was considered statistically significant. All statistics were performed with SPSS software version 28.0 (SPSS).

3 | RESULTS

3.1 | Study population

MSCT studies of 83 patients were transmitted for FEops HEARTguide™ computer simulations. Quality was insufficient for computer simulations in 6/83 (7.2%) cases (5/6 motion artefacts, 1/6 incomplete visualization of the ascending aorta). Therefore, the study cohort consisted of 77 patients undergoing a TAVI-procedure between October 2020 and April 2022. Baseline characteristics are depicted in Table 1. Median age was 79.9 years (25th–275th percentile 74.2–83.8), 42% was male, median BMI was 27.0 kg/m^2 (25th–75th percentile 22.8–34.0) and median Surgeon's Predicted Risk of Mortality (STS-PROM) was 2.8% (25th–75th percentile 1.8–4.1) with clinical frailty in 35%. MSCT-analysis revealed a mean annulus area of 443 mm^3 (±91.3) and a severely calcified aortic valve in 74% of the patients. The mean Agatston score was 4405 ± 978 in male patients and 2824 ± 1368 in female patients. The challenging anatomy was a bicuspid valve in 17 patients (22%), a small annulus in 13 (17%) patients, and a severely calcified tricuspid valve in 47 patients (61%).

3.2 | Procedure and 30-day outcomes

Preprocedural planning changed after computer simulations in 35% of cases (change in both valve size selection and target implantation height [1.3%], only valve size selection [10.4%] or only target implantation height [23%]). Procedural characteristics are shown in Table 2. Predilatation was performed in 62% and postdilatation in 27%. Evolut size was 23 mm in 5%, 26 mm in 31%, 29 mm in 46%, and 34 mm in 18%. Valve migration occurred in two (3%) patients, a second valve was necessary in three (4%) patients and conversion to surgery in one (1%) patient. Valve migration, need for second valve or conversion to surgery did not occur in any of the patients in which the valve size changed based on the computer simulations.

The 30-day outcomes are displayed in Table 3. New LBBB occurred in 14% and a permanent pacemaker was implanted in 10 patients (13%) (total AV block in 9 patients and a brady-tachy syndrome in 1). The implantation depth relative to Non-coronary cusp(NCC), as measured by angiography, was 5.6 ± 3.8 for the patients without a new PPI versus versus 5.7 ± 4.0 for the patients who received a new PPI ($p = 0.71$).(Supporting Information: Table 1) Echocardiography post-TAVI showed none-trace PVL in 71.1% of the patients, mild PVL in 22% and moderate PVL in five patients (6.5%).

TABLE 1 Baseline characteristics.

	Patients
Age	79.9 (74.2–83.8)
Male gender	32 (41.6)
BMI	27.0 (22.8–34.0)
Medical history	
Hypertension	45 (58.4)
COPD	16 (20.8)
Diabetes	23 (29.9)
PAD	6 (7.8)
History of Ischemic heart disease	13 (16.9)
History of PCI	17 (22.1)
History of CABG	7 (9.1)
History of stroke	17 (22.1)
Atrial fibrillation	21 (27.3)
Clinical presentation	
NYHA class >2	42 (54.6)
CCS class >2	6 (7.8)
Syncope	5 (6.5)
Frailty	27 (35.1)
STS-score	2.8 (1.8–4.1)
Echocardiography	
LVEF (%)	57 (55–60)
LVEDD (mm)	45.8 ± 6.5
Peak aortic gradient (mmHg)	76.2 ± 19.1
Mean aortic gradient (mmHg)	45 (38–55)
AV max velocity (m/s)	4.3 ± 0.6
AVA (cm^2)	0.74 ± 0.20
aortic regurgitation >mild	10 (13.0)
mitral regurgitation >mild	6 (7.8)
Tricuspid regurgitation >mild	7 (9.1)
MSCT analysis	
Bicuspid aortic valve	17 (22.1)
Annulus area	443.3 ± 91.3
Annulus mean diameter	23.9 ± 2.4
LVOT mean diameter	23.3 ± 2.7
SOV mean diameter	31.7 ± 4.0
Left coronary height	14.6 ± 2.6
Right coronary height	17.9 ± 3.0
Aortic valve calcification > moderate	57 (74.0)
Agatston score males	4405 ± 978
Agatston score females	2824 ± 1368
LVOT calcification > moderate	10 (13.0)
Indication PRECISE	
Bicuspid aortic valve	17 (22.1)
Small annulus	13 (16.9)
Severe tricuspid aortic valve calcification	47 (61.0)

Abbreviations: AV, aortic valve; AVA, aortic valve area; BMI, body mass index; CABG, coronary artery bypass graft; CCS, Canadian Cardiovascular Society; COPD, chronic obstructive pulmonary disease; LVEDD, left ventricular end diastolic dimensions; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; NYHA, New York Heart Association; SOV, sinus of Valsalva; STS, Society of Thoracic Surgeons.

3.3 | Computer simulations

The computer simulations that more closely matched the procedure in terms of valve size and implantation depth were compared with the relevant clinical events. The contact pressure index was significantly higher in patients with a new PPI, compared to those without (16.0% [25th–75th percentile 12.0–21.0] vs. 3.5% [25th-75th percentile 0–11.3], $p < 0.01$) (Figure 1). A cut-off value of 11.5% correlated well with PPI (AUC 0.83 [95% confidence interval (CI) 0.72–0.94], sensitivity 86%, specificity 76%) (Figure 2A). Two patients (4.3%) with a contact pressure index ≤14% and five patients (31.3%) with a contact pressure >14% received a new PPI ($p < 0.01$) (Supporting Information: Table 2).

The predicted PVL was 5.7 mL/s (25th–75th percentile 1.3–11.1) in patients with none-trace PVL, 12.7 (25th–75th percentile 5.5–19.1) in mild PVL and 17.7 (25th–75th percentile 3.6–19.4) in moderate PVL (Figure 1). A PVL cutoff of 12.2 mL/s helped discriminating patients with >trace PVL (AUC 0.69 [95% CI 0.55–0.82], sensitivity 59%, specificity 79%) (Figure 2B). Eleven patients (19.3%) with a PVL simulation ≤16 mL/s and 11 patients with a PVL > 16 mL/s (61.1%) had a PVL >trace ($p < 0.01$) (Supporting Information: Table 2).

4 | DISCUSSION

PRECISE-TAVI is the first multicenter, prospective study to evaluate the added value of computer simulations to preprocedural planning in patients with a challenging anatomy receiving an Evolut Pro-valve. The main findings are that computer simulations with FEops HEARTguide™ (1) changed the preprocedural planning in 35% of the patients, (2) well predicted the risk for PVL and (3) identified the risk for new PPI post-TAVI (Figure 3).

Preprocedural planning is increasingly important for optimal sizing and to identify anatomical risk factors for adverse events.[1] Optimal valve size selection leads to a proper THV fit in the native

TABLE 2 Procedural characteristics.

	Patients
Procedural change computer simulations	
Valve size	9 (11.7)
Larger valve	6 (7.8)
Smaller valve	3 (3.9)
implantation depth	18 (23.4)
Higher	14 (18.2)
Lower	4 (5.2)
Procedure	
Anesthesia	
Local	63 (81.8)
General	14 (18.2)
Access	
Femoral	75 (97.4)
axillary	2 (2.6)
Cerebral embolic protection	27 (35.1)
Predilatation	48 (62.3)
Valve size	
23	4 (5.2)
26	24 (31.2)
29	35 (45.5)
34	14 (18.2)
Postdilatation	21 (27.3)
Procedural complications	
Procedural death	0
Valve embolization	2 (2.6)
Need for second valve	3 (3.9)
Conversion to surgery	1 (1.3)
Cardiac tamponade	3 (3.9)

Note: Characteristics of the TAVI procedure.

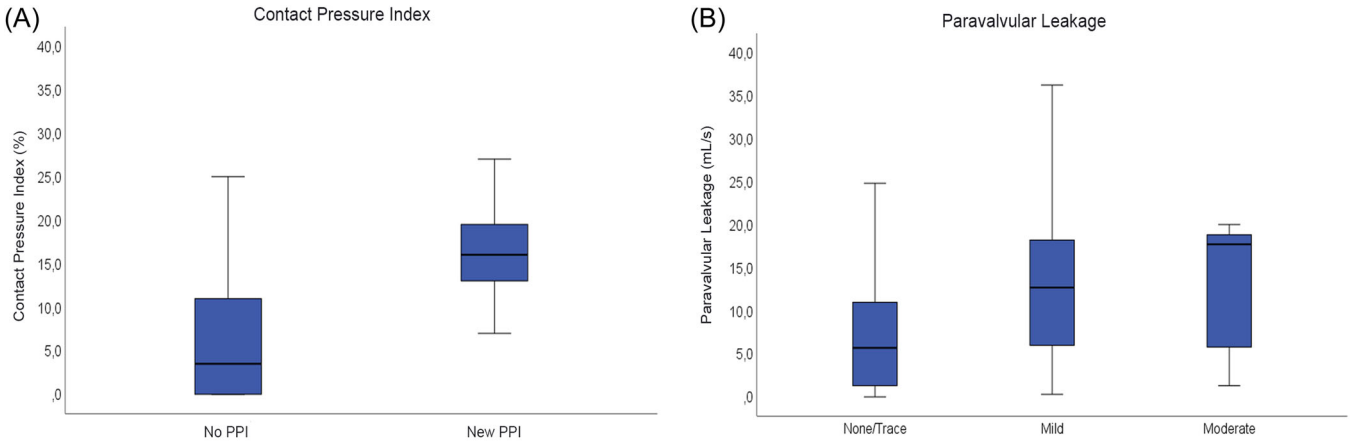
TABLE 3 Thirteen-day outcomes.

	Patients
Death	1 (1.3)
Myocardial infarction	0
Disabling stroke	1 (1.3)
Acute kidney injury	1 (1.3)
Major bleeding	3 (3.9)
Major vascular complication	6 (7.8)
Pacemaker implantation	10 (13.0)
ECG	
Rhythm	
Sinus rhythm	52 (70.3)
Atrial fibrillation	14 (18.2)
Paced	8 (10.4)
AV block	
New first degree AVB	9 (11.7)
Bundle branch block	
New LBBB	11 (14.2)
New RBBB	4 (5.2)
Echocardiography	
LVEF (%)	59 (55–60)
LVEDD (mm)	47.2 ± 5.6
Peak aortic gradient (mmHg)	15 (10–21)
Mean aortic gradient (mmHg)	8 (5–11)
AV max velocity (m/s)	1.9 (1.6–2.3)
AVA (cm^2)	1.7 (1.6–2.4)
PVL	
None-trace	55 (71.4)
Mild	17 (22.1)
Moderate	5 (6.5)
Mitral regurgitation > mild	5 (6.5)
Tricuspid regurgitation > mild	6 (7.8)

Abbreviations: AV, aortic valve; AVA, aortic valve area; AVB, atrioventricular block; LBBB, left bundle branch block; LVEDD, left ventricular end diastolic dimensions; LVEF, left ventricular ejection fraction; PVL, paravalvular leakage; RBBB, right bundle branch block.

anatomy ensuring adequate hemodynamic valve performance, proper sealing with no PVL and avoiding excessive contact pressure in the LVOT that may result in conduction disorders. Conventional MSCT imaging tools do not consider device-host interactions. Indeed, aortic root shape (elliptical vs. circular, vertical vs. horizontal, long vs. short LVOT) and calcifications (location, amount/volume) may affect how a THV is deployed and seated in situ. Arguably, device-host interactions may be reinforced in more complex anatomical phenotypes such as bicuspid aortic valves, heavily calcified tricuspid valves, and small anatomies. Severe calcifications of the aortic valve lead to frame eccentricity post-TAVI which enhances the severity of PVL.[6] Also, high calcium burden, especially in the left coronary cusp (LCC) is a risk factor for PPI.[7] TAVI in patients with BAV is associated with multiple procedural adverse events, including a higher moderate-severe PVL-rate and new PPI, especially in patients with a calcified raphe.[8,13] In small anatomies, self-expandable valves are hemodynamically superior to balloon-expandable valves, however the >trace PVL rate remains high between 49% and 75%.[14,15]

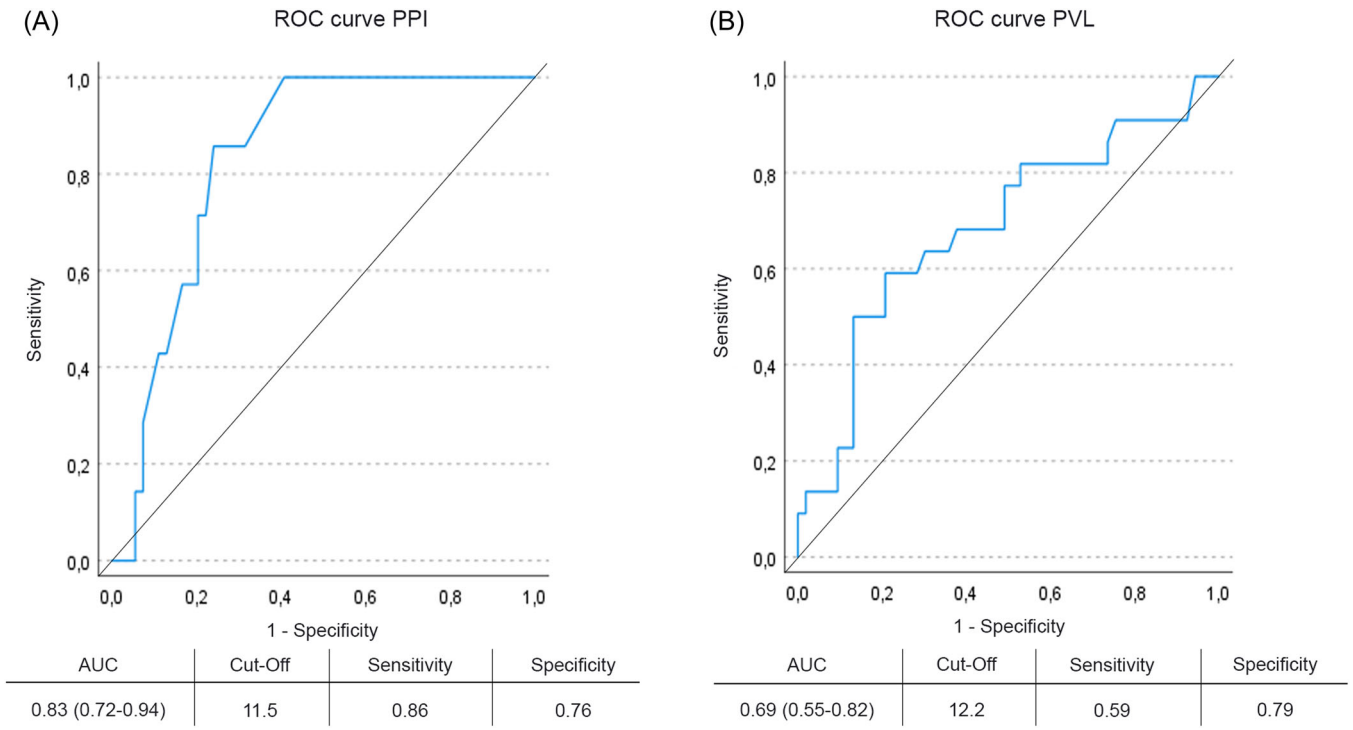
Our study demonstrates that computer simulations of these device-host interactions may complement procedural planning. Local



	No PPI	New PPI	P-Value
Contact Pressure index (%)	3.5 (0.0-11.3)	16.0 (12.0-21.0)	<0.01

	None/Trace	Mild	Moderate	P-value
Paravalvular Leakage (mL/s)	5.7 (1.3-11.1)	12.7 (5.5-19.1)	17.7 (3.6-19.4)	0.04

FIGURE 1 Predicted computer simulations. (A) the median contact pressure index, (B) the median predicted PVL per PVL grade. PPI, permanent pacemaker implantation; PVL, paravalvular leakage. [Color figure can be viewed at wileyonlinelibrary.com]



AUC	Cut-Off	Sensitivity	Specificity
0.83 (0.72-0.94)	11.5	0.86	0.76

AUC	Cut-Off	Sensitivity	Specificity
0.69 (0.55-0.82)	12.2	0.59	0.79

FIGURE 2 ROC curves. (A) ROC curve to predict new PPI. (B) ROC curve to predict >trace PVL. AUC, area under the curve; PPI, permanent pacemaker implantation; PVL, paravalvular leakage; ROC, receiver-operating characteristic. [Color figure can be viewed at wileyonlinelibrary.com]

heart teams changed their strategy in a third of the patients to help mitigate PVL and conduction disorders in complex anatomies. Computer simulations prompted operators to change size and to aim for a higher THV implantation in 12% and 23% of the cases respectively. The 13% PPI rate should be seen in the context of complex anatomies where reported PPI rates vary between 14% and 26%.[7,13,16]

In our study, FEops HEARTguide™ simulations predicted >trace PVL fairly well. The new defined PVL cutoff of 12.2 mL/s is lower than the 16 mL PVL cutoff reported in the FEops HEARTguide™ validation study. However, this 12.2 mL cutoff in PRECISE-TAVI discriminated <trace from >trace PVL whereas the 16 mL threshold in the validation study was used to predict >mild PVL (sensitivity 0.72 and specificity 0.78). Interestingly, in

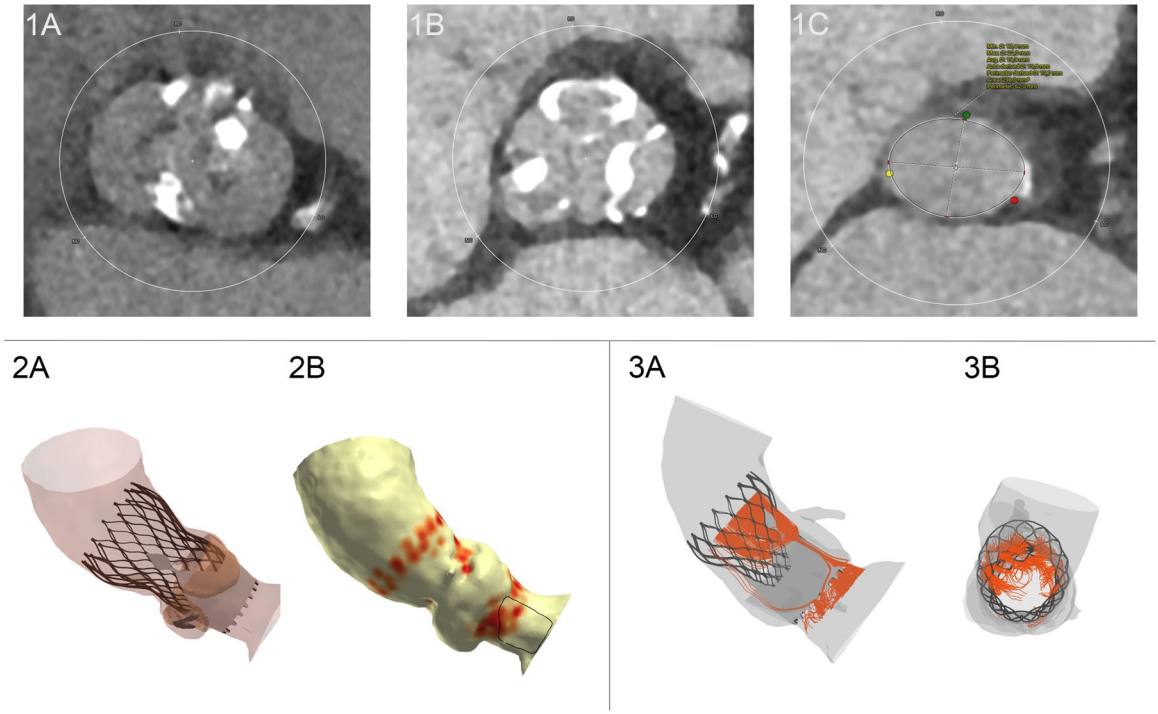


FIGURE 3 Central illustration: CT-images from the three included complex anatomy, that is; bicuspid aortic valve (Sievers 0) (1A), severely calcified (1B), and small anatomy (1C). (2A) visualization of the FEops HEARTguide simulation for PPI prediction: prediction of the frame deformation after THV deployment, (2B) visualization of the contact pressure (red spots) exerted on the structures around the TAVI valve (i.e., Aorta, aorta annulus, LVOT). The contact pressure index is defined as the relative area of contact within the region of interest (square with black line) and used as an indication for risk of conduction abnormalities. Visualization of the FEops HEARTguide simulation for prediction of PVL: PVL leak is shown as orange streamlines from a front view (3A) and a top view (3B). PVL, paravalvular leakage. [Color figure can be viewed at wileyonlinelibrary.com]

our study a PVL > 16 mL/s was associated with >trace PVL in 61% of cases versus only 19% when PVL flow <16 mL/s. A specific threshold for >trace PVL seems relevant as mild PVL may also be associated with longer hospitalizations and mortality.[17] Furthermore, we identified a step-wise increased in computer-derived PVL flow as postprocedural PVL severity increased, consistent with recent findings.[18] The incidence of >trace PVL in our study is similar to what has been reported in the postmarket FORWARD Pro study with 41% >trace PVL and 2% moderate-severe PVL in a population that was not selected for its complex anatomy but rather aimed to reflect every day practice.

In PRECISE-TAVI, a contact pressure index of 11.5% was a good predictor for PPI post-TAVI (sensitivity 0.86, specificity 0.76) and compares with the 14% threshold in the original validation study for any conduction abnormalities (PPI or new LBBB) (sensitivity 0.95, specificity 0.54).[9] In our study a contact pressure >14% resulted in a PPI rate of 31% versus 4% when contact pressure remained ≤14%. Contact pressure will increase with deeper THV implantation. Mean depth of implantation (DOI) was 5.7 ± 4.0 for patients with PPI versus 5.6 ± 3.8 mm for patients with no PPI, showing that implantation depth alone is not a good predictor for PPI post-TAVI. The PPI rate in PRECISE-TAVI was 13% and compares favorably with PPI rates in postmarket registries (FORWARD 18%; FORWARD Pro 19%), a RCT in low-risk patients with PPI (17%) and comparable to a propensity-matched analysis using new implantation techniques (12%).[5,19–21] New implantation techniques such as the double S curve and the cusp overlap technique were not systematically applied in PRECISE-TAVI. Intuitively, a cusp overlap technique should result in higher DOI with corresponding lower contact pressure and potentially lower PPI. The length of the membranous septum also correlates with PPI. In particular a short MS (<3 mm) is associated with a higher PPI because there is a higher likelihood of contact interference between the THV frame and the His Bundle.[22]

FEops HEARTguide™ not only considers MS length but also accounts for the interaction of the THV with the surrounding anatomical structures resulting in contact pressure on the region of the conduction system. This contact pressure may correlate better with PPI than MS length per se.

The PRECISE TAVI Cohort A study demonstrated how computer simulations can be of added value for TAVI risk stratification in patients with severe AS and a challenging anatomy. Further scientific backbone may require a randomized controlled clinical trial that would compare conventional CT planning with advanced CT planning that includes computer simulations.

5 | LIMITATIONS

PRECISE-TAVI is a prospective observational study that only considered the Evolut Pro platform in patients with predefined complex anatomies. There was no independent screening committee, and all patients were selected by the respective local heart teams. The decision to perform additional manoeuvres to correct PVL or to proceed with PPI was at the discretion of the treating physician. Of note, total AV block was identified in 90% of patients with PPI. Echocardiograms after TAVI were evaluated by local imagers and not by an independent echocardiography Core Laboratory. Although the ROC-curves for calculated cut-off points for PPI and >trace PVL had a favorable AUC, a larger cohort study should be performed to validate these cut-off points. Finally, computer simulations predict what ideally would happen for a specific THV size and implantation depth in a specific anatomy. Operators may not always manage to implant the THV in the exact same location as suggested by the simulation. Also, a one-shot implantation may have a different effect than multiple repositioning attempts that may result in more device LVOT interactions and trauma.

6 | CONCLUSION

Feops HEARTguide™ simulations may provide enhanced insights in the risk for PVL or PPI after TAVI with a self-expanding supra-annular THV in complex anatomies.

CONFLICT OF INTEREST STATEMENT

Cameron Dowling reports grants from Medtronic, Johan Bosmans works as clinical proctor for Medtronic CoreValve, Robert Gooley reports personal fees from Boston Scientific, Martin Swaans reports proctoring fees for training/educational servicies to the department of cardiology from Boston Scientific, Abbott Vascular, Edwards Lifesciences, Cardiac dimensions, Philips Healthcare and Bioventrix inc., Stephen J. Brecker reports consultancy fees from Medtronic & Aortic Innovations, Matti Adam reports grants and personal fees from Medtronic, Jenavalve, Edwards Lifesciences and Boston Scientific, Nicolas M. Van Mieghem has received research support from Abbott, Boston Scientific, Edwards Lifesciences, Medtronic, PulseCath, Daiichi Sankyo, Pie Medical, Materialise and consultancy fees from Abbott, Anteris, Boston Scientific, Medtronic, Abiomed, PulseCath, Daiichi Sankyo, Telefex. All other authors have nothing to declare.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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