European Heart Journal Supplements (2022) **24** (Supplement B), B36–B41
The Heart of the Matter
https://doi.org/10.1093/eurheartj/suac005

ESC
European Society
of Cardiology

Fully automated measurement of aortic root anatomy using Philips HeartNavigator computed tomography software: fast, accurate, or both?

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KEYWORDS
Computed tomography;
Aortic valve;
Transcatheter aortic valve implantation

Cardiac computed tomography (CT) is vital for safety and efficacy of transcatheter aortic valve implantation (TAVI). We aimed to determine the accuracy of fully automated CT analysis of aortic root anatomy before TAVI by Philips HeartNavigator software. This prospective, academic, single-centre study enrolled 128 consecutive patients with native aortic valve stenosis considered for TAVI. Automated HeartNavigator software was compared to the standard manual CT analysis by experienced operators using FluoroCT software. The sizing of the aortic annulus by perimeter and area significantly differed between both methods: mean perimeter was 76.43 mm vs. 77.52 mm ($P < 0.0001$) using manual FluoroCT vs. automated HeartNavigator software; mean area was 465 mm^2 vs. 476 mm^2 ($P < 0.0001$). Interindividual variability testing revealed mean differences between the two operators were 1.21 mm for the aortic annulus perimeter and 9 mm^2 for the aortic annulus area. The hypothetical self-expandable transcatheter prosthesis sizing resulted in 80% agreement in 80% of cases. The time required to perform the automated CT analysis was significantly shorter than the time required for manual analysis (mean 17.8 min vs. 2.1 min, $P < 0.0001$). Philips HeartNavigator fully automated software for pre-TAVI CT analysis is a promising technology. Differences detected in aortic annulus dimensions are small and similar to the variability of manual CT analysis. Automated prediction of optimal fluoroscopic viewing angles is accurate. Correct transcatheter prosthesis sizing requires clinical oversight.

Introduction

Transcatheter aortic valve implantation (TAVI) is an established treatment for severe aortic stenosis with continuously expanding indications. Cardiac computed tomography (CT) is the preferred imaging method for aortic root anatomy; it provides precise measurement of the aortic annulus, coronary artery take-off, and sinuses of Valsalva, while permitting definitions of optimal fluoroscopic viewing angles.[1,2] These measurements determine the optimal size of the transcatheter prosthesis and help to achieve excellent sealing in the aortic annulus without causing excessive pressure on the cardiac conduction system. In addition, there is a need to determine the coronary

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ostia height above the aortic annulus and the width of the corresponding sinuses of Valsalva; these assessments help to prevent coronary artery occlusion by the prosthesis and the resulting clinical consequences. The practical issues that affect CT analysis possibly differ among healthcare systems and hospitals; cardiologists, radiologists, radiographers, catheterization laboratory technicians, nurses, and industry product specialists can participate in this process. However, considering the increasing number of patients undergoing evaluation for TAVI, manual CT analysis requires increasing amount of time. Thus, we compared standard manual CT analysis of aortic root anatomy with a fully automated CT analysis using Philips HeartNavigator software.

Methods

Study population

This prospective, academic, single-centre study included all consecutive patients admitted for TAVI in University Hospital Královské Vinohrady, Prague, between 1 October 2019 and 31 March 2021. Patients with degenerated surgical bioprosthetic valves were excluded from this study. All included patients provided written informed consent; data were prospectively entered into a dedicated anonymized database. The study was funded by the Intercardis project. The study protocol complied with the Declaration of Helsinki and was approved by the local Ethical Committee.

Cardiac computed tomography acquisition

Cardiac CT was performed using either a 128-detector-row scanner (Siemens Somatom AS+, Siemens Healthineers, Erlangen Germany) or a dual source 2 × 128-detector-row scanner (Siemens Somatom Drive, Siemens Healthineers, Erlangen Germany). Standard acquisition techniques were applied. Typically, 100 mL of contrast agent (iodine content 400 mg/mL) was administered intravenously at a rate of 4 mL/s. Oral or intravenous β-blockers were used to control the heart rate only in selected stable patients with resting tachycardia only when scanned by single source CT (Somatom AS+); bolus tracking was used to synchronize the contrast medium injection with scanning. Retrospective electrocardiography gating with electrocardiogram-controlled tube current modulation was used, scanning only 25–75% of the RR interval in full radiation dose, images were reconstructed in both best systolic and best diastolic phases. The acquisition was performed using a slice thickness of 0.6 mm, images were reconstructed using 0.4 mm increments in a small field of view, typically 12.5 × 12.5 cm.

Cardiac computed tomography analysis

The operator identified the best diastolic phase; the same CT dataset was used for both manual and automated analyses.

Manual CT analysis using dedicated FluoroCT software (Circle Cardiovascular Imaging Inc., Calgary, Canada) was performed by trained and experienced catheterization laboratory technicians (L.B. and N.V.); it was supervised by a cardiologist with extensive CT experience (V.K.). A complete description of the methodology of aortic root measurement using this software has been previously published.[3,4] In brief, the en face view was determined using the spline, which was defined by the most basal attachment points of left, right, and non-coronary aortic cusps. In this view, the aortic annulus was circled by manually placed segmentation points that were connected using FluoroCT software with a cubic spline interpolation method; then, the aortic annulus perimeter (circumference) and area were measured. In images that depicted calcification, a line was drawn in the middle of the calcification. The coronary artery height was measured in a perpendicular manner, as the distance from the lower edge of the coronary ostium to the aortic annulus plane. The diameters of the sinuses of Valsalva were measured from the left, right, and non-coronary cusps to the opposing commissure on a plane 10 mm above the aortic annulus. The left ventricular outflow tract was measured on a plane 5 mm below the aortic annulus. A standard S-curve defined the optimal perpendicular views of the aortic annulus. The three standard optimal implantation views were a three-cusp view with the right cusp in the middle between left and non-coronary cusps, a right and left cusp overlap view, and a right and non-coronary cusp overlap view. Standard cranial (CRA)/caudal (CAU) and right anterior oblique (RAO)/left anterior oblique (LAO) fluoroscopic views of the C-arm were derived from the sagittal (oblique) and transverse views, respectively. The intraindividual variabilities of both operators were determined using 15 measurements of a single patient's CT dataset. Interindividual variability between operators was determined using a 10-patient sample size.

All CT analysis using the Philips HeartNavigator (Philips Healthcare, The Netherlands) software was fully automated. In brief, the CT dataset is imported from hospital database in the standard DICOM format, HeartNavigator then automatically segments tissue, anatomical structures, landmarks, calcium, and planes of the heart for TAVI. Identical measurements as described above for FluoroCT software are provided with the exception that HeartNavigator software does not provide separate measurements of the left, right, and non-coronary sinuses of Valsalva, rather it provides the perimeter of the sinuses. Hence, the separate measurements were performed manually. All other measurements were fully automated, and no corrections by operators were allowed. The CT analysis is then available for fusion imaging with fluoroscopy during the procedure.

Statistical analysis

Continuous variables are presented in graphs and tables as means and standard deviations. Categorical variables are reported as counts and frequencies. Continuous variables were compared between groups using Student's *t*-test or the Mann–Whitney *U* test. Categorical variables were compared between groups using the chi-squared test or Fisher's exact test. *P*-values <0.05 were considered statistically significant. All statistical analyses were performed using IBM SPSS Statistics, version 26. Graphical analyses were performed using Sigma Plot, version 14.

Results

Our study included 128 consecutive TAVI patients. The baseline characteristics of the study cohort are presented in *Table 1*; the characteristics are typical for a TAVI population between 2019 and 2021. Only two patients had pure aortic regurgitation with non-calcified aortic cusps; the other 126 patients had severe and calcified aortic stenosis. All CT datasets exhibited good quality. A comparison of manual and automated measurements of aortic root anatomy is presented in *Table 2*. The sizing of the aortic annulus by perimeter and area significantly differed between methods, but the numerical differences were small, for example, the difference in aortic annulus perimeter was only 1.09 mm. This difference is graphically illustrated by Bland-Altman analysis of the aortic annulus perimeter in *Figure 1*.

All other measured parameters, except for the right coronary artery height and the non-coronary sinus of Valsalva diameter, were significantly different between methods; however, the numerical differences were again small. The left ventricle outflow tract was measured 4.6 ± 0.6 mm below the level of the aortic annulus using HeartNavigator; it was pre-defined as 5.0 mm when using FluoroCT. Similarly, automated analyses of the sinuses of Valsalva were performed at 12.7 ± 1.3 mm above the level of the aortic annulus, compared with the pre-defined 10.0 mm when using FluoroCT. The time required to perform the automated analysis was significantly shorter than the time required for manual analysis.

Intraindividual and interindividual variability testing of manual FluoroCT aortic root anatomy measurements by our two operators revealed that all intraclass correlation coefficients were >0.91. However, the mean differences between the two operators were 1.21 mm for the aortic annulus perimeter (*Figure 2*) and 9 mm^2 for the aortic annulus area.

Both manual and automated measurements of the aortic annulus perimeter were used to determine the appropriate self-expandable Medtronic Evolut transcatheter prosthesis size, in accordance with the manufacturer's sizing table (Medtronic Inc., Minneapolis, MN, USA). This simulation of clinical decision-making led to the selection of the same size prosthesis in 80% of cases. In 4% of cases, the prosthesis was one size smaller when using automated HeartNavigator measurement; in 16% of cases, the prosthesis was one size larger (*Figure 3*).

Optimal fluoroscopic viewing angles are summarized in *Table 3*; they are nearly identical in manual and automated CT analyses, such that the difference is always $<5°$.

Table 1 Baseline patient characteristics ($n = 128$)

	Count (%) or mean ± standard deviation
Age (years)	79.8 ± 8.1
Men	68 (53%)
Height (cm)	169.1 ± 8.7
Weight (kg)	81.9 ± 17.0
NYHA III + IV	81 (63%)
Diabetes mellitus	51 (40%)
Smoking (past or current)	58 (45%)
Hypertension	107 (84%)
Pacemaker before TAVI	20 (16%)
Aortic valve area (cm^2)	0.75 ± 0.2
EuroScore I logistical (%)	11.3 ± 9.4
EuroScore II (%)	5.2 ± 5.4

NYHA, New York Heart Association; TAVI, transcatheter aortic valve implantation.

Discussion

This study provides a detailed comparison of pre-TAVI aortic root analysis between automated Philips HeartNavigator software and the standard manual technique. The major findings of this study were as follows. First, aortic root measurements differed between automated and manual analyses; however, the numerical differences were small and similar to intra- and interindividual variability differences during manual analysis. Second, both methods recommend identical sizes of the transcatheter prosthesis in 80% of patients. Third, automated CT analysis is more rapid than manual analysis. Fourth, the determination of optimal fluoroscopic viewing angles for TAVI using automated Philips HeartNavigator software provides results nearly identical to manual analysis.

The first description of semi-automated aortic annulus sizing CT software (3mensio, Pie Medical Imaging, The Netherlands) was published in 2011[5]; it showed excellent correlation with manual measurement. In addition, this CT analysis software has demonstrated excellent reproducibility.[6,7] Manual (multiple software) or semi-automated CT analysis of aortic annulus with 3mensio software is currently in routine clinical use with clinical outcomes validated by multiple years of experience. In a small study in Egypt (https://doi.org/10.1016/j.ejrnm.2018.02.007), fully automated software (Synapse 3D, Fujifilm Healthcare, Japan) demonstrated accurate results; however, this software is not widely available in Europe. Additionally, a fully automated academic software was adapted from its originally intended echocardiography use and demonstrated encouraging results at University Hospital Leuven, Leuven, Belgium; thus far, it is not available for clinical use.[8] However, the Philips HeartNavigator software can easily be integrated into a cardiac catheterization laboratory and used for the fusion imaging of a 3D CT dataset over angiographic images. We believe that this software should be objectively validated before routine clinical use and our study provides the first evaluation of the accuracy of this medical software for aortic root sizing before TAVI.

The small but statistically significant difference in most aortic root measurements is probably caused by the suboptimal automatic delineation of contrast-filled anatomic structures. This can be easily corrected manually, with minimal time required. Additionally, it is unclear which contouring method is used by HeartNavigator; the absence

Table 2 Comparison of aortic root anatomy manual and automated measurements ($n = 128$)

	Manual FluoroCT analysis		Automated HeartNavigator analysis		
	Mean	SD	Mean	SD	*P*-value
Aortic annulus perimeter (mm)	76.43	7.78	77.52	7.93	$P < 0.0001$
Aortic annulus area (mm^2)	465	43	476	47	$P < 0.0001$
Left ventricular outflow tract perimeter (mm)	78.49	9.99	75.82	8.46	$P < 0.0001$
Left coronary artery height (mm)	13.29	2.7	12.39	2.59	$P < 0.0001$
Right coronary artery height (mm)	14.87	3.54	14.92	2.77	$P = 0.79$
Left sinus of Valsalva diameter (mm)	32.29	4	33.29	3.36	$P < 0.0001$
Right sinus of Valsalva diameter (mm)	30.65	3.36	31.88	3.83	$P < 0.0001$
Non-coronary sinus of Valsalva diameter (mm)	32.14	3.83	32.3	3.94	$P = 0.1$
Sinus of Valsalva perimeter (mm)	103.77	11.53	105.61	12.53	$P < 0.0001$
Time required for analysis (min)	17.8	3.5	2.1	0.7	$P < 0.0001$

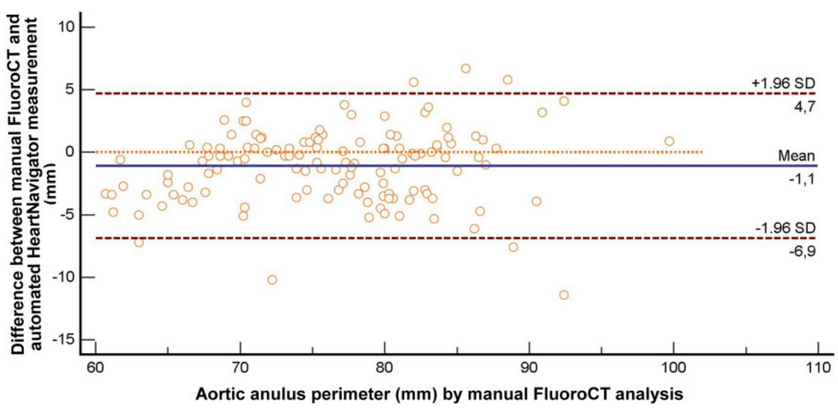

Figure 1 Bland-Altman analysis of the difference between manual FluoroCT and automated HeartNavigator measurements of the aortic annulus perimeter.

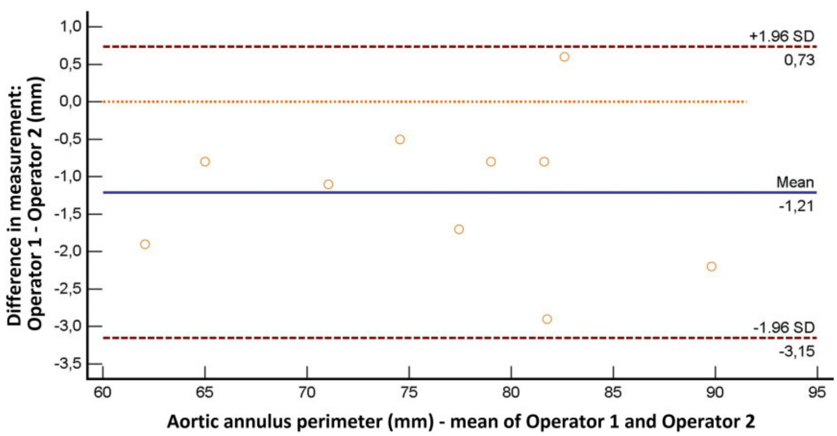

Figure 2 Bland-Altman analysis of the difference between manual FluoroCT measurements of the aortic annulus perimeter by two operators.

of interpolation (smoothing) could lead to overestimation of the aortic annulus perimeter.[2] Manual CT analysis relies on the operator's experience and expertise. In our study, intra- and interindividual variability testing demonstrated excellent reproducibility, consistent with the findings in previous studies.[5-8] Nevertheless, the observed variability in our study is numerically similar to the difference between automated and manual CT analysis (*Figures 1 and 2*). The Bland-Altman limits of agreement of the two operators for the measurement of aortic annulus perimeter were −3.15 to 0.73 mm in our study; this is similar to the range of −5.40 to 6.59 mm reported by Stortecky *et al.*[6] Two other groups have analysed inter- and intraobserver variabilities of manual or semi-automated CT analysis of aortic root; they showed similar limits of agreement for aortic annulus perimeter (reported differences in perimeter-derived diameter must be multiplied by π).[9,10] Notably, the comparison of CT perimeter-derived aortic annulus diameter with intraoperative direct sizing by cardiac surgeon had limits of agreement from −3.16 to 2.05 mm, which correspond to approximately −9 to 6 mm for perimeter.[11]

The measurement of aortic annulus dimensions is important for the selection of a transcatheter prosthesis with optimal oversizing. The perimeter is generally used for self-expandable prostheses; the aortic annulus area determines the balloon-expandable prosthesis sizing.[2] We have found theoretical self-expanding Evolut prosthesis sizing agreement between manual and automated CT analysis in 80% of patients. In borderline cases, simple manual contour correction and multi-observer interpretation might lower the rate of sizing discrepancies.[12]

The time (15 min) saved by fully automated CT pre-TAVI analysis appears minimal, but it is clinically relevant because increasing numbers of patients are undergoing this remarkably successful procedure. Additionally, the CT operators in this study were highly trained; the time saved by automated analysis might be more pronounced for less experienced operators.

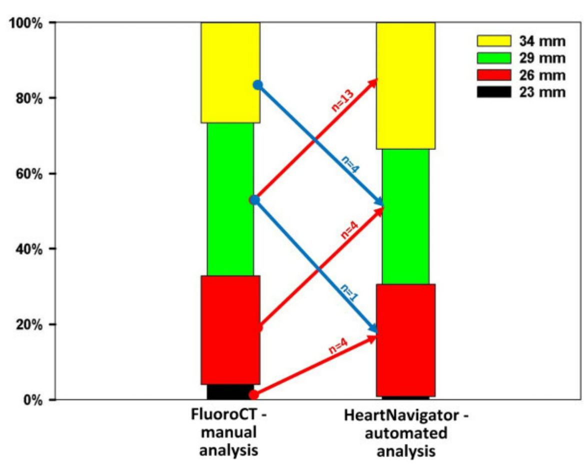

Figure 3 Comparison of Medtronic Evolut self-expandable transcatheter prosthesis sizing between manual FluoroCT and automated HeartNavigator measurements.

To our knowledge, this study is the first to evaluate the accuracy of predicted patient-specific optimal fluoroscopic viewing angles using fully automated CT analysis. Optimal fluoroscopic projection minimizes foreshortening and allows operators to confidently place the transcatheter prosthesis into optimal depth below the aortic annulus. For balloon-expandable prosthesis, a coplanar three-cusp view is typically used. The right and left coronary cusp overlap technique for self-expandable prosthesis implantation results in lower rates of conduction disturbances. We have found excellent agreement between manual and automated CT analyses. The difference of 5° results in <1% foreshortening, which is not clinically relevant.

This study had several limitations. First, we used the best quality diastolic phase, rather than a systolic phase; because of dynamic changes in the aortic annulus, this might have led to dimensional underestimation. However, this limitation presumably did not influence our comparative study.[13] Second, the small number of patients with bicuspid aortic valve did not allow evaluation of this important subgroup. Third, the potential clinical implications were demonstrated only using a self-expandable Evolut prosthesis (the prosthesis most frequently used in our centre). However, we presume that results would be similar for other transcatheter prostheses with different cut-offs between sizes, because the Bland–Altman analysis showed uniform differences across all sizes of the aortic annulus. Fourth, we did not attempt to evaluate procedural outcomes because real-life decision-making is much more complex—considerations include the amount and distribution of calcification, protrusion of calcification into outflow tract, risk of paravalvular regurgitation, and atrioventricular conduction block. Last, no comparison with other existing software was made.

In conclusion, Philips HeartNavigator fully automated software for CT analysis of aortic root anatomy is a promising time-saving technology. Differences detected in aortic annulus dimensions are small and similar to the variability of manual CT analysis. Automated prediction of optimal fluoroscopic viewing angles is accurate. Correct transcatheter prosthesis sizing requires clinical oversight.

Funding

Supported by project Interventional treatment of life-threatening cardiovascular diseases – INTERCARDIS, project EU Nr. CZ.02.1.01/0.0/0.0/16_026/0008388.

Table 3 Optimal fluoroscopic implantation viweing angles by manual and automated measurement ($n = 128$)

	Manual FluoroCT analysis		Automated HeartNavigator analysis	
	RAO (−)/ LAO (+)	CAU (−)/ CRA (+)	RAO (−)/ LAO (+)	CAU (−)/ CRA (+)
Three-cusp view (mean ± SD)	6 ± 10	−4 ± 12	9 ± 8	1 ± 9
Left and right cusp overlap view (mean ± SD)	−15 ± 12	−25 ± 13	−13 ± 9	−22 ± 12
Right and non-coronary cusp overlap view (mean ± SD)	28 ± 11	18 ± 14	25 ± 12	18 ± 12

Conflict of interest: V.K. reports consultant contracts, lecture fees, and grant support from Philips, Medtronic, and BBraun. P.T. reports consultant contracts, lecture fees, and grant support from Medtronic and BBraun. M.N. is an employee of Medtronic Czechia. All other authors have no potential conflict of interest.

Data availability

The data underlying this article will be shared on reasonable request to the corresponding author.

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