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Automated 3D Analysis of Pre-Procedural MDCT to Predict Annulus Plane Angulation and C-Arm Positioning

Benefit on Procedural Outcome in Patients Referred for TAVR

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OBJECTIVES The aim of this study was to determine whether pre-procedural analysis of multidetector row computed tomography (MDCT) scans could accurately predict the "line of perpendicularity" (LP) of the aortic annulus and corresponding C-arm angulations required for prosthesis delivery and impact the outcome of the procedure.

BACKGROUND Optimal positioning of the transcatheter aortic prosthesis is paramount to transcatheter aortic valve replacement (TAVR) procedural success.

METHODS All patients referred for TAVR at our center underwent a routine pre-procedural MDCT scan. A 3-dimensional (3D) analysis using software dedicated to define the LP of the aortic annulus and the corresponding C-arm positioning was performed in 71 consecutive patients. In 35 patients, the results of the MDCT analysis were not available at the time of the procedure (angiography cohort). In that cohort the position of the C-arm was determined during the procedure using ad-hoc angiography. In 36 patients, the MDCT analysis was performed pre-procedure and results were available at the time of the procedure (MDCT cohort). In that cohort the position of the C-arm was derived from the MDCT analysis rather than by ad-hoc angiography.

RESULTS Intraobserver and interobserver reproducibility of MDCT analysis to predict the LP of the aortic annulus were excellent (kappa = 1 and 0.94, respectively). Patient variations of the LP ranged >70°. Compared with the angiography cohort, the MDCT cohort was associated with a significant decrease in implantation time (p = 0.0001), radiation exposure (p = 0.02), amount of contrast (p = 0.001), and risk of acute kidney injury (p = 0.03). Additionally, the combined rate of valve malposition and aortic regurgitation was also reduced (6% vs. 23%, p = 0.03).

CONCLUSIONS Automated 3D analysis of pre-implantation MDCT accurately predicts the LP of the aortic annulus and the corresponding C-arm position required for TAVR. With this approach, the implantation of the balloon-expandable prosthetic valve can be performed without an aortogram in the majority of cases and still be safe, with a low rate of valve malpositioning and regurgitation. (J Am Coll Cardiol Img 2013;6:238–48) © 2013 by the American College of Cardiology Foundation

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Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure performed in patients with severe aortic stenosis and that are at high surgical risk (1,2). Optimal positioning of the prosthetic valve during TAVR is crucial in order to avoid valve embolization, coronary ostial obstruction, perivalvular regurgitation, and conduction disturbance (3).

During deployment of the valve prosthesis, an optimal view of the aortic annulus where the valve will be implanted has to be determined (1,2). The aim of the optimal view is to position the x-ray tube C-arm perpendicular to the aortic annulus plane in order to achieve an appropriate delivery of the valve during TAVR. Previous studies have shown that the aortic valve is typically directed in a cranial and anterior fashion with angulation to the right, and that corresponding C-arm positions describe a line in a 2-dimensional space. This line is known as the "line of perpendicularity" of the C-arm to the annulus (4). Selecting the best angiographic view usually requires the intraprocedural performance of several angiograms in different angulations of the C-arm, using a considerable amount of contrast with its known possible nephrotoxic effect and radiation for both patients and operators. An accurate pre-procedural assessment of the line of perpendicularity of the annulus would help planning TAVR procedures.

Multidetector row computed tomography (MDCT) provides detailed anatomic assessment of the aortic root and valve annulus, and assesses the suitability of iliofemoral access. MDCT has also significant potential to assess the aortic root in relation to the body axis (4). Pre-procedural angle prediction of the C-arm with MDCT may decrease the number of angiograms required during the procedure, shortening procedure time, radiation dose, and contrast usage, and may increase the likelihood of an optimal implantation of the valve prosthesis by optimizing the orientation during device placement.

The present study was designed to evaluate whether automated 3-dimensional (3D) analysis of pre-procedural MDCT scans could be used to: 1) reproducibly define the aortic annulus plane and the line of perpendicularity of the annulus to be used for the TAVR procedure; 2) define the inter-individual variation of the line of perpendicularity of the aortic annulus among patients; and 3) improve safety parameters and clinical outcomes of the TAVR procedure.

METHODS

Study population. All consecutive patients with severe aortic stenosis considered to be at high or prohibitive surgical risk (as evaluated by a multidisciplinary heart team) and referred to our center for TAVR with a balloon-expandable endoprosthesis between January 2009 and June 2011 were included in the study (Fig. 1).

Pre-procedural MDCT was performed in all patients within 3 months before the TAVR procedure. The automated MDCT 3D software analysis (3mensio Valves, version 3.0, 3mensio Medical Imaging BV, the Netherlands) has been available in our institution since December 2009. Analysis of the pre-procedural MDCT was performed for all patients. Based on the performance and on the availability of the results of this analysis to the operator at the time of the procedure, 2 cohorts were constituted. In the angiography cohort, the analysis of the pre-procedural MDCT was performed after the TAVR procedure had already been performed. In this cohort, the results of MDCT analysis were not available to the operator at the time of the procedure. In the MDCT cohort, the analysis was performed before the procedure, and the results of MDCT analysis were available to the operator at the time of the procedure.

At the time of MDCT software availability, 24 procedures had already been performed. These 24 patients were analyzed with the MDCT 3D software retrospectively (Angiography Cohort A).

Forty-seven additional patients were treated from December 2009 until June 2011. In 1 of every 4 patients randomly chosen (n = 11), the automated 3D software analysis was not performed before but after the procedure, and the operators were therefore performing the procedure without knowledge of the results of the MDCT 3D analysis. The outcome of this group (Angiography Cohort B, n = 11) was compared with the outcome of the previous group (Angiography Cohort A, n = 24) to evaluate any significant impact on clinical outcome of change over time in practice and clinical experience of the operators (see the following text).

In 3 of every 4 patients (n = 36), the MDCT 3D analysis was performed before the procedure, and the results were provided to the operators before the beginning of the procedure. This group constituted the MDCT cohort. The patients for whom the

ABBREVIATIONS AND ACRONYMS

3D = 3-dimensional
AR = aortic regurgitation
CT = computed tomography
LAO = left anterior oblique
MDCT = multidetector row computed tomography
RAO = right anterior oblique
TAVR = transcatheter aortic valve replacement

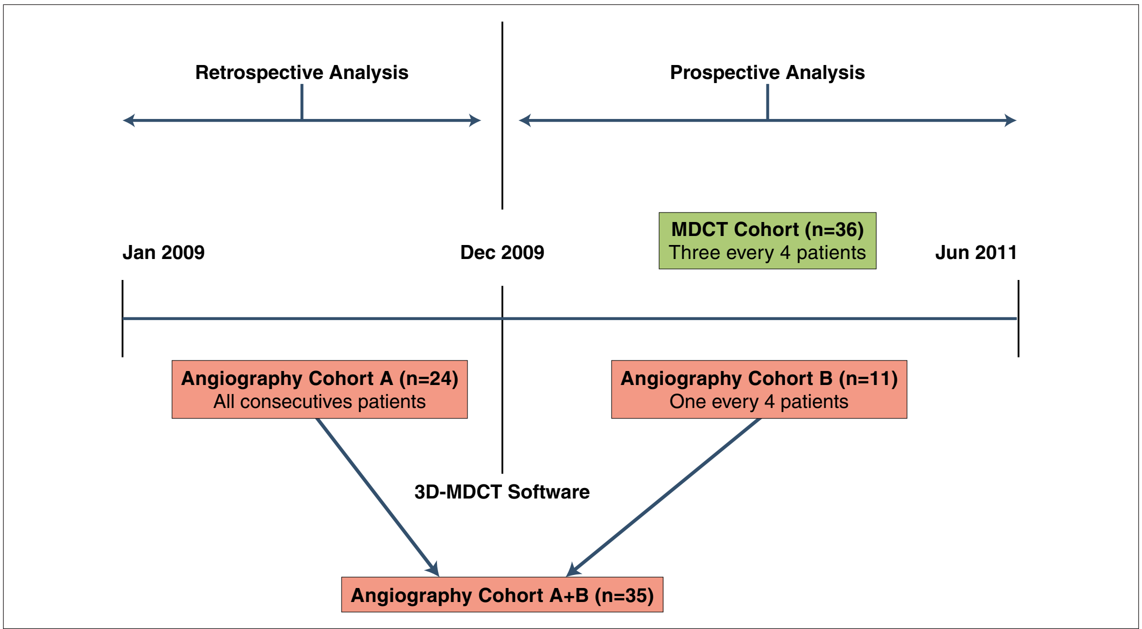

Figure 1. **Flowchart of the Study**

All consecutive patients treated between January 2009 and June 2011 were part of the study (n = 71). Automated multidetector row computed tomography (MDCT) 3-dimensional (3D) software (3-mensio) was available in December 2009. All consecutive patients treated between January 2009 and December 2009 constituted the Angiography Cohort A (n = 24). From January 2010 until June 2011, 1 of every 4 patients was included in the Angiography Cohort B (n = 11), and 3 of every 4 patients were included in the MDCT cohort (n = 36).

results of the 3D MDCT analysis (n = 24 + 11 = 35) were not made available to the operators at the time of the procedure constituted Angiography Cohort A+B.

Multidetector row computed tomography. As part of the work-up procedure, the patients underwent MDCT within 3 months before TAVR. The detailed MDCT procedure is described in the supplementary materials in the Online Methods.

Automated 3D image analysis of MDCT. All MDCT images were analyzed by a procedure-independent operator, who was trained to use the dedicated 3D aortic valve analysis 3-mensio software. For the 35 patients in the angiography cohort, analyses were completed on 2 separate occasions by the dedicated operator. A second operator completed a third series of analysis.

For each patient, the image quality of the computed tomography (CT) was rated into 3 groups by the operators: excellent, adequate, or inadequate, depending on potential degradations due to calcification, motion, or contrast issues. The severity of aortic root calcification was classified into 4 groups: minimal (<25% of total circumference), mild (25% to 50%), moderate (50% to 75%), and severe (75% to 100%) (5). The process to determine the aortic annulus plane and the predicted line of perpendicularity of the aortic annulus is described in the supplementary materials in the Online Methods and in Figure 2.

For each patient, the software provides an infinite series of C-arm positions (defined by their combination of cranio-caudal and right anterior oblique/left anterior oblique [RAO-LAO] angulation), where the C-arm is perpendicular to the annulus plane. This series is named the predicted line of perpendicularity of the annulus. For each patient, the predicted "line of perpendicularity" of the annulus can be drawn on a cranio-caudal axis/right-left axis figure (Fig. 3).

TAVR procedure. The prosthetic stented Edwards SAPIEN (until August 2010) or SAPIEN XT (since August 2010) valves (Edwards Lifesciences, Irvine, California) were mechanically crimped on a balloon catheter immediately before implantation. The Retroflex or Novaflex delivery systems (Edwards Lifesciences) were used for device implantation via the femoral artery. Until August 2010, the femoral artery was accessed via a surgical cut-down; since August 2010, it has been performed through a percutaneous puncture. The Ascendra and Ascendra 2 delivery systems (Edwards Lifesciences) were used in case of apical access.

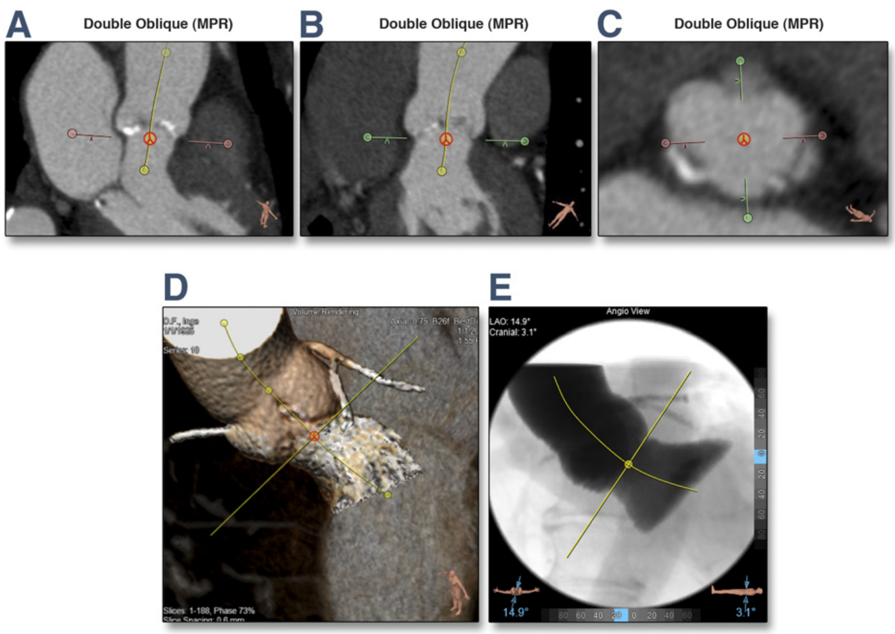

Figure 2. Defining the Line of Perpendicularity of the Aortic Annulus Using Automated MDCT 3D Software Analysis

After defining the central line of the ascending aorta **(yellow line)**, the valve region is visualized in 3 double oblique multiplanar reconstruction (MPR) viewports **(A to C)**. The 2 double oblique views show perpendicular cross sections through the aortic valve **(A and B)**. The other shows the annulus plane in short axis **(C)**. The level of the annulus plane relative to the central line can be changed by dragging the **red icon** at the level of the annulus plane. The orientation of the plane can be refined by dragging the **green (A)** and **pink lines (B)** in the oblique views and verified by rotating the corresponding **green** and **pink handles** on the view of the annulus plane **(C)**. The corresponding 3D view is presented **(D)**. A simulated angiogram with corresponding C-arm angles displayed on the 2 **bottom corners** is obtained **(E)**. A virtual C-arm can be rotated along the aortic centerline by dragging the **eye icon** in the left view. The simulated projection is updated interactively. The aortic centerline and the aortic annulus plane are drawn over the simulated angiogram. A full description of the method is provided as supplementary materials (Online Methods). Abbreviations as in Figure 1.

Transfemoral and transapical aortic valve replacement were performed under general anesthesia in the catheterization laboratory and are described in the supplementary materials (Online Methods) (6,7). All patients, including those treated through a transapical approach, were indeed placed flat on their backs during the procedure.

Besides the use of the C-arm aligned with the plane of the aortic annulus, the operator was free to choose the projection that suited the procedure. Among the considerations used to define an appropriate projection for the implantation were achieving a projection in which the right coronary cusp was oriented towards the x-ray detector and a projection in which the annulus projection was not superimposed with the spine and not superimposed with the delivery catheter present in the descending aorta.

The angiography cohort and the MDCT cohort: specificities. In patients in the MDCT cohort (n = 36), the position of the C-arm was chosen among the positions proposed by the MDCT analysis and included in the predicted line of perpendicularity of the annulus. No angiography of the aortic root was performed. The balloon-mounted endoprosthesis was positioned with the aim to locate the unexpanded endoprosthesis mid-way at the level of the virtual line connecting the insertion site of the 3 cusps to the aortic wall. The first angiogram was performed as part of the delivery while the balloon-mounted endoprosthesis was sitting within the aortic annulus to validate the height of the endoprosthesis relative to the annulus; rapid pacing was then started, and the endoprosthesis was delivered.

In case the alignment of the annulus appeared to be inaccurate to the operator, the rapid pacing was not started, and delivery was not performed. Additional angiograms were then performed to define a proper C-arm angulation before proceeding to the delivery under rapid pacing.

In patients in the Angiography Cohort A+B (n = 35), the proper position of the C-arm was determined empirically using test angiograms ac-

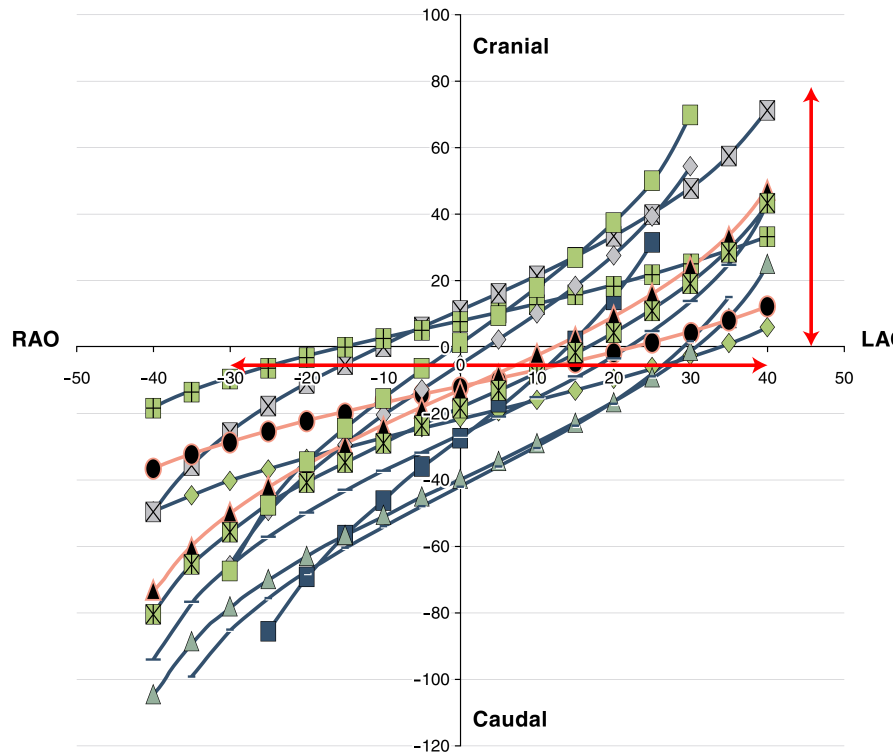

Figure 3. Individual Lines of Perpendicularity of the Aortic Annulus Derived From MDCT 3D Analysis in the 35 Patients From the Angiography Cohort

From patient to patient and for any given RAO-LAO positioning, the appropriate cranio-caudal position can vary within an 80° range. From patient to patient and for any given cranio-caudal positioning, the appropriate RAO-LAO position can vary within a 70° range. LAO = left anterior oblique; RAO = right anterior oblique; other abbreviations as in Figure 1.

cording to standard practice. Once the proper position of the C-arm was defined, the aortic annulus was crossed with the balloon-mounted endoprosthesis, and the procedure was carried out in a similar fashion to that in the MDCT cohort using a final angiogram to validate the height of the endoprosthesis just before beginning delivery.

The major difference between the patients included in the Angiography Cohort A and those included in the Angiography Cohort B is the period in which they were treated. The Angiography Cohort B was the most recent and was contemporary with the MDCT cohort. The comparison between the 2 angiography cohorts was used to evaluate the potential impact of a learning curve or procedural changes over time in practice as well as a potential increase in operator expertise.

Although the reduction in contrast and radiation was not mandated by the protocol, it was expected to be a consequence of the use of the MDCT-based rather than the standard angiography-based strategy.

Procedural characteristics and follow-up. Implantation time was defined as the time between introduction and removal of the delivery sheath. For all procedures, the number of test angiograms, the amount of contrast (milliliters) and radiation (Greys) delivered to the patient were recorded. The need for post-implantation balloon dilation of the endoprosthesis was also recorded. Valve malposition was defined as an inadequate position of the device requiring the implantation of a second valve or an emergent surgery. Post-procedural aortic regurgitation (AR) was evaluated by transthoracic echocardiography on the day of the procedure and was classified as none/trivial (= 0), mild (= 1), moderate (= 2), moderate-to-severe (= 3), or severe (= 4). An AR grade ≥2 was considered significant. Post-procedural acute kidney injury was defined as an increase in serum creatinine by >25% or 44 μmol/l (0.5 mg/dl) (8). Thirty-day outcomes, including the implantation of a permanent pacemaker or the occurrence of myocardial infarction, stroke, or death were recorded. The primary endpoint was pre-defined as the occurrence of the composite endpoint of occurrence of valve malposition and/or AR grade ≥2 post-procedure. Secondary endpoints were: 1) implantation time; 2) amount of contrast; 3) amount of radiation delivered to the patient during the procedure; 4) occurrence of post-procedural acute kidney injury; and 5) mortality at 30 days.

Statistical analysis. Continuous variables were expressed as mean ± standard deviation, and categorical variables were reported as frequencies. For comparison between categorical variables, a chi-square test was used, and an independent-sample *t* test was used to compare continuous values. In order to adjust to potential confounding factors, multivariate linear regression or multivariate logistic regression analyses were performed as appropriate. Reproducibility of MDCT 3D analysis was investigated using kappa statistics (9). For these analyses, a 40° range of RAO-LAO angulations; between RAO 20° and LAO 20°; was considered. Cranio-caudal angulation was provided for any 1° increment of RAO-LAO angulation. If for any of these 40 positions, the cranio-caudal angulation was >5° outside the prediction, then the whole analysis was considered discordant. Analyses were performed using IBM SPSS Statistics 19.0 (IBM, Armonk, New York).

RESULTS

Baseline and characteristics of the study population. A total number of 71 patients were included in this study, 36 patients in the MDCT cohort and 35 patients in the Angiography Cohort A+B. The baseline clinical and echocardiography characteristics of the population are presented in Table 1. A little more than 50% of the population were women, the mean age was 80 ± 6 years, and the mean logistic EuroSCORE was 18 ± 11.

Within the angiography cohort, no significant difference was observed between the patients treated before (Cohort A, n = 24) or after (Cohort B, n = 11) the availability of the automated 3D analysis of MDCT. Similarly, no difference was observed between the Angiography Cohort A+B and the MDCT cohort.

Reproducibility of 3D MDCT analysis as performed in the Angiography Cohort A+B. The quality of the CT scan was considered excellent in 83% (59 of 71) and adequate in 17% (12 of 71) of cases. In no

Table 1. Clinical and Echocardiographic Characteristics at Baseline (N = 71)

	Angiography Cohort A (n = 24)	Angiography Cohort B (n = 11)	p Value	Angiography Cohort A+B (n = 35)	MDCT Cohort (n = 36)	p Value
Age, yrs	79 ± 7	78 ± 9	0.71	79 ± 9	82 ± 5	0.06
Men	12 (50)	5 (45)	0.90	17c(49)	15c(42)	0.56
BMI, kg/m^2	25.6 ± 6.9	27.3 ± 4.3	0.48	26.2 ± 6.0	26.7 ± 5.5	0.67
Hypertension	17 (71)	9 (82)	0.69	26 (74)	27 (75)	0.96
Dyslipidemia	15 (62)	6 (55)	0.72	21 (60)	16 (44)	0.18
Diabetes	5 (21)	5 (45)	0.23	10 (29)	12 (33)	0.61
Smoking	3 (13)	2 (18)	0.63	5 (14)	5 (14)	0.99
CAD	16 (67)	9 (82)	0.44	25 (71)	23 (64)	0.50
Prior MI	8 (33)	4 (36)	0.91	12 (34)	8 (22)	0.26
Prior PCI	8 (33)	3 (27)	0.90	11 (31)	11 (31)	0.94
Prior CABG	6 (25)	4 (36)	0.69	10 (29)	4 (11)	0.08
CVD	9 (37)	2 (18)	0.44	11 (31)	7 (19)	0.27
PVD	6 (25)	2 (18)	0.93	8 (23)	7 (19)	0.73
Renal disease	5 (21)	3 (27)	0.69	8 (23)	14 (39)	0.22
Creatinine, μmol/l, median (IQR)	107 (55)	110 (81)	0.35	109 (46)	91 (68)	0.49
COPD	7 (29)	3 (27)	0.91	10 (29)	12 (33)	0.61
Prior malignant disease	6 (25)	2 (18)	0.93	8 (23)	9 (25)	0.88
Logistic EuroSCORE	19.7 ± 12.8	16.2 ± 11.8	0.30	18.3 ± 11.8	18.5 ± 10.8	0.94
Peak aortic gradient, mm Hg	73.0 ± 23.4	71.4 ± 24.0	0.76	72.5 ± 23.4	66.3 ± 23.6	0.30
Aortic valve area, cm^2	0.70 ± 16	0.72 ± 14	0.32	0.71 ± 15	0.71 ± 19	0.91
LVEF, %	54.9 ± 12.4	51.3 ± 11.6	0.41	53.7 ± 12.4	52.4 ± 10.9	0.67

Values are mean ± SD or n (%).
BMI = body mass index; CABG = coronary artery bypass grafting; CAD = coronary artery disease; COPD = chronic obstructive pulmonary disease; CVD = cerebrovascular disease; IQR = interquartile range; LVEF = left ventricular ejection fraction; MDCT = multidetector row computed tomography; MI = myocardial infarction; PCI = percutaneous coronary intervention; PVD = peripheral vascular disease.

case was the quality of the CT considered inadequate. Calcification of the aortic root was classified as minimal (4% [n = 3]), mild (18% [n = 13]), moderate (48% [n = 34]), or severe (30% [n = 21]).

Within a margin of 5°, intraobserver (35 of 35, kappa = 1) and interobserver (34 of 35, kappa = 0.94) reproducibility of the 3D automated MDCT prediction of the line of perpendicularity of the annulus was excellent.

Interindividual variation of the line of perpendicularity of the annulus. Interindividual variation of the line of perpendicularity of the annulus among patients in the angiography cohort is shown in Figure 3. It shows the heterogeneity of the orientation of the line of perpendicularity of the annulus from patient to patient with a range of 70° in the cranio-caudal axis and 80° in the right-left axis. This demonstrates that for each patient, the proper position of the C-arm can be anywhere in a range of 70° in the cranio-caudal axis for every fixed right-left position, and anywhere in a range of 80° in the right-left axis for every fixed cranio-caudal position.

Procedural characteristics and clinical outcome in the angiography and MDCT cohorts. Procedural characteristics are presented in Table 2. Within the angiography cohort, no significant differences were observed in prosthesis diameter, TAVR approach, procedural outcome, and 30-day outcome between the procedures performed before (Cohort A, n = 24) or after (Cohort B, n = 11) the availability of the automated 3D analysis of MDCT. The lack of difference between the 2 populations demonstrated that "time" or "learning curve" were not key predictors of outcome in this series. It also validated the combination of these 2 populations into a single population, the Angiography Cohort A+B.

The comparison between the Angiography Cohort A+B and the MDCT cohort demonstrates no difference in choice of the prosthesis diameter. A trend for a reduced use of the transapical approach (p = 0.09) was observed in the MDCT cohort (Table 2).

In the Angiography Cohort A+B, test angiograms were performed in every patient before crossing the valve with the balloon-mounted endopros-

Table 2. Procedural Characteristics and 30-Day Outcome

	Angiography Cohort A (n = 24)	Angiography Cohort B (n = 11)	p Value	Angiography Cohort A+B (n = 35)	MDCT Cohort (n = 36)	p Value
Diameter of implanted valve prosthesis						
23 mm	7 (29)	3 (30)		10 (28.6)	11 (30.6)	
26 mm	17 (71)	7 (29)	0.32	24 (68.6)	24 (66.7)	0.98
29 mm	0 (0)	1 (9)		1 (2.9)	1 (2.8)	
TAVR approach						
Transfemoral	11 (46)	7 (64)	0.32	18 (51)	26 (72)	0.09
Transapical	13 (54)	4 (36)		17 (49)	10 (28)	
Procedural outcome						
Implantation time, min	64 ± 18	61 ± 17	0.76	63± 17	46 ± 11	<0.0001
Contrast medium, ml	185 ± 124	170 ± 101	0.37	180 ± 109	108 ± 34	0.001
Radiation, Gy	1,688 ± 1,185	1,637 ± 999	0.57	1,671 ± 1,111	1,180 ± 617	0.02
Test angiograms before delivery						
0	0 (0)	0 (0)		0 (0)	35 (97)	
1	3 (12)	1 (9)	0.77	4 (11)	1 (3)	<0.0001
≥2	21 (88)	10 (91)		32 (89)	0 (0)	
Valve malposition*	2 (8)	1 (9)	0.94	3 (9)	0 (0)	0.07
AR grade ≥2 by TTE†	4 (17)	2 (18)	0.91	6 (17)	2 (6)	0.11
Valve malposition* and/or AR grade ≥2 by TTE†	6 (25)	3 (27)	0.88	8 (23)	2 (6)	0.03
Post-procedural acute kidney injury	8 (33)	3 (27)	0.90	11 (31)	4 (11)	0.03
30 day outcome						
Myocardial infarction	1 (4)	0 (0)	0.99	1 (3)	0 (0)	0.98
Stroke	0 (0)	1 (9)	0.66	1 (3)	1 (3)	0.99
Permanent pacemaker	0 (0)	1 (9)	0.66	1 (3)	1 (3)	0.99
Mortality	5 (21)	2 (18)	0.85	7 (20)	2 (6)	0.06

Values are n (%) or mean ± SD. *Valve malposition requiring implantation of a second valve or emergent surgery; †as evaluated on post-procedural TTE performed on the same day. AR = aortic regurgitation; TAVR = transcatheter aortic valve replacement; TTE = transthoracic echocardiography; other abbreviations as in Table 1.

thesis. The number of test angiograms ranged from 1 to 5. In 4 of 35 patients, only 1 test angiogram was needed. In 31 of 35 patients, at least 2 test angiograms were performed. In the MDCT cohort, no test angiogram was required in 35 of 36 of the patients. In 1 of 36 patients, the alignment of the annulus appeared to be inaccurate to the operator. In this patient, 1 additional angiogram was performed in order to define a proper C-arm angulation before proceeding to the delivery (Table 2).

The comparison between Angiography Cohort A+B and the MDCT cohort demonstrated that the use of automated 3D analysis of MDCT to predict the line of perpendicularity of the annulus and to choose the appropriate C-arm position to deliver the prosthesis is associated with a reduction of implantation time (46 ± 11 min vs. 63 ± 17 min, $p < 0.0001$) (Fig. 4A), radiation exposure (1,180 ± 617 Gy vs. 1,671 ± 1,111 Gy, $p = 0.02$) (Fig. 4B), and amount of contrast delivered (110 ± 13 ml vs. 180 ± 119 ml, $p = 0.001$, Fig. 4C). Similarly, the number of patients with post-procedural acute kidney injury was also lower (11% vs. 31%, $p = 0.03$) (Fig. 4D). The use of MDCT-derived predictions was also associated with a reduced need for balloon redilation of the endoprosthesis post-implantation (3% vs. 20%, $p = 0.02$) and a reduced risk of valve malposition and/or AR grade ≥2 (6% vs. 23%, $p = 0.03$) (Fig. 4E). Finally,

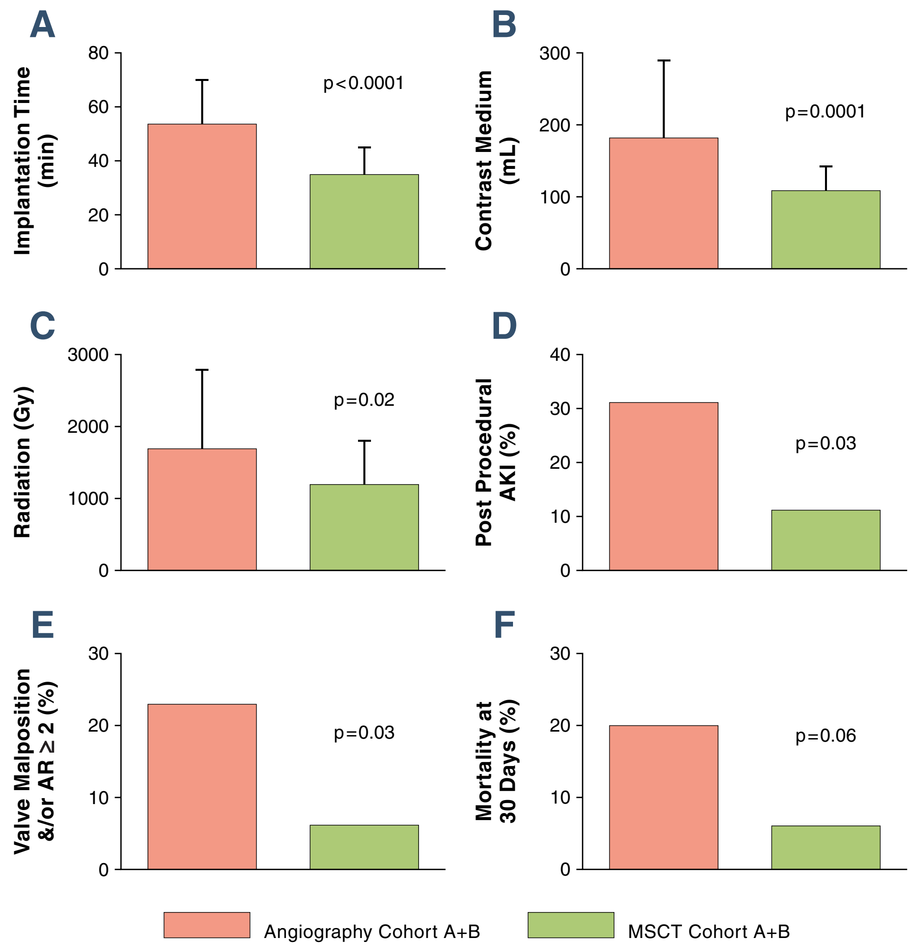

Figure 4. Clinical Benefit of Using the Pre-Defined Line of Perpendicularity of the Aortic Annulus as Determined by 3D Analysis of MDCT

Pre-procedural 3D analysis of MDCT and pre-procedural prediction of C-arm position (MDCT cohort, **green bars**) is associated with a decrease in implantation time **(A)**, radiation exposure **(B)**, amount of contrast **(C)**, risk of acute kidney injury (AKI) **(D)**, or the combined endpoint of valve malposition/aortic regurgitation (AR) grade ≥2 **(E)**, and a trend for a decrease in mortality **(F)** when compared with procedures performed without data from the MDCT analysis available (angiography cohort, **pink bars**). Abbreviations as in Figure 1.

a trend for a reduction in 30-day mortality (6% vs. 20%, p = 0.06) (Fig. 4F) was also observed. These results were not significantly modified after adjustment on the approach (transapical vs. transfemoral) used for the delivery.

DISCUSSION

Optimal positioning of the transcatheter aortic prosthesis is paramount to procedural success, and this requires optimal positioning of the x-ray tube C-arm perpendicular to the aortic annulus, the line of perpendicularity (4). The present study demonstrates that: 1) the magnitude of interindividual variation of the aortic annulus angulation among patients and of the corresponding line of perpendicularity is high; 2) automated 3D analysis of pre-implantation MDCT has the ability to reproducibly predict the angulation of the aortic annulus and the corresponding line of perpendicularity for C-arm position of the x-ray tube; and 3) determination of the line of perpendicularity by MDCT before the procedure allows implantation of the balloon-expandable prosthetic valve without aortogram in the majority of cases and still be safe, with a low rate of valve malpositioning and regurgitation.

Magnitude of interindividual variation of 3D aortic annulus orientation. Although difficulties to properly define the line of perpendicularity of the aortic annulus has been experienced by physicians performing TAVR procedures (4), to the best of our knowledge, the precise interindividual variations have not been reported before. Although the overall orientation of the line of perpendicularity is going from caudal to cranial when the C-arm is moved from right to left, it is an important finding of the present study that the magnitude of variation is more than 70° in the cranio-caudal axis and more than 80° in the right-left axis. These interindividual variations explain why when performing empirical positioning of the C-arm during a TAVR procedure, several attempts using contrast injection may be required to define an appropriate C-arm position; it also explains why pre-procedural definition of the line of perpendicularity may be important.

Ability of automated 3D analysis of pre-implant MDCT to accurately predict the angulation of the aortic annulus and the corresponding line of perpendicularity of the annulus for C-arm positioning. Intraobserver (kappa = 1) and interobserver (kappa = 0.94) reproducibility of defining the line of perpendicularity with the software and the methodology used in the present study was excellent. This information is of importance, because in their preliminary report, Gurvitch et al. (4) did not provide any information on the reproducibility of the methods used. It must be noted that the high reproducibility observed in the present study was also achieved in a population where only MDCT scans with an excellent or adequate imaging quality were used.

The quality of the prediction, illustrated by the use of MDCT prediction without correction of the C-arm in 35 of 36 cases, contrasts with previously reported results by Gurvitch et al. (4), in which attempted prediction of the line of perpendicularity by MDCT was considered excellent in only 50% of the population. The possible reasons for our better prediction in the present study are the following: 1) a better imaging quality of the MDCT scans used, with 83% of scans considered excellent, whereas this was the case in only 50% of the patients in the study by Gurvitch et al. (4); 2) a more extensive dataset was provided to the physicians involved in the procedure. Indeed, although in the study by Gurvitch et al. only 3 predefined combinations of angulations were provided to the operator, in the present study, the complete line of perpendicularity dataset, from RAO 40° to LAO 40° with increments of 5° each, was provided to the operator. Therefore, in the present study, the operator had a larger choice of C-arm positions to meet his or her needs.

Use of the predicted line of perpendicularity of the annulus by automatic 3D analysis of pre-implant MDCT is associated with a better procedural and 1-month outcome. Safety and peri-procedural morbidity remains one of the major limitations to the use of TAVR (10). In the present study, several parameters of morbidity were improved by the use of the predicted line of perpendicularity of the annulus by pre-procedural MDCT analysis. In particular, the risk of valve malposition and AR grade ≥2 was significantly reduced.

In the present study, precision in valve positioning was improved by using pre-procedural definition of the line of perpendicularity of the annulus. It allowed prevention of valve malposition requiring the need for a second valve or emergent valve surgery or AR. Such benefit is highly important in the light of recent studies showing that post-procedural AR is the major predictor of mortality at 1 year after TAVR (11,12). This issue will become even more important in the near future if we choose to treat patients with a lower surgical risk, in which the predictability of the result will be a major criterion of choice between TAVR and conventional surgery.

These results were achieved while using less contrast media during the procedure, which lead to a decrease in the frequency of contrast-induced acute kidney injury. The decrease in contrast use was mainly related to the fact that test angiograms to search for the line of perpendicularity of the annulus and for the optimal position of the C-arm were no longer required. This is particularly important because contrast-induced kidney injury is a major cause of morbidity and mortality after transcatheter interventions (13), and because acute kidney injury has been shown to be associated with an increase in short-term and long-term mortality following TAVR (14,15).

A benefit in radiation exposure was also observed. As for the decrease in contrast media, this benefit was secondary to the decreased need of angiograms and to the reduced time needed to perform the procedure. Because high radiation exposure may increase the risk of skin lesions (16) and cancer (17), such benefit is important in patients with a potentially longer life expectancy. This latter group will increase; in the near future, we will use TAVR in younger patients with fewer comorbidities. This benefit is also important for the safety of the operators (18), especially in high-volume centers or in delivery approaches in which the usual radiation protection glass shield cannot be used (transapical, transaortic).

Switching from general to local anesthesia is key to reducing the invasiveness of this type of procedure. To achieve this goal, a reduction of the total duration of the procedure is needed. In that regard, the reduction of the time needed for the procedure by a mean of 17 min is an important step.

Study limitations. This was a single-center study, and patient referral and medical management may have influenced the results. It was also a nonrandomized study; however, the prospective design of the study and the consecutive nature of the population provide accurate information on the ability of pre-procedural MDCT analysis to accurately predict the line of perpendicularity of the aortic annulus and the corresponding positions of the C-arm.

Although the safety benefit (reduced contrast and radiation use) was not mandated by the protocol, it was expected to be a consequence of the use of the MDCT-based strategy rather than the routine angiography-based strategy. Nevertheless, because such benefit was not assured, it was important to validate this potential in a clinical situation. Indeed, in case the predicted angulations would have been inaccurate, the operator would have no choice but to perform additional angiograms to correct the position of the C-arm, thus cancelling the expected benefit.

Prediction of C-arm angulation was performed using dedicated 3mensio software. Although it is likely that similar predictions could be achieved with other software, this will need validation. In addition, because all patients were placed flat on their backs during the procedure, these results cannot be extrapolated to those using a cushion to tilt the left side of the chest for transapical delivery. In that case, some correction of the angulation will have to be applied. Finally, as the study was restricted to patients treated with a balloon-expandable bioprosthesis, the benefit of this strategy for the implantation of a self-expandable bioprosthesis remains to be validated.

CONCLUSIONS

Clinical implications. Based on a prospective, consecutive, and comparative series, the present report provides important information on the use of pre-procedural automated 3D analysis of MDCT to predict the line of perpendicularity of the annulus and the corresponding position of the C-arm. It further demonstrates that with this approach, the implantation of the balloon-expandable prosthetic valve can be performed without an aortogram in the majority of cases and still be safe, with a low rate of valve malpositioning and regurgitation. The use of this strategy will also become important when TAVR will be evaluated in younger and lower-risk patients. In this patient subset, predictability and safety of the procedure will be critical in order to match the results achieved with conventional surgery.

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Key Words: aortic stenosis ■ MDCT ■ TAVR ■ valvular heart disease.

▶APPENDIX

For an expanded Methods section, please see the online version of this paper.