Simulated prosthesis overlay for patient-specific planning of transcatheter aortic valve implantation procedures

Sündermann, Simon H; Gessat, Michael; Maier, Willibald; Kempfert, Jörg; Frauenfelder, Thomas; Nguyen, Thi D L; Maisano, Francesco; Falk, Volkmar

Abstract: OBJECTIVE: We tested the hypothesis that simulated three-dimensional prosthesis overlay procedure planning may support valve selection in transcatheter aortic valve implantation (TAVI) procedures. METHODS: Preoperative multidimensional computed tomography (MDCT) data sets from 81 consecutive TAVI patients were included in the study. A planning tool was developed, which semiautomatically creates a three-dimensional model of the aortic root from these data. Three-dimensional templates of the commonly used TAVI implants are spatially registered with the patient data and presented as graphic overlay. Fourteen physicians used the tool to perform retrospective planning of TAVI procedures. Results of prosthesis sizing were compared with the prosthesis size used in the actually performed procedure, and the patients were accordingly divided into three groups: those with equal size (concordance with retrospective planning), oversizing (retrospective planning of a smaller prosthesis), and undersizing (retrospective planning of a larger prosthesis). RESULTS: In the oversizing group, 85% of the patients had new pacemaker implantation. In the undersizing group, in 66%, at least mild paravalvular leakage was observed (greater than grade 1 in one third of the cases). In 46% of the patients in the equal-size group, neither of these complications was observed. CONCLUSIONS: Three-dimensional prosthesis overlay in MDCT-derived patient data for patient-specific planning of TAVI procedures is feasible. It may improve valve selection compared with two-dimensional MDCT planning and thus yield better outcomes.

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Simulated Prosthesis Overlay for Patient-Specific Planning of Transcatheter Aortic Valve Implantation Procedures

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Objective: We tested the hypothesis that simulated three-dimensional prosthesis overlay procedure planning may support valve selection in transcatheter aortic valve implantation (TAVI) procedures.

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Results: In the oversizing group, 85% of the patients had new pacemaker implantation. In the undersizing group, in 66%, at least mild paravalvular leakage was observed (greater than grade 1 in one third of the cases). In 46% of the patients in the equal-size group, neither of these complications was observed.

Conclusions: Three-dimensional prosthesis overlay in MDCT-derived patient data for patient-specific planning of TAVI procedures is feasible. It may improve valve selection compared with two-dimensional MDCT planning and thus yield better outcomes.

Key Words: Heart valve, transapical approach, Computed tomography imaging, 3D modeling, Transcatheter aortic valve replacement.

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Video clip is available online.

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Transcatheter aortic valve implantation (TAVI) has evolved into a routine procedure for treating aortic valve stenosis in high-risk patients.[1] Multidimensional computed tomography (MDCT) images are used for the visualization and measurement of aortic root landmarks and distances.[2,3] Despite careful planning, paravalvular leakage[4] and atrioventricular block[5] remain the most frequent complications after TAVI. In this study, a newly developed prototype planning software was used.[6,7] With this software, three-dimensional (3D) templates of the CoreValve [Medtronic, Inc, Minneapolis, MN USA (CoreValve)] and SAPIEN [Edwards Lifesciences, Inc, Irvine, CA USA (SAPIEN)] prostheses can be virtually implanted in MDCT-derived 3D aortic root models in addition to the regular two-dimensional (2D) visualization. We hypothesize that the use of these 3D TAVI prosthesis templates might improve the planning of TAVI procedures.

METHODS

Preoperative computed tomographic (CT) angiographies of 81 patients were used to acquire retrospective planning data with the 3D-template tool by 14 clinicians (8 surgeons, 3 cardiologists, 2 radiologists, 1 anesthesiologist) who participated in the study as active participants. The local authorities approved the study (KEK-ZH No. 2011–0393). Because of its

retrospective character, written informed consent from the patients was not required, but the anonymization of patient data was handled very strictly.

End points were relevant paravalvular aortic insufficiency (AI, grade > 1+) and new pacemaker (PM) implantation. Postoperative transesophageal and transthoracic echocardiography reports and images from up to 3 months after intervention were used to classify paravalvular AI from 0 (no paravalvular AI) to grade 4 (severe paravalvular AI). Indications for perioperative new PM implantation were new conduction system disorders such as third-degree or advanced second-degree atrioventricular block not expected to resolve or the presence of sinus node dysfunction and documented symptomatic bradycardia in accordance with the American College of Cardiology/American Heart Association/Heart Rhythm Society recommendations for device-based therapy of cardiac rhythm abnormalities.[8]

Risk factors for the development of AI (ie, New York Heart Association class IV, absence of previous valve surgery, asymmetric calcification,[9] and oval annulus shape[4]) and new PM implantation [ie, porcelain aorta, absence of previous aortic valve surgery,[10] and preoperative right bundle branch block (RBBB)[11]] were assessed from the medical reports of the patients.

Imaging and Preprocedural Planning

All preoperative CT examinations were performed using a second-generation, 128-slice DSCT system (Somatom Definition Flash, Siemens Healthcare, Forchheim, Germany). Iopromide 40 mL (Ultravist 300, 300 mg/mL; Bayer Schering Pharma, Berlin, Germany) was injected at a flow rate of 4 mL/s, followed by 40-mL bolus of saline solution at the same flow rate. Bolus tracking in the ascending aorta was performed with a signal attenuation threshold of 100 Hounsfield units. A craniocaudal scan direction was chosen in all protocols. The scan ranged from the apex of the lung to the symphysis. The CT scan was started automatically based on the previous 10 heartbeats to reach the 60% R-R interval at the level of the valve.

Before the actual implantations, which were performed between January 2010 and January 2012, prosthesis selection was based on imaging as follows: the center line of the aortic root and the ascending aorta was drawn semiautomatically using dedicated software (3mensio benzslicer 4.3, Bilthoven, the Netherlands). The aortic annulus was defined by marking the three insertion points of each leaflet at the nadir of the sinus. The largest and shortest diameters and the circumference were measured.

Asymmetric calcification was regarded as present when the leaflet and annulus of one sinus visually had at least the same level of calcification as the two other sinuses together. The annulus shape was classified as oval when the longer diameter was equal to or greater than 120% of the shorter diameter.

Study-Specific Retrospective Planning With 3D TAVI Templates

Planning Software

The prototype planning software was developed as described previously.[6,7] We used the open-source software libraries VTK and DCMTK and the open-source framework OpenMAF 2.0 as the basis for development. The planning workflow implemented in this tool is depicted in Figure 1 and can be seen in video 1, SDC, http://links.lww.com/INNOV/A60.

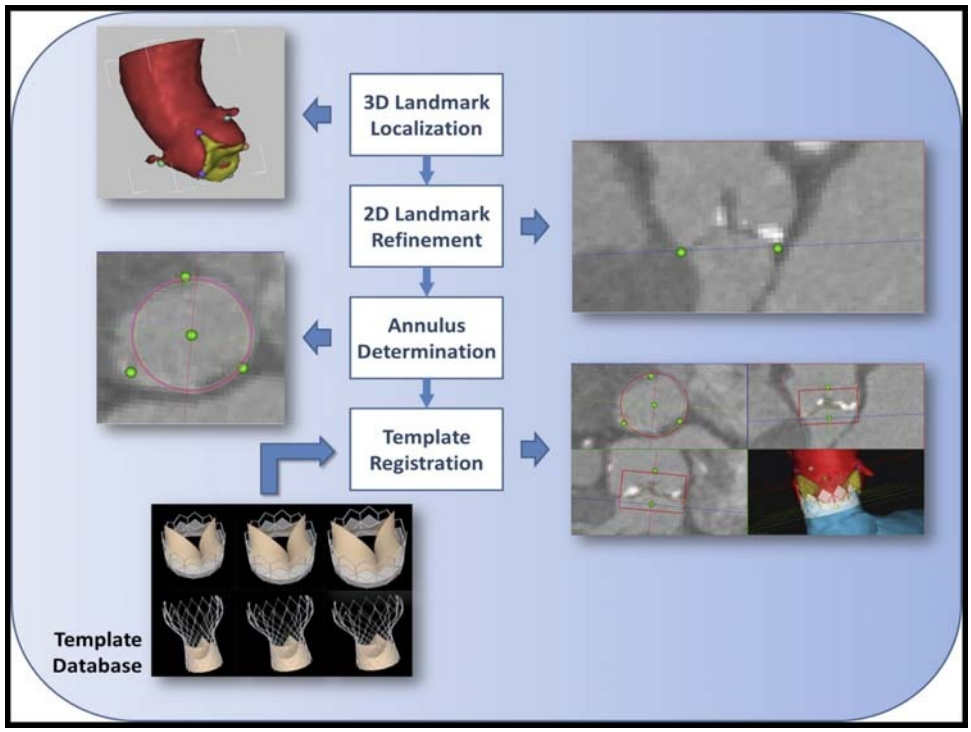

FIGURE 1. Workflow of 3D template based TAVI planning as used in the study. 3D, three dimensional; TAVI, transcatheter aortic valve implantation.

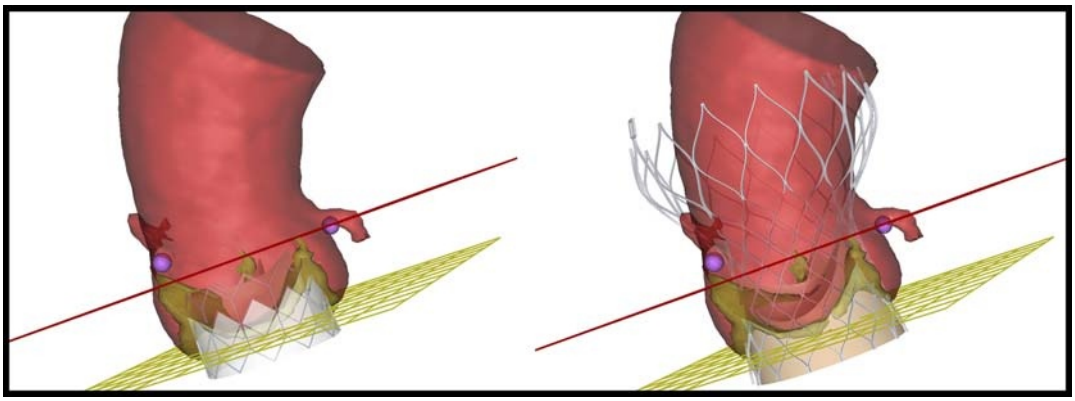

FIGURE 2. Automatically registered 3D templates representing the SAPIEN valve (Edwards Lifesciences) (left side) and CoreValve (Medtronic) (right side) prostheses. 3D, three dimensional.

Data Import

Patient MDCT images and segmentations of the aortic root, aortic valve, and left ventricle are imported from a local storage or via the network from a PACS [picture archiving and communication system] server.

Three-dimensional Landmark Localization

A 3D visualization of the segmentations is presented to the user who is prompted to localize eight landmarks on the segmented surfaces: the three nadirs of the aortic valve sinus, the three aortic valve commissures, and the two coronary ostia (00:00–00:30 in the video, SDC, http://links.lww.com/INNOV/A60).

Automatic Plane Computation

Three planes are computed from these landmarks: the basal or annular plane (yellow), which is defined by the three nadirs of the sinus; the commissural plane (blue) through the three commissures; and the coronary plane (red), which is parallel to the sinus plane and runs through the lower of the two ostia (right lower window in the video from 00:30, SDC, http://links.lww.com/INNOV/A60).

Two-dimensional Landmark Refinement

The 3D visualization allows for quick orientation and identification of the landmarks (and thereby definition of the three planes), but because of limitations in the segmentation accuracy, the selected landmarks are not 100% accurate. To improve the accuracy, the user is prompted to check and refine each landmark in a 2D cross-sectional visualization of the CT images. The system automatically offers three different triplanar sections showing all three commissures, all three sinus, or both coronary landmarks, respectively. At the press of a button the user can switch between these three views, refine the landmark positions, and thereby update the plane definitions (00:31–00:57 in the video, SCD, http://links.lww.com/INNOV/A60).

Annulus Sizing

After refinement and confirmation of the landmarks, a circle of best fit through the aortic annulus is computed according to the sinus landmarks and visualized in the cross-sectional view. The user may adjust the radius and the center of this circle manually (00:58–01:15 in the video, SDC, http://links.lww.com/INNOV/A60).

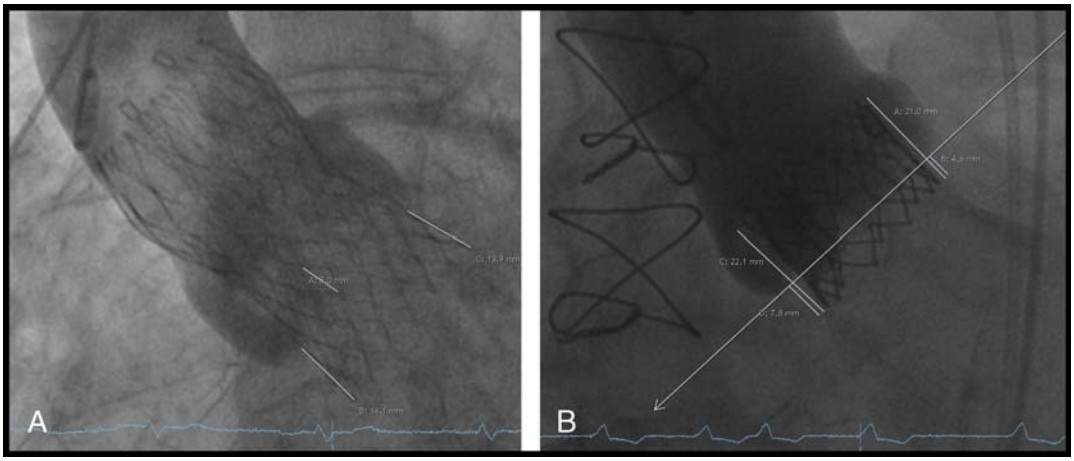

FIGURE 3. Measurement of the implantation depth of the CoreValve (Medtronic) prosthesis (left side) and the SAPIEN Valve (Edwards Lifesciences) prosthesis. The formula to calculate the part of the SAPIEN prosthesis below the annulus is as described by Nijhoff et al[13]: [(D / C) + (B / A)] / 2 × 100].

TABLE 1. Baseline Characteristics

	Total	Equal Size	Undersizing	Oversizing	*P*
n	81	54	20	7	
Age, mean (SD), y	84 (6)	83 (6)	85 (4)	84 (4)	0.4
Female sex, n (%)	44 (54.3)	32 (59)	9 (45)	3 (42)	0.5
Logistic EuroSCORE, mean (SD), %	21.3 (11.8)	20.2 (9.1)	25.1 (17.9)	19.3 (7.3)	0.3
Left ventricular ejection fraction, mean (SD), %	55.1 (12.7)	56.9 (11.7)	51.8 (14.8)	50 (12.8)	0.2
NYHA class (III-IV), n (%)	59 (73)	36 (67)	18 (90)	5 (71)	0.1
Previous aortic valve surgery, n (%)	3 (3.7)	3 (5.6)	0	0	0.5
Previous CABG, n (%)	18 (22.2)	15 (28)	3 (15)	0	0.2
Coronary heart disease, n (%)	45 (55.6)	28 (52)	12 (60)	5 (71.4)	0.6
Peripheral vascular disease, n (%)	24 (29.6)	15 (27.8)	8 (40)	1 (14.3)	0.4
Previous myocardial infarction, n (%)	8 (9.9)	6 (11.1)	1 (5)	1 (14.3)	0.7
Previous PCI, n (%)	29 (35.8)	17 (31.5)	9 (45)	3 (42.9)	0.5
Previous stroke/TIA, n (%)	9 (11.1)	5 (9.3)	3 (15)	1 (14.3)	0.8
Renal failure, n (%)	34 (42)	22 (40.7)	9 (45)	3 (42.9)	0.9
COPD, n (%)	6 (7.4)	3 (5.6)	2 (10)	1 (14.3)	0.6
Pulmonary hypertension, n (%)	3 (3.7)	3 (5.6)	0	0	0.5
AF, n (%)	18 (22.2)	8 (14.8)	7 (35)	3 (42.9)	0.1
RBBB	8 (9.9)	5 (9.3)	1 (5)	2 (28.6)	0.2
LBBB	7 (8.6)	11 (6.1)	3 (15)	1 (14.3)	0.3
Peak aortic valve gradient, mean (SD), mm Hg	72.8 (22,8)	74.5 (21)	70.8 (26.8)	63.8 (27.4)	0.6
Mean aortic valve gradient, mean (SD), mm Hg	44.9 (14.6)	45.8 (13.2)	44.5 (18.2)	39.6 (15)	0.6
AVA, mean (SD), cm^2	0.7 (0.2)	0.7 (0.2)	0.7 (0.2)	0.8 (0.3	0.3
Oval annulus	47 (58)	33 (61.1)	10 (50)	4 (57.1)	0.6
Asymmetric calcification	24 (30)	15 (27.8)	4 (20)	5 (71.4)	<0.05
Porcelain aorta	3 (3.7)	3 (5.6)	0	0	0.5

AF, atrial fibrillation; AVA, aortic valve area; CABG, coronary artery bypass grafting; COPD, chronic obstructive pulmonary disease; LBBB, left bundle branch block; NYHA, New York Heart Association; PCI, percutaneous coronary intervention; RBBB, right bundle branch block; TIA, transient ischemic attack.

Automatic Implant Template Registration

Once the annular ring is accepted, the system automatically registers 3D templates representing the SAPIEN valve (Edwards Lifesciences, Inc, Irvine, CA USA) and CoreValve (Medtronic, Inc, Minneapolis, MN USA) prostheses with the annulus (Fig. 2). The prosthesis templates are positioned perpendicular to the sinus plane at the center of the circle that was defined to mark the annulus. Implantation depth is defined such that the nadirs of the implants' leaflets are at the level of the natural nadirs of the aortic valve sinus. In the case of the SAPIEN prostheses, the vertical distance to the coronary ostia is also considered hereby. A 1-mm safety margin is maintained between the distal rim of the prostheses and the lower ostium (01:16–01:45 in the video, SDC, http://links.lww.com/INNOV/A60).

Implant Selection

The user may adjust the orientation and position in three dimensions of each template and choose the best-fitting template. Two-dimensional and 3D visual overlays of the CT images, anatomical models, and 3D templates were provided to allow for a visual assessment of the suitability of each of the available implant prostheses. The main criterion for selection was not a numerical (diameter) but a visual selection of the optimal match of valve size and type (01:46–3:21 in the video, SDC, http://links.lww.com/INNOV/A60).

The resulting selection, the final landmark positions, and the spatial registration that determines the orientation and

TABLE 2. Procedural Details; SAPIEN: SAPIEN (32 Patients) and SAPIEN XT (14 Patients)

	Total	Undersizing	Oversizing	*P*
n	81	20	7	—
CoreValve implantation, n (%)				
23 mm	1 (1)	1 (5)	0	—
26 mm	13 (16)	1 (5)	0	—
29 mm	20 (25)	6 (30)	5 (71)	—
31 mm	1 (1)	0	0	—
SAPIEN implantation, n (%)				
23 mm	20 (25)	5 (25)	0	—
26 mm	21 (26)	7 (35)	1 (14)	—
29 mm	5 (6)	0	1 (14)	—
Transapical access, n (%)	10 (12)	0	0	—
Postdilatation, n (%)	9 (11)	5 (25)	0	0.3
Implantation depth CoreValve, mean (SD), mm	12.2 (5.3)	12.6 (4.6)	10.4 (5.4)	0.5
Implantation depth SAPIEN, mean (SD), % of stent height	7.9 (11.5)	9 (10)	−10 (16)	0.3
Annulus rupture, n (%)	0	0	0	—
Coronary obstruction, n (%)	0	0	0	—
Peri-interventional MI, n (%)	0	0	0	—
Access site complications, n (%)	4 (5)	2 (10)	0	1
Other complications, n (%)	7 (9)	1 (5)	1 (14)	1

MI, myocardial infarction.

position of the selected valve template in relation to the coordinate system of the CT image are stored to a local hard drive or a PACS server via the network.

Each case was planned by three participants. The assignment of patients to participants was based on a semirandomized scheme, which ensured that the distribution of complications in each participant's data set matched the distribution in the complete data set. The participants had to choose the optimal size of the CoreValve and of the SAPIEN valve for each patient. Figure 2 shows the virtually implanted prostheses. Where the three observers arrived at differing results for the same patient, these results were aggregated based on a majority vote.

For each patient, the valve size selected was compared with that of the actually implanted valve. The patients were divided into three groups. Those for whom retrospective planning proposed a prosthesis smaller than actually implanted were labeled the "oversizing" group. Those where retrospectively a larger prosthesis was planned than actually implanted were the "undersizing" group. All other patients had equal sizing.

The study participants did not have access to the outcome data and did not know before or during the retrospective planning process which valve type had been implanted.

The time for the whole planning process was measured, starting with the placement of the first landmark at the segmented aorta and finishing at the final decision on prosthesis size.

Postinterventional Evaluation of Depth of Prosthesis Implantation

Deep implantation of the CoreValve prosthesis is a risk factor for permanent PM implantation after the intervention.[12] Therefore, the depth of implantation was assessed from the intraoperative angiography of the final implant position in the implant projection in left anterior oblique view.

The distance from the annulus to the lowest point of the stent was measured at both margins of the Medtronic CoreValve Revalving System (CoreValve) prosthesis from the nadir of the noncoronary sinus and the left coronary sinus, and the mean implantation depth was calculated. The height of a stent cell (8 mm) was taken as the reference structure to confirm the accuracy of the measurements.

For the SAPIEN prostheses, the part of the stent below the annulus was assessed as described by Nijhoff et al.[13] The measurements were performed using Synedra software (version 3.3.0.12; Synedra Information Technologies GmbH, Innsbruck, Austria). Exemplary images of the measurement for both prostheses are shown in Figure 3.

Statistics

Continuous variables were calculated as means with SD. Differences in the means of continuous variables were calculated by Student *t* test or one-way analysis of variance. For static variables, χ^2 test was used to compare the groups. Logistic regression was used to calculate the association of risk factors and new PM implantation and the development of significant paravalvular insufficiency. Multivariable logistic regression modeling was performed to determine the independent predictors of new PM implantation using purposeful selection of covariates. Variables associated at univariate analysis with new PM implantation (all with $P < 0.1$) as well as those judged to be of clinical importance from previously published literature were eligible for inclusion in the multivariable model-building process. For paravalvular leakage, no association with any of the variables was found in the univariate analysis. Therefore, no multivariate analysis was performed. A P value of less than 0.05 was considered significant. Data analysis was performed using IBM SPSS Statistics, version 22.0 (IBM Corporation, Armonk, NY USA).

RESULTS

Baseline Characteristics and Risk Factors

Baseline characteristics are summarized in Table 1. The number of patients who had coronary artery bypass grafting in their history was higher in the undersizing group (15% vs 0%), more patients had peripheral vascular disease in the undersizing group (40% vs 14%), previous myocardial infarction was more common in the oversizing group (14% vs 5%), and more patients showed RBBB before implantation RBBB (29% vs 5%) and asymmetric calcification (71% vs 20%) in the oversizing group. No relevant differences were seen for the other parameters.

Procedural Details

Thirty-five patients had received a CoreValve, and 46 patients had received a SAPIEN (32 patients SAPIEN, 14 patients SAPIEN XT) prosthesis (Table 2). Implantations were mainly performed by transfemoral access (87.7%). None of the patients experienced coronary obstruction or annulus rupture during the intervention or showed signs of peri-interventional myocardial infarction. Four patients had inguinal vascular access site complications, and one patient from the undersized group had a prosthesis dislocation, which ended in hemodynamic instability and finally in the death of the patient. Four patients had prosthesis embolization (one patient with CoreValve implantation from the equal-size group; one patient with CoreValve implantation from the oversizing group; one patient from the SAPIEN group, who primarily had CoreValve implantation, that embolized; and one patient form the equal-size

TABLE 3. Procedural Outcome

	Total	Undersizing	Oversizing	*P*
n	81	20	7	
Paravalvular leak (at least moderate), n (%)	10 (11)	7 (35)	0	0.1
SAPIEN	3 (4)	2 (10)	0	
CoreValve	7 (9)	5 (25)	0	
Paravalvular leak (at least mild), n (%)	45 (56)	17 (85)	4 (57)	0.3
New PM implantation, n (%)	14 (17)	2 (10)	6 (85)	0.001
SAPIEN	5 (6)	1 (5)	2 (29)	
CoreValve	9 (11)	1 (5)	4 (57)	
Stroke, n (%)	0	0	0	—
30-d mortality, n (%) (n = 81)	4 (4.9)	3 (15)	0	0.5
6-mo mortality, n (%) (n = 63)	6 (7.3)	4 (20)	1 (14.3)	0.5
1-y mortality, n (%) (n = 51)	7 (8.5)	5 (25)	1 (14.3)	0.3
2-y mortality, n (%) (n = 21)	7 (8.5)	5 (25)	1 (14.3)	0.3

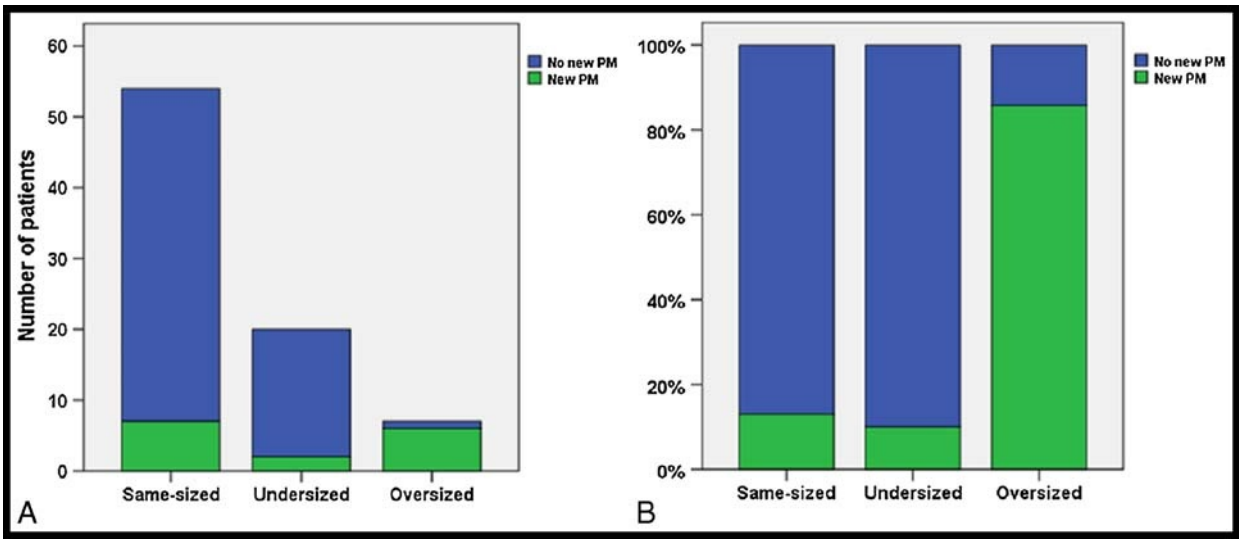

FIGURE 4. Distribution of new PM implantation in the equal-size, undersizing, and oversizing groups. A, The number of patients in each group. B, The percentage of new PM implantations in each group. PM, pacemaker.

SAPIEN group) during the implantation; all valves were replaced during the same intervention. One of these patients died 2 days after the event. Another patient had right ventricular perforation, probably caused by the temporary PM probe; sternotomy and suturing of the rupture site were necessary. All other implantations were uneventful.

The mean (SD) implantation depth of the CoreValve prostheses was 12.2 (5.3) mm [12.6 (4.6) vs 10.4 (5.4) mm for the undersizing vs the oversizing group, P = 0.5]. At the noncoronary sinus, the mean (SD) implantation depth was 12.4 (5.5) mm [11.7 (4.1) vs 10.7 (5) mm for the undersizing group vs the oversizing group, P = 0.7]. The mean (SD) implantation depth at the left coronary sinus was 11.9 (5.7) mm [13.6 (5.3) vs 11.8 (5.8) mm for the undersizing group vs the oversizing group, P = 0.5].

The mean (SD) implantation depth for the SAPIEN prostheses was 8.4% (11.6%) of prosthesis height below the annulus [9% (10%) vs −10% (15.6%) for the undersizing group vs the oversizing group, P = 0.3].

Outcome

Mortality rate within 30 days after implantation was 4.9%, 6-month mortality was 7.3%, and 1- and 2-year mortality was 8.5%. No patient experienced stroke, 15 patients (18.5%) required a new PM, and 10 patients (12.3%) had relevant paravalvular regurgitation (grade > 1+).

Retrospective Planning

Retrospective planning resulted in 243 plans. Time needed for the retrospective planning varied between 2 and 15 minutes. A learning curve could be seen for the participants. In seven cases (9%), a smaller prosthesis and in 20 cases (24%), a larger

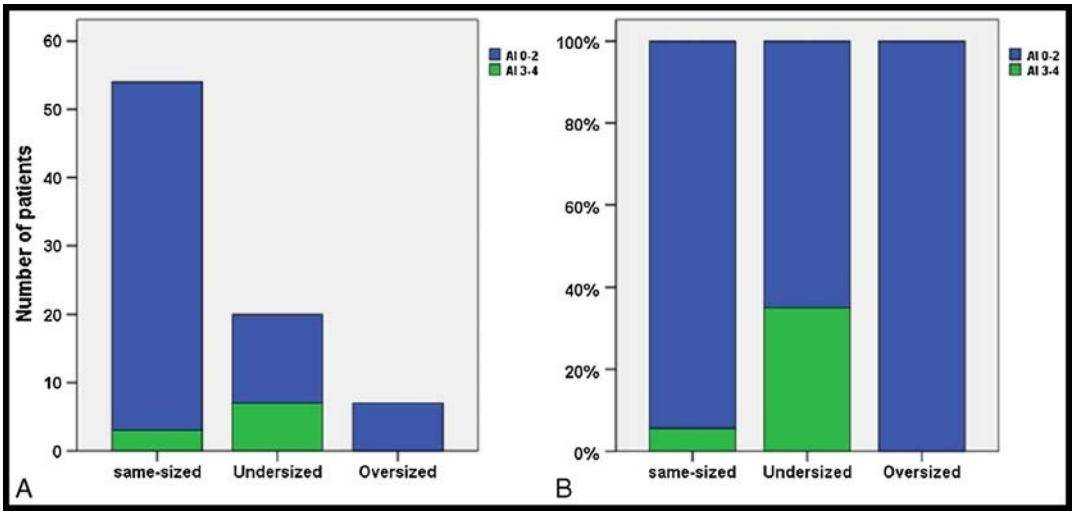

FIGURE 5. Distribution of paravalvular leakage of more than grade 2 in the equal-size, undersizing, and oversizing groups. A, The number of patients with relevant paravalvular leak in each group. B, The percentage of relevant paravalvular leak in each group. AI 0-2, no to mild paravalvular leak; AI 3-4, moderate to severe paravalvular leak. AI, aortic insufficiency.

prosthesis would have been chosen by the participants. Results are documented in Table 3.

The rate of new PM implantations was 18% in the total patient cohort. In the oversizing patient cohort, the rate of new PM implantations was much higher than in the undersizing group (85% vs 10%, $P = 0.001$). In the equal-size group, the rate of new PM implantations was 13% (Fig. 4). Sixty percent of the patients with new PM implantation had a CoreValve.

The rate of relevant paravalvular leakage was 12% in the total cohort. In the undersizing group, 35% of the patients had relevant paravalvular leakage, whereas in the oversizing group, no relevant AI was seen ($P = 0.1$). In the group with equal sizing, the rate of relevant paravalvular leakage was 5.6% (Fig. 5). Moreover, almost all patients (85%) in the undersized group showed at least mild paravalvular leakage after the procedure. Patients in the oversizing group had no or mild paravalvular AI in 57% of the cases ($P = 0.3$). In 46% of the cases in which retrospective planning resulted in equal-size choice, neither of these complications was observed.

Univariate logistic regression showed that preoperative RBBB, left bundle branch hemiblock (LBHB), and the affiliation to the sizing group were associated with the need for postinterventional new PM implantation. The results are summarized in Table 4. In the purposeful selection of covariates, LBHB was excluded. The multivariate analysis showed RBBB and the affiliation to the sizing group to be independent predictors for postoperative new PM implantation ($P = 0.006$ and $P = 0.004$, respectively). The depth of implantation of CoreValve prostheses was not associated with new PM implantations. In contrast, the depth of implantation of SAPIEN prostheses was associated with new PM implantation. The patients with new PM implantations in the SAPIEN group had significantly higher implantations [10% (11%) below the annulus vs −2% (12%) below the annulus, $P = 0.01$]. For relevant paravalvular leakage, no significant association with the tested variables was found.

TABLE 4. Results for the Univariate Logistic Regression of Potential Risk Factors Leading to Postinterventional New PM Implantation

	Odds Ratio	95% Confidence Interval	P
Sizing group	3.7	1.6–8.6	0.002
RBBB before intervention	10.5	2.2–51	0.004
Sex	1.3	0.4–4.2	0.6
EuroSCORE	1	0.9–1	0.2
Previous valve surgery	0	—	1
Previous CABG	0.2	0.03–1.7	0.1
Coronary heart disease	0.9	0.3–2.8	0.8
Previous myocardial infarction	0.6	0.07–5.3	0.6
Previous PCI	0.9	0.3–2.9	0.8
LBBB before intervention	1.9	0.3–11	0.5
LBHB before intervention	3.6	0.9–15	0.08
Atrial fibrillation	1.3	0.4–4.9	0.6
Porcelain aorta	0	—	1
Oval annulus	1	0.3–3.3	0.9
Transapical access	1.1	0.2–5.9	0.9
Valve type	0.4	0.1–1.4	0.2
Postdilatation	0	—	1
Deep implantation	1	0.3–3.5	0.9
Noncoronary sinus depth (CV)	1	0.8–1.1	0.6
Left coronary sinus depth (CV)	0.9	0.8–1	0.2
Mean depth (CV)	0.9	0.8–1.1	0.3
Mean depth (SAPIEN)	0.9	0.8–1	0.03

CV, CoreValve; LBBB, left bundle branch block; LBHB, left bundle hemiblock; PCI, PCI, percutaneous coronary intervention; RBBB, right bundle branch block.

DISCUSSION

We used 3D TAVI prosthesis templates to investigate the hypothesis that this tool might improve the planning of TAVI procedures compared with conventional 2D MDCT measurements.

Paravalvular regurgitation is seen more frequently after TAVI than after surgical aortic valve replacement and is associated with increased late mortality.[4] In addition, TAVI is frequently associated with new conduction defects, which result in LV asynchrony and subsequent impairment of LV function.[14,15] Correct preoperative prosthesis selection is a crucial part of a TAVI procedure to avoid these complications.

For presurgical evaluation of valve pathology, transthoracic and transesophageal echocardiography are the criterion standards.[16] For the planning of TAVI procedures, additional information is necessary because direct visualization and sizing of the valve are not possible. Echocardiographic measurement of the annulus diameter was used when TAVI was first introduced but is a less precise option than MDCT because the aortic annulus often is oval and intraobserver variability is higher than with MDCT.[17] Today, commonly used measurements for decision making with regard to prosthesis selection are different geometric parameters of the aortic annulus and aortic root and the grade and location of calcification in 2D MDCT images.[18]

To support TAVI planning, an imaging system that uses 3D templates of the Edwards SAPIEN valve and application of this system to DynaCT images of a cohort of 31 patients were described in previous works.[6,7] In this study, atrioventricular block and paravalvular leakage were observed in those patients where retrospective planning would have proposed a different size of prosthesis. A strong limitation of that study was the small number of patients and the fact that only one physician participated. Moreover, DynaCT is an intraoperative modality not commonly used and has been shown to be inferior to preoperative CT with regards to the accuracy of annulus dimension measurements.[19]

In the present study, we used an advanced version of the previously proposed planning system, with additional templates for the CoreValve. The study design was strengthened by having three independent study participants to plan each of the 81 data sets. The results showed that almost all patients who required a new PM after the intervention were in the oversizing group and almost all patients planned retrospectively for a larger prosthesis showed at least mild paravalvular leakage after the procedure. Furthermore, the rate of relevant AI was higher in the undersizing group than in the oversizing or equal-size group. None of these results reached statistical

significance. This is most probably attributable to the small number of events that can be compared.

We are aware that it can only be an assumption that the choice of a smaller size valve would not have led to paravalvular leakage and, vice versa, that the choice of a larger prostheses would have reduced the rate of new PM implantations. In addition, the majority of patients who required new PM implantation had received a CoreValve (66%). It is well-known that the rate of new conductive tissue disorders necessitating new PM is higher after CoreValve implantation than after SAPIEN implantation.[14,20]

The mean depth of implantation of CoreValve prostheses in this series is very low compared with that in recent series,[20,21] but no association between implantation depth and new PM implantation was found. Of course, this might be due to small sample sizes within the groups. In addition, there was no difference between the oversizing and undersizing patient groups with regard to implantation depth.

The results of this study underline the importance of planning tools. Different ways of planning a procedure can lead to different results.[22] They also indicate that 3D template-based planning may be a good additional tool to prevent paravalvular leakage and new PM implantation.

Several limitations apply. This study is retrospective in character and only includes patients treated at one center. The planning was performed in a clinical setting with real patient data; nevertheless, the physicians knew that their planning decisions would not affect patient treatment. Five participants were involved in the original valve selection and implantation; because more than 6 months lay between treatment and retrospective planning for the study, the bias generated by that involvement was regarded as negligible but cannot be excluded completely. Probably the main limitation of the study concerns the CoreValve group: the average depth of implantation is much deeper than the depth considered best practice today. This reflects an early learning curve and may have influenced the outcomes of the study. One consequence could be the low positive predictive value of concordant sizing. In the equal-size group, only approximately half of the patients were free from either new PM implantation or paravalvular leak. This also shows that besides sizing other factors such as the implantation technique and anatomic factors (calcification, left ventricular outflow tract geometry, aortic angulation) play a major role.

CONCLUSIONS

The use of 3D prosthesis templates for the planning of TAVI procedures is feasible. The ability to visually assess the fit of an implant with the individual patient's anatomy helps physicians in determining the optimal implant size and position and might provide an additional tool to improve planning of TAVI procedures so as to prevent paravalvular leakage and new PM implantation. A more contemporary prospective randomized trial is needed to overcome the limitations of this study and to clearly show the positive impact of 3D template-based procedure planning.

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CLINICAL PERSPECTIVE

This is an excellent report describing a planning tool for transcatheter aortic valve implantation (TAVI) using a three-dimensional model of the aortic root created from a data set obtained by preoperative multidimensional computer tomography. The authors looked at 81 consecutive patients and retrospectively used this tool to plan the TAVI procedure. They compared the prosthesis sizing obtained with this planning tool to the prosthesis size used in the actually performed procedure. In the group of patients in which there was actual oversizing (retrospective planning predicted a smaller prosthesis), 85% of the patients had new pacemaker implantation. In the patients in which there was undersizing in the actual procedure, the majority had at least a mild paravalvular leak. In the 46% of patients in which the prosthesis used matched that recommended by the planning tool, neither of these complications were observed.

This type of simulation is an important advance, and planning tools such as this one have the potential to greatly refine implantation techniques. This group is to be congratulated for their beautiful work. The ability to visually assess the fit of an implant with the actual patient's anatomy could limit procedural complications. Future prospective studies from this group and others will continue to define the role of simulated procedural planning in improving TAVI outcomes.