JACC: CARDIOVASCULAR INTERVENTIONS VOL. 6, NO. 5, 2013

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
http://dx.doi.org/10.1016/j.jcin.2012.12.128

Impact of Post-Implant SAPIEN XT Geometry and Position on Conduction Disturbances, Hemodynamic Performance, and Paravalvular Regurgitation

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Objectives This report sought to study the impact of the balloon-expandable SAPIEN XT (Edwards Lifesciences, Irvine, California) transcatheter heart valve (THV) stent frame geometry and position on outcomes of transcatheter aortic valve replacement (TAVR).

Background Post-implant THV geometry and position might impact atrioventricular conduction, hemodynamic performance, and annular sealing.

Methods Eighty-nine consecutive patients who underwent TAVR with a Sapien XT THV had pre- and post-implant multidetector computed tomography, transthoracic echocardiography, and electrocardiograms performed to assess THV stent geometry, atrioventricular conduction, and hemodynamic performance.

Results The THV Circularity (THV eccentricity <10% [eccentricity = minimum stent diameter/maximum stent diameter]) and under-expansion (THV area/nominal THV area <90%) were present in 97.8% (2 of 89) and 0%, respectively. Low THV implantation was associated with new left bundle branch block and complete heart block (3.4 ± 2.0 mm vs. 5.5 ± 2.9 mm, $p = 0.01$) and with the need for permanent pacemaker implantation (3.5 ± 2.0 mm vs. 7.1 ± 2.5 mm, $p = 0.001$). In contrast, labeled THV size and THV area oversizing was not associated with atrioventricular conduction disturbances. The relation between inflow stent frame area and annular area was related to paravalvular regurgitation ($p = 0.025$). Labeled prosthesis size but not prosthesis expansion or eccentricity was related to valve gradient ($p = 0.005$) and effective orifice area ($p < 0.001$).

Conclusions Low implantation depth of balloon-expandable THVs is associated with clinically significant new conduction disturbances and permanent pacemaker implantation. Importantly, annular area oversizing was not associated with these complications. (J Am Coll Cardiol Intv 2013;6:462–8) © 2013 by the American College of Cardiology Foundation

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Manuscript received October 5, 2012; revised manuscript received November 30, 2012, accepted December 21, 2012.

Balloon-expandable transcatheter heart valves (THV) are compressible bioprostheses that are crimped for introduction to obtain functional shape after deployment (1,2). Optimal performance and durability assume complete and symmetrical expansion (3) in the correct position. Implant height (4–6) and incomplete or asymmetrical expansion (7) might affect leaflet coaptation, effective orifice area, valvular and paravalvular regurgitation (PAR), stent anchoring, atrioventricular conduction, or THV durability. There is, however, a paucity of data and limited assessment of the impact of post-implant balloon-expandable THV geometry on cardiac conduction disturbances, PAR, and hemodynamic performance. Our group has previously shown that patients requiring a permanent pacemaker (PPM) had low implanted balloon-expandable THVs, but the study size was too small for statistical analysis (4). Post-implant balloon-expandable THV eccentricity has also been shown to impact PAR in another study (7), but again the cohort was small with only 42 patients. Therefore, we sought to evaluate the post-implant THV geometry and position of the SAPIEN XT (Edwards Lifesciences, Irvine, California) THV by multidetector computed tomography (MDCT) and its impact on atrioventricular conduction, hemodynamic performance, and PAR in a large cohort of consecutive patients undergoing transcatheter aortic valve replacement (TAVR).

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Methods

Subjects. Patients with symptomatic severe aortic stenosis (all tricuspid), who underwent TAVR at St. Paul's Hospital, University of British Columbia, Vancouver, Canada, were assessed by pre- and post-implant MDCT, transthoracic echocardiography (TTE), and 12-lead standard electrocardiograms (ECG). A transesophageal echocardiogram (TEE) was performed during TAVR. All patients gave written informed consent, and the procedure was approved by the local ethics committee.

MDCT. The MDCT examinations were performed on a 64-slice high-definition scanner, Discovery HD 750 (GE Healthcare, Waukesha, Wisconsin). A contrast-enhanced protocol with 80 to 120 ml of iodixanol 320 (GE Healthcare, Piscataway, New Jersey) injected at 5 ml/s followed by 30 ml of normal saline was used. Patients with an estimated glomerular filtration rate <30 ml/m^2 were not scanned. Collimation width was 0.625 mm, detector coverage was 40 mm, reconstructed slice thickness was 1.25 mm, and the slice interval was 1.25 mm. Scan pitch was adjusted/heart rate between 0.16 and 0.20, and gantry rotation time was 0.35 s. Measurements were taken in diastole at 75% of the R-R interval, owing to optimal image quality and a lack of difference in stent size and configuration throughout the cardiac cycle due to the rigid stent structure. Peak tube current (300 to 725 mA) and tube voltage (100 to 120 kVp) were based on body mass index (body weight in kilograms divided by the squared height in meters), and ECG-gated dose modulation was applied. To avoid the blooming and beam hardening effect of the cobalt-chromium stent frame, MDCT images were reconstructed with both standard and hard convolution kernels. The stent frame of each THV was assessed at 3 cross-sectional levels (inflow, mid-portion, and outflow). The minimum external stent diameter, maximum external stent diameter, and the external stent area were measured at each level by tracing along the external margins of the stent frame. An experienced level-3 cardiac computed tomography (CT) reader measured all stent levels 3 times, and the data represent the mean of the 3 measurements. The CT angiography reader was blinded toward all outcome measures of this study, including TTE, TEE, and ECG results as well as clinical outcome data.

The THV eccentricity was calculated as: (1 − [minimum external stent diameter/maximum external stent diameter]) as measured by MDCT. A THV was considered noncircular, when the eccentricity was 10% or more for all 3 levels (inflow, mid-portion, and outflow).

The THV expansion was defined as the MDCT-derived outer stent frame area divided by the nominal external valve area. Under-expansion was defined as an expansion ratio of 90% or less at all 3 levels (inflow, mid-portion, and outflow).

Oversizing was defined as the numerical difference between the stent frame inflow short-axis diameter and the annulus diameter measured by TTE (effective TTE diameter oversizing) or TEE (effective TEE diameter oversizing). Effective MDCT area oversizing was defined as the MDCT-derived outer stent frame area divided by the MDCT-derived native annular area.

The distance from the stent frame inflow to the aortic annulus (most basal insertion of the native aortic leaflets) was measured (THV implant height), and the distance from the stent frame outflow to the inferior border of the left coronary artery ostium was measured.

Echocardiography. Echocardiography was performed by 3 different operators, experienced in pre- and post-TAVR echocardiography assessments, and was reported according to Valve Academic Research Consortium criteria (8). The

Abbreviations and Acronyms

CHB = complete heart block
CT = computed tomography
ECG = electrocardiogram
LBBB = left bundle branch block
MDCT = multidetector computed tomography
PAR = paravalvular regurgitation
PPM = permanent pacemaker
RBBB = right bundle branch block
TAVR = transcatheter aortic valve replacement
TEE = transesophageal echocardiography
THV = transcatheter heart valve
TTE = transthoracic echocardiography

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diameter of the aortic annulus was measured in 1 plane by TTE in the parasternal long-axis view and by TEE in a 3-chamber view.

ECGs. All ECGs were read by a single cardiologist. A left bundle branch block (LBBB) was defined by a QRS width ≥120 ms, a broad, monophasic R-wave in I, V_5, V_6, the absence of septal Q waves in leads I, V_5, V_6, delayed intrinsicoid deflection (≥0.06 s) in left precordial leads, and wide S-wave after initially small R waves in the right precordial leads. A right bundle branch block (RBBB) was defined by a QRS width ≥120 ms, a secondary R-wave in the right precordial leads (rsr, rsR, or rSR), an S-wave in left-sided leads (I, V_5, V_6), and delayed intrinsicoid deflection (≥0.05 s) in the right precordial leads.

Statistical analysis. Analyses were performed with the SPSS statistics software (version 20.0, SPSS, Inc., Chicago, Illinois). Continuous variables are reported as mean ± SD. Continuous variables were tested for a normal distribution and compared by the Student *t* test. For comparison of more than 2 continuous parametric variables, an analysis of variance was used. Categorical variables were compared by the Fisher exact test. All tests were 2-tailed, and a p value below 0.05 was considered statistically significant.

Results

Patients. Eighty-nine consecutive patients who underwent TAVR and post-TAVR MDCT at our institution were included in this study. Baseline patient characteristics are outlined in Table 1.

THV geometry. Diameters and areas of the THV stent at the inflow, mid-portion, and outflow are shown in Table 2. The THV expansions and circularities are shown in Table 3 according to THV sizes. No valves were under-expanded at all 3 levels (inflow, mid-portion, and outflow). Two valves (2.2%) were under-expanded at the mid-level, and 1 (1.1%) was under-expanded at the outflow. Under-expansion and the grade of expansion were not related to native MDCT annular measurements (short annular diameter, long annular diameter, annular area, annular eccentricity) or MDCT area oversizing of the native annulus.

All but 2 valves (2.2%) were circular. Circularity was not related to native MDCT annular eccentricity, diameter, or area. The THV stent outflow was on average 0.3 ± 2.6 mm below the inferior border of the left coronary artery ostium, and the THV stent inflow was on average 3.6 ± 2.2 mm below the aortic annulus (most basal insertion of the native aortic leaflets).

Atrioventricular conduction. Patients who had a pre-existing PPM before TAVR (n = 11; 12.4%) were excluded from all conduction delay analysis. Four patients (5.1%) required a new PPM, because of complete heart block (CHB), and 4 patients (5.1%) developed a new LBBB. Patients, who received a new PPM had a longer baseline QRS width (108 ± 22 ms vs. 138 ± 25 ms, p = 0.01), a longer baseline PR interval (188 ± 37 ms vs. 290 ± 0 ms, p = 0.009), and significantly lower implanted THVs (inflow to annulus distance 3.5 ± 2.0 mm vs. 7.1 ± 2.5 mm, p = 0.001) (Fig. 1). There was a nonsignificant trend toward more new PPM in patients with a pre-existing RBBB (p = 0.063). Age, baseline heart rate, THV size, and THV annular area oversizing were not associated with the need for a new PPM (p = ns for all).

Table 1. Patient Characteristics (n = 89)

Age (yrs)	82 ± 8
Sex	54 (61%) male, 35 (39%) female
Height (cm)	169 ± 11
Weight (kg)	77 ± 18
BMI (kg/m^2)	27 ± 6
Diabetes	28% (25)
Hypertension	84% (75)
Dyslipidemia	73% (65)
Smoking history	40% (36)
COPD	23% (20)
NYHA functional class	
I	2% (2)
II	14% (12)
III	73% (65)
IV	11% (10)
Prior cerebrovascular accident	12% (11)
Prior open heart surgery	38% (34)
Porcelain aorta	12% (11)
Prior permanent pacemaker	12% (11)
Baseline LBBB	10.1% (9)
Baseline RBBB	10.1% (9)
Atrial fibrillation	27% (24)
STS PROM (%)	7.1 ± 4.3
GFR (ml/min)	59 ± 20
Labeled prosthesis size (SAPIEN XT)	
20 mm	2.2% (2)
23 mm	37.1% (33)
26 mm	52.8% (47)
29 mm	7.9% (7)

Values are mean ± SD, n (%), or % (n). SAPIEN XT (Edwards Lifesciences, Irvine, California).
BMI = body mass index; COPD = chronic obstructive pulmonary disease; GFR = glomerular filtration rate; LBBB = left bundle branch block; NYHA = New York Heart Association functional class; RBBB = right bundle branch block; STS PROM = Society of Thoracic Surgeons predicted risk of mortality.

Patients who developed a new LBBB or CHB had a longer baseline QRS width (107 ± 21 ms vs. 128 ± 31 ms, p = 0.01) and significantly lower implanted THVs (3.4 ± 2.0 mm vs. 5.5 ± 2.9 mm, p = 0.01).

The THV geometry and positions for each patient with a new LBBB or CHB are shown in Table 4.

Hemodynamic performance. The mean gradient was reduced from 40.7 ± 17.5 mm Hg to 10.7 ± 4.2 mm Hg post-TAVR ($p < 0.001$), and the effective valve orifice area increased from 0.69 ± 0.16 cm^2 to 1.66 ± 0.42 cm^2 post-TAVR ($p < 0.001$). The THV geometry and effective

Table 2. SAPIEN XT Post-Implant Stent Diameters and Areas

Labeled Prosthesis Size	Inflow Mean Diameter (mm)	Mid-Portion Mean Diameter (mm)	Outflow Mean Diameter (mm)	p Value	Inflow Area (cm^2)	Mid-Portion Area (cm^2)	Outflow Area (cm^2)	p Value
20 mm	19.5 ± 0.6	19.2 ± 0.4	19.6 ± 0.1	0.759	3.3 ± 0.1	3.3 ± 0.2	3.3 ± 0.3	0.941
23 mm	23.1 ± 0.7	23.0 ± 0.8	23.0 ± 0.8	0.878	4.3 ± 0.3	4.3 ± 0.3	4.3 ± 0.3	0.944
26 mm	25.9 ± 0.7	25.9 ± 0.7	25.9 ± 0.6	0.950	5.4 ± 0.3	5.4 ± 0.2	5.5 ± 0.3	0.156
29 mm	28.8 ± 0.3	28.7 ± 0.3	28.6 ± 0.4	0.762	6.6 ± 0.1	6.5 ± 0.3	6.5 ± 0.2	0.290

There were no significant differences in valve areas or mean diameters at the inflow, mid-portion, and outflow within labeled valve sizes.

valve orifice areas were adjusted for labeled prosthesis size. Stent diameter, area, expansion, and eccentricity were not related to valve gradient or effective valve orifice area. The only significant factor explaining the effective valve orifice area or the valve gradient was the labeled prosthesis size (Table 5).

PAR. Paravalvular regurgitation was absent in 22 (24.7%), mild in 60 (67.4%), moderate in 5 (5.6%), and moderate-to-severe in 2 (2.2%) patients. Due to the low rate of more-than-mild PAR, grades of PAR were bundled to the binary outcome of mild-or-more and no PAR to assess THV geometry predictors for PAR. Table 6 shows differences of various oversizing measurements between patients with any versus no PAR. The stent inflow area in relation to the native MDCT annular area (effective MDCT area oversizing; $p = 0.025$) and the difference between the CT-measured stent inflow long-axis and the native annular long-axis diameter (effective long-axis oversizing; $p = 0.026$) were associated with PAR, whereas actually the THV stent diameter was undersized in comparison with the MDCT native annulus long axis. There was a nonsignificant trend toward more PAR, when the difference of the native annulus diameter measured by TEE to the THV inflow diameter (effective TEE diameter oversizing) was small (2.3 ± 1.0 mm vs. 1.7 ± 1.4 mm; $p = 0.067$). Prosthesis size, THV expansion, THV eccentricity, or THV inflow to annulus distance did not show any significant association with PAR.

Discussion

Our study evaluating a large consecutive TAVR cohort suggests that THV implantation depth, as defined by MDCT, is strongly associated with clinically significant conduction disturbances. Implantation depth was the only post-THV measure that was associated with conduction disturbances with annular area oversizing not showing a convincing relationship with this outcome. The ability to better understand potential causes of conduction abnormalities is of significant importance, because it has been previously shown that new onset LBBB (9) and other conduction disturbances (10,11) post-TAVR predict worse clinical outcomes (9). As such, our data help elucidate the mechanisms of conduction disturbances post-TAVR and possible strategies to reduce these complications in the future.

The rates for new PPM implantations after TAVR vary by the valve implanted (12). Although PPM rates after implantation with a Medtronic CoreValve were 24.4%, the rates with the SAPIEN and SAPIEN XT THV were 7.4% in the large UK Transcatheter Aortic Valve Implantation registry (12). Previously identified risk factors for a new PPM after TAVR include pre-existing RBBB (5), low baseline heart rate (13), and age (13). For the CoreValve prosthesis, oversizing (13) and the stent extending deeper into the left ventricular outflow tract (5) have been proposed as reasons for more PPM implantations. Although THV size and oversizing the annulus are commonly perceived as predictors for conduction disturbances, oversizing the native aortic annulus measured by TTE, TEE, or MDCT or labeled valve size were not associated with the need for a new PPM or the development of conduction delays in our study. Importantly, our data suggest that implantation depth defined as the distance between the native annulus and the THV inflow on MDCT is strongly associated with the need for a new PPM and the occurrence of a new LBBB or CHB.

Table 3. SAPIEN XT Post-Implant Valve Expansion and Eccentricity

Labeled Prosthesis Size	Inflow Expansion	Mid-Portion Expansion	Outflow Expansion	p Value	Inflow Eccentricity	Mid-Portion Eccentricity	Outflow Eccentricity	p Value
20 mm	104.6 ± 1.6	105.1 ± 6.8	103.5 ± 10.8	0.941	3.2 ± 2.4	0.5 ± 0.7	2.5 ± 0.7	0.374
23 mm	103.9 ± 7.6	103.8 ± 7.5	103.7 ± 7.0	0.944	2.5 ± 2.6	2.5 ± 3.1	2.7 ± 2.6	0.876
26 mm	101.9 ± 5.4	102.1 ± 5.4	102.9 ± 5.1	0.156	2.4 ± 2.2	2.8 ± 2.5	2.4 ± 2.9	0.488
29 mm	99.1 ± 2.0	97.8 ± 2.0	97.9 ± 3.7	0.290	3.5 ± 1.9	2.9 ± 1.9	4.3 ± 2.6	0.215

Values are percentages. There were no significant differences in eccentricity or expansion between labeled valve sizes and between inflow, mid-portion, and outflow within single valve sizes.

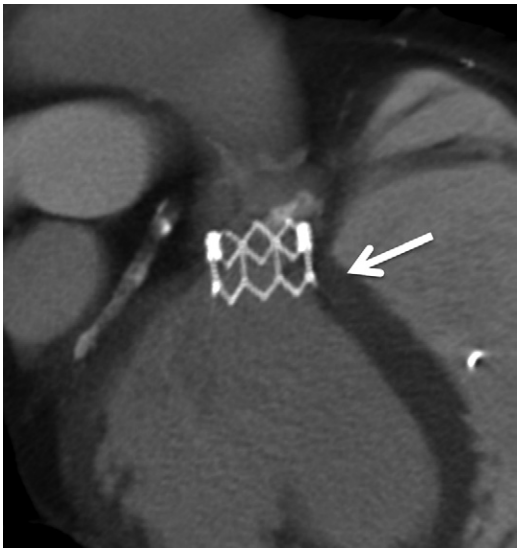

Figure 1. Stent Compressing the Interventricular Septum

Coronal oblique maximum intensity projection from a cardiac computed tomography examination of an 83-year-old male patient 3 days post-transcatheter aortic valve replacement complicated by the development of heart block. The inferior margin (arrow) of the balloon-expandable prosthesis is 7.0 mm below the native annulus and seems to be compressing the interventricular septum.

Table 5. SAPIEN XT Post-Implant Valve Gradient and Effective Orifice Areas According to Labeled Transcatheter Heart Valve Size

Labeled Prosthesis Size	Mean Gradient (mm Hg)	Valve Area (cm^2)
20 mm	17.5 ± 10.6	1.5 ± 0.3
23 mm	11.6 ± 4.4	1.5 ± 0.3
26 mm	10.3 ± 3.4	1.7 ± 0.4
29 mm	7.3 ± 2.4	2.3 ± 0.5

The only predictor for the mean gradient or the effective orifice area was the labeled valve size ($p = 0.001$ and $p < 0.001$, respectively). Stent expansion and eccentricity were not related to hemodynamic performance measures.

Our data have potential practical implications for sizing and positioning during TAVR. Although operators have historically performed TAVR with a belief that stretching the annulus causes atrioventricular block, our analysis suggests that the pressure of the stent on the inter-ventricular septum below the annulus is primarily responsible for conduction disturbances. In our study new LBBB, CHB, and the need for PPM were associated with low implant height, long PR interval, and longer QRS width. As such, one could surmise that higher implantation in patients with long PR intervals or long QRS durations might reduce the necessity for PPM implantation and avoid conduction delays. Of course, this has to be counterbalanced by the risk for embolization or significant PAR related to "high" THV implantation (14). This has to be especially considered when implanting smaller-diameter THVs, which also have a shorter landing zone due to decreased stent height.

Paravalvular regurgitation is associated with worse prognosis after TAVR (15,16). We hypothesized that the post-implant THV geometry defined by expansion and eccentricity might explain PAR. However, neither expansion nor eccentricity explained PAR. This contrasts with a smaller study with 42 patients (7), which showed an association between stent eccentricity and PAR. The SAPIEN XT THV consistently became circular and fully expanded, irrespective of the native annular anatomy. A strong post-implant MDCT association with PAR was the relation of the outer stent frame inflow area to the native annular area (effective annular area oversizing). This finding supports a prior study that showed a similar relationship between THV area oversizing and PAR burden and severity (7).

Although the THV stent diameter was generally smaller than the MDCT native annulus long axis, this did not translate to an unacceptable rate of PAR in this cohort. However, patients with any degree of PAR had more undersized valves measured by stent diameter in comparison with the MDCT native annulus long axis. The explanation

Table 4. Stent Geometry and Position in Patients With Conduction Disturbances

Conduction Disturbance	Prosthesis Size (mm)	Inflow Expansion (%)	Inflow Eccentricity (%)	Annular Area Oversizing (%)	Implant Depth (mm)
LBBB 1	23	102.9	3	Na	4.0
LBBB 2	26	93.8	1.2	−1.4	0.5
LBBB 3	29	100.0	5.4	10.9	6.5
LBBB 4	29	97.6	4.1	15.2	4.5
CHB 1	26	111.7	1.5	14	7
CHB 2	26	97.4	2.7	0.4	10
CHB 3	26	109.8	1.2	−3.5	4
CHB 4	26	100.6	4.2	0.8	7.3

The implant depth was significantly lower in patients who developed new conduction disturbances compared with patients who did not (3.4 ± 2.0 mm vs. 5.5 ± 2.9 mm, $p = 0.01$).
CHB = complete heart block; LBBB = left bundle branch block.

Table 6. Association of PAR With Different Oversizing Measurements

Oversizing Measurement	No PAR (n = 22)	Mild or More PAR (n = 67)	p Value
TTE effective diameter oversizing	2.4 ± 1.8	2.4 ± 2.1	0.953
TEE effective diameter oversizing	2.3 ± 1.0	1.7 ± 1.4	0.067
MDCT effective short diameter oversizing	3.7 ± 1.8	3.5 ± 1.8	0.730
MDCT effective long diameter oversizing	−0.7 ± 2.3	−1.9 ± 1.9	0.026
MDCT effective area oversizing (%)	12.8 ± 11.4	4.9 ± 12.9	0.025

Values are millimeters, unless otherwise indicated.
MDCT = multidetector computed tomography; PAR = paravalvular regurgitation; TEE = transesophageal echocardiography; TTE = transthoracic echocardiography.

might be that, as the oval native annulus becomes less eccentric by placement of a rigid and consistently circular THV stent, the native annulus short axis widens, and the native annulus long axis shortens, thereby sealing the paravalvular space. Oversizing measurements based on TEE showed only a trend toward more PAR with less oversizing, which is in accordance with previous reports (17), highlighting limitations of 2-dimensional assessments of the complex aortic annulus shape.

The finding of THV circularity and full expansion in most of our patients also accounts for the lack of an association between THV geometry and transvalvular gradient or the effective THV orifice area. The only significant predictor for valve area and gradient was the labeled THV size. These data would suggest that, in patients with borderline annular size, the selection of a larger prosthesis might allow for reduction in both transvalvular gradients and a lower likelihood of patient prosthesis mismatch. However, the potential benefits of more extensive area oversizing must be balanced with the potential risk of annular injury (18).

Study limitations. Although this is the largest reported cohort of post-implant MDCT evaluation of the geometry and position of balloon-expandable THVs, the absolute numbers for the measured outcomes are still relatively small and warrant confirmation in larger trials. Because most patients received 23- or 26-mm THV sizes, the results have to be interpreted with caution with regard to the smaller 20-mm THV (n = 2) and the larger 29-mm THV (n = 7). The PAR analysis was based on none versus any degree of PAR, because more-than-mild PAR was rarely observed. However, the clinical impact of mild PAR is subject to ongoing debate. We chose, on the basis of an internal MDCT sizing algorithm (19), the labeled valve size to slightly oversize the native annulus area (annulus area oversizing in this cohort 6.7 ± 12.6%). We cannot exclude that aggressive area oversizing (>20%) could have increased the rate of new LBBB or CHB, irrespective of implant depth.

Conclusions

A low implantation of balloon-expandable THVs is associated with clinically significant new conduction disturbances and PPM implantation. Importantly, annular area oversizing was not associated with these complications. Future studies might show whether purposeful higher implantation can reduce conduction abnormalities without increasing risk.

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Key Words: left bundle branch block ■ MDCT ■ permanent pacemaker ■ TAVR.