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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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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