Transcatheter Aortic Valve Implantation With Different Valve Designs for Severe Device Landing Zone Calcification

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Summary

Severe device landing zone calcification (DLZ-CA) predicted paravalvular leak (PVL) and post-dilatation (PD) after transcatheter aortic valve implantation (TAVI). The aim of this study was to determine the influence of DLZ-CA on PVL or PD rates after SAPIEN XT (XT) versus CoreValve (CV).

We analyzed patients undergoing TAVI who had severe DLZ-CA. Severe DLZ-CA defined the upper left ventricular outflow tract calcification; the cross-sectional region 2 mm inferior to the annular plane. PVL was evaluated at 30-days using transsthoracic echocardiography. Overall, 133 patients had XT-TAVI and the remaining 41 patients had CV-TAVI. Two patients had annulus injury in the XT group (oversizing 20.2% and 20.5% for two XT cases). PD was less frequently performed in the XT group (34.1% versus 12.8%; \( P = 0.002 \)), but PVL rates were similar between both groups (42.1% versus 41.5% for the XT and CV groups, respectively; \( P = 0.94 \)). Importantly, excessive oversizing or the degree of filling volume was not associated with decreased PVL after XT-TAVI (\( P \) non-significant for all). On multivariate analysis, CV-TAVI was found to be one of the independent predictors of need for PD (Odds ratio 3.63, 95% confidence interval 1.55 to 8.53, \( P = 0.003 \)).

In the setting of severe DLZ-CA, XT and CV have similar rates of PVL but XT had less need for PD. Excessive oversizing with XT carries a risk of root injury which could be further increased by DLZ-CA. (Int Heart J 2017; 58: 56-62)

Key words: Calcification, TAVI, TAVR, Post-dilatation, PVL, PAR

Transcatheter aortic valve implantation (TAVI) is a well-established alternative to surgical aortic valve replacement for high-risk patients with severe aortic valve stenosis.\(^1,2\) Paravalvular leak (PVL) is an important complication of TAVI that has been shown to be associated with increased mortality.\(^2,3\) Among the early generation transcatheter heart valves (THV), two device types have been in widespread use: the self-expandable Medtronic CoreValve (CV) (Medtronic, Minneapolis, MN, USA) and the balloon-expandable Edwards SAPIEN XT valve (XT) (Edwards Lifesciences, Irvine, CA, USA). Previous studies have been published on the safety and efficacy of both devices.\(^1,2,4-6\) The CHOICE study demonstrated that the use of a balloon-expandable (BE) THV resulted in a lower rate of need for post-dilatation (PD) or of PVL after TAVI compared to self-expanding (SE) THV.\(^4\) Furthermore, calcium in the aortic-valvular complex (AVC) is a well-known predictor of PVL, PD, and annulus injury following TAVI.\(^7,11\) Importantly, device landing zone (DLZ) calcification has been shown to be a strong predictor of PVL, PD, annulus injury, and new PPMI after XT or CV implantations.\(^7,10,11\) It was particularly found to be related to PVL after BE- or SE-TAVI\(^7\) and to predict aortic root injury following BE-TAVI,\(^11\) if DLZ calcification was located inferior to the annulus region. In predicting PVL or PD, however, the interaction between heavily calcified DLZ and the valve type is not well understood. The aim of this study was to determine the influence of severe DLZ calcification on PVL and PD rates following XT versus CV implantations.

**Methods**

**Study population and procedure:** Between January 2013 and June 2015, a total of 525 consecutive high-risk patients with symptomatic severe aortic stenosis (aortic valve area < 1.0 cm²) were treated with XT or CV at our institution and were prospectively included in our TAVI database. We included in the current analysis patients with severe DLZ calcification defined as upper left ventricular outflow tract (LVOT) calcification (Figure 1). The upper LVOT region was defined as the cross-sectional region 2 mm inferior to the annular plane (Figure 1).\(^7,8,11,12\) After excluding patients with the absence of up-
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Table I. Baseline Clinical Characteristics

|                      | Overall (n = 174) | CV (n = 41) | XT (n = 133) | P   |
|----------------------|-------------------|------------|-------------|-----|
| Age, years           | 81.5 ± 9.3        | 81.6 ± 9.4 | 81.0 ± 9.1  | 0.72|
| Female               | 57 (32.8%)        | 16 (39.0%) | 41 (30.8%)  | 0.33|
| Hypertension         | 159 (91.4%)       | 38 (92.7%) | 121 (91.0%) | 0.51|
| Dyslipidemia         | 143 (82.2%)       | 33 (80.5%) | 110 (82.7%) | 0.75|
| Diabetes             | 50 (28.7%)        | 13 (31.7%) | 37 (27.8%)  | 0.69|
| COPD                 | 50 (28.7%)        | 12 (29.3%) | 38 (28.6%)  | 0.94|
| Coronary artery disease | 109 (62.6%)   | 19 (46.3%) | 90 (67.7%)  | 0.014|
| Cerebrovascular disease | 51 (29.3%)     | 11 (26.8%) | 40 (30.1%)  | 0.69|
| Peripheral artery disease | 41 (23.6%)   | 1 (2.4%)   | 40 (30.8%)  | < 0.001|
| NYHA class 3/4       | 161 (92.5%)       | 38 (92.6%) | 123 (92.5%) | 0.97|
| History of any cardiac surgery | 40 (23.0%)   | 6 (14.6%)  | 34 (25.6%)  | 0.15|
| History of PPM       | 30 (17.2%)        | 7 (17.1%)  | 23 (17.3%)  | 0.97|
| Atrial fibrillation  | 15 (8.6%)         | 4 (9.8%)   | 11 (6.3%)   | 0.47|
| eGFR, mL/minute      | 47.1 ± 16.3       | 46.9 ± 15.7| 47.2 ± 16.6 | 0.94|
| BNP, pg/mL           | 567.8 ± 778.9     | 577.4 ± 729.0 | 564.8 ± 796.5 | 0.93|
| Logistic EURO score, % | 209.9 ± 14.7    | 16.6 ± 10.4| 22.2 ± 15.6 | 0.010|

Values are mean ± SD, or n (%). BNP indicates brain natriuretic peptide; COPD, chronic obstructive pulmonary disease; CV, CoreValve; eGFR, estimated glomerular filtration rate; NYHA, New York Heart Association; PPM, permanent pacemaker; and XT, SAPIEN XT.

per LVOT calcification (252 patients), previous bioprosthesis (45 patients), and patients with poor CT imaging quality (8 patients), a total of 174 patients were included in the final analysis. These patients were divided into two groups according to valve design. Sizing for THV was based on pre-TAVI CT imaging.

An ECG-gated MDCT study was only performed if renal function was considered satisfactory, as is routine clinical practice; this was generally if the serum creatinine was ≤ 2.0 mg/dL. Patients were evaluated using a Siemens Somatom Cardiac 64 or Siemens Somatom Flash scanner (Siemens Medical Solutions USA Inc., Malvern, PA, USA) using collimation of 0.6 mm at a fixed pitch of 0.2 with an injection of 50-110 cc of Isovue 370. A dedicated protocol was formulated, with 120 kV and tube current modified according to the patient size. Image acquisition was, for the most part, performed with retrospective ECG gating. CT DICOM data were analyzed by a dedicated core laboratory using 3-mensio Valves softwareTM (version 7.0, Pie Medical Imaging, Maastricht, the Netherlands). For reconstruction of mid-systolic data, the cine/movie feature of this software was used to determine the point in the cardiac cycle where the aortic valve was maximally open. For reconstruction, mid-systolic data was used.13

Oversizing was determined as follows: calculated perimeter oversizing (%) = (THV perimeter/annulus perimeter – 1) × 100; calculated area oversizing (%) = (THV area/annulus area – 1) × 100. The manufacturer’s recommended nominal inflation volume of the deployment balloon for the 23-, 26-, and 29-mm transfemoral Novaflex delivery system (Edwards Lifesciences, Inc.) are 17, 22, and 33 mL, respectively. The nominal inflation volumes for the 23-, 26-, and 29-mm transapical Ascendra+ delivery system (Edwards Lifesciences, Inc.) are 16, 20, and 30 mL, respectively. A recently validated 850 Hounsfield unit threshold was used to detect areas of calcium in the region of interest.8

The decision to proceed with TAVI was with the consensus of a dedicated heart team including experienced clinical and interventional cardiologists and cardiovascular surgeons. Transesophageal echocardiography was performed after TAVI at 30-days. PVL and life-threatening bleeding were graded according to the VARC guidelines.14,15
The study complied with the Declaration of Helsinki: a locally appointed Ethics Committee approved the research protocol and informed consent was obtained from all subjects.

Statistical analysis: Continuous variables were tested for a normality of distribution using the Shapiro-Wilk test and reported and analyzed appropriately thereafter. Categorical variables were compared by chi square statistics or the Fisher exact test. The Mann-Whitney $U$ test was used in the case of abnormal distribution. Parameters significant for prediction of PD ($P < 0.05$) were entered into a multivariable logistic regression.

Table II. Procedural Characteristics

|                        | Overall ($n = 174$) | CV ($n = 41$) | XT ($n = 133$) | $P$ |
|------------------------|---------------------|--------------|---------------|-----|
| Aortic valve area, cm$^2$ | 0.64 ± 0.14         | 0.67 ± 0.16  | 0.63 ± 0.14   | 0.073 |
| Aortic jet peak velocity, m/s | 4.28 ± 0.82        | 4.30 ± 0.74  | 4.27 ± 0.84   | 0.83 |
| Mean pressure gradient, mmHg | 49.4 ± 38.8        | 46.9 ± 16.1  | 50.1 ± 43.5   | 0.64 |
| LVEF, %                | 56.9 ± 15.0         | 59.5 ± 12.7  | 56.1 ± 15.6   | 0.21 |
| Mean aortic annulus diameter, mm | 24.9 ± 2.5    | 24.3 ± 2.3   | 25.1 ± 2.6    | 0.09 |
| Aortic annulus eccentricity$^\dagger$ | 5.1 ± 1.9        | 5.1 ± 1.8    | 5.1 ± 2.0     | 0.84 |
| Mean aortic annulus perimeter, mm | 78.9 ± 7.9    | 77.2 ± 7.3   | 79.4 ± 8.1    | 0.12 |
| Degree of oversizing by area, % | 23.0 ± 15.5       | 41.6 ± 12.1  | 17.4 ± 11.6   | <0.001 |
| Degree of oversizing by perimeter, % | 8.9 ± 6.9        | 17.1 ± 5.5   | 6.4 ± 5.1     | <0.001 |
| Degree of oversizing (XT area, CV peri) | 17.3 ± 10.5       | 17.1 ± 5.5   | 17.4 ± 11.6   | 0.82 |
| Aortic valve calcium volume, mm$^3$ | 333.0 ± 358.3     | 342.7 ± 418.3 | 330.0 ± 339.4 | 0.83 |
| LVOT calcium volume, mm$^3$ | 32.7 ± 50.1        | 40.5 ± 58.1  | 30.3 ± 47.4   | 0.45 |
| Alternative approach | 16 (9.2%)           | 0            | 16 (9.2%)     | 0.01 |

Prosthesis, mm

|     | Overall ($n = 174$) | CV ($n = 41$) | XT ($n = 133$) | $P$ |
|-----|---------------------|--------------|---------------|-----|
| 23 mm | 21 (12.1%)           | 1 (2.4%)     | 20 (15.0%)    |     |
| 26 mm | 66 (37.9%)           | 10 (24.4%)   | 56 (42.1%)    |     |
| 29 mm | 75 (43.1%)           | 18 (43.9%)   | 57 (42.9%)    |     |
| 31 mm | 12                  | 12 (29.3%)   | -             |     |

Values are mean ± SD or n (%). CV indicates CoreValve; LVEF, left ventricular ejection fraction; LVOT, left ventricular outflow tract; and XT, SAPIEN XT. Oversizing was determined as follows: calculated perimeter oversizing (%) = (THV perimeter/annulus perimeter – 1) × 100; calculated area oversizing (%) = (THV area/annulus area – 1) × 100. $^\dagger$All scans used were contrast scans; threshold for detection was set at 850 Hounsfield Units. $^*$Aortic annulus eccentricity was calculated as the maximum annulus diameter minus the minimum annulus diameter.

Figure 2. Aortic root injury cases. We have two case experiences. Both cases had a 29 mm XT valve with > 20% oversizing by area. A: Annulus hematoma after XT implantation. B: Post valve implantation, hemopericardium was recorded by TEE.
model using a forward method. All of the analyses were considered significant at a two-tailed $P$ value of less than 0.05. SPSS statistics software 22.0 (SPSS, Chicago, IL) was used to perform all statistical evaluations.

**RESULTS**

**Patients or procedural characteristics:** The XT group included 133 patients and the remaining 41 patients were included in the CV group. Baseline clinical procedural characteristics are shown in Table I. Patients in the XT group had higher surgical risk as predicted by the logistic EuroSCORE. Prevalence of peripheral artery disease was significantly higher in the XT group. Other clinical baseline parameters were comparable.

Mean oversizing by XT-THV was 17.1 ± 5.5% (range, -26.5 to 49.6%) versus 17.4 ± 11.6% in the CV group (range, 5.5 to 31.0%) ($P = 0.82$). Undersizing was present in 6 patients (4.5%) in the XT group and in none of the patients in the CV group. The most common THV size used in the XT and CV groups was the 29-mm (42.9% and 43.9%, respectively). No significant differences were found in aortic valve calcium volume (CA) or LVOT CA between both groups (XT versus CT: aortic valve CA; $330.0 ± 339.4 \text{ mm}^3$ versus $342.7 ± 418.3 \text{ mm}^3$; $P = 0.82$, LVOT CA: $30.3 ± 47.4 \text{ mm}^3$ versus $40.5 ± 58.1 \text{ mm}^3$; $P = 0.45$, respectively). Two patients with aortic anulus injury were observed (oversizing 20.2% and 20.5% for two XT cases) (Table II, Figure 2).

**PVL and post-dilatation:** Overall, mild or more PVL was present in 42.1% of the patients in the XT group and in 41.5% of the patients in the CV group ($P = 0.94$) (Table III). In the XT group, 11 patients (8.3%) had moderate PVL. On the other hand, 4 patients (9.8%) had moderate PVL after CV implantations. XT and CV had similar rates of mild or more PVL. Figure 3 illustrates the incidence of mild or more PVL stratified by the extent of MDCT area oversizing percentage. Moreover, in both groups there was no significant change in the rates of mild or more PVL despite an increased degree of oversizing (PVL versus no PVL: 16.9 ± 13.3% versus 17.8 ± 10.3%; $P = 0.66$; for XT, 17.3 ± 5.7% versus 17.0 ± 5.6%; $P = 0.85$; for CV, respectively). Patients with mild or more PVL were found to have borderline significantly higher aortic valve calcification compared to patients with none/trace PVL (424.4 ± 465.5 mm$^3$ versus 266.8 ± 235.7 mm$^3$, respectively, $P = 0.06$). PD was less frequently performed in the XT group (34.1% versus 12.8%, $P = 0.002$) (Table III). Eccentric annulus was associated with mild or more PVL (eccentricity index: 0.79 ± 0.08 versus 0.82 ± 0.06; $P = 0.04$).

### Table III. Outcomes at 30 days

|                      | Overall (n = 174) | CV (n = 41) | XT (n = 133) | $P$  |
|----------------------|-------------------|-------------|-------------|------|
| Mortality            | 2 (1.1%)          | 1 (2.4%)    | 1 (0.8%)    | 0.42 |
| Stroke/transit ischemic attack | 5 (2.9%)          | 0           | 5 (3.6%)    | 0.26 |
| Need for 2nd prosthesis | 5 (2.9%)          | 2 (4.9%)    | 3 (2.3%)    | 0.34 |
| Aortic annulus injury | 2 (1.1%)          | 0           | 2 (1.5%)    | 0.58 |
| Non-fatal myocardial infarction | 2 (1.1%)          | 1 (2.4%)    | 1 (2.4%)    | 0.42 |
| PVL at 30-days       |                   |             |             |      |
| None/trace           | 101 (58.0%)       | 24 (58.5%)  | 77 (57.8%)  | 0.94 |
| Mild                 | 58 (33.3%)        | 13 (31.7%)  | 45 (33.8%)  | 0.80 |
| Moderate or severe   | 15 (8.6%)         | 4 (9.8%)    | 11 (8.3%)   | 0.49 |
| Need for post-dilatation | 31 (12.8%)       | 14 (34.1%)  | 17 (12.8%)  | 0.006|

Values are mean ± SD or n (%). CV indicates CoreValve; PVL, paravalvular leak; and XT, SAPIEN XT.

Figure 3. Mild or more PVL according to oversizing. All patients were divided into 4 categories based on oversizing. No significant difference in PVL rates was found in either group. CV indicates CoreValve; PD, post-dilatation; PVL, paravalvular leak; and XT, sapienXT.
Independent predictors of the need for PD: Variables significant for prediction of the need for PD were entered into a multivariable logistic regression model (Table IV). On multivariate analysis, CV-TAVI was found to be an independent predictor of PD (Odds ratio, 3.22; 95% confidence interval, 1.3 to 7.7, \( P = 0.10 \)). CV, aortic valve CA, and annulus eccentricity were found to be independent predictors for the need for PD in the setting of severe DLZ calcification (CV: odds ratio, 3.63; 95% CI, 1.55 to 8.53; \( P = 0.003 \), aortic valve CA: odds ratio, 1.001; 95% CI, 1.00 to 1.002; \( P = 0.04 \), eccentric annulus: odds ratios, 0.001; 95% CI, 0.00 to 0.93; \( P = 0.047 \)).

Relation between device filling volume and PVL after XT implantation: Analysis of the relationship between device inflation volume and mild or more PVL rates after XT implantation is shown in Figure 4. It revealed that the degree of filling volume was not related to decreased rates of mild or more PVL despite excessive oversizing (nominal filling volume 37.5% of mild or more PVL versus under filling volume 39.9%, \( P = 0.57 \)). Similarly, below 10% oversizing with additional inflation volume was not statistically significant for decreased PVL (additional filling volume 47.4% of mild or more PVL versus nominal filling volume 45.5%, \( P = 0.67 \)).

**DISCUSSION**

There is limited data available regarding PVL rates following SE or BE-TAVI in patients with severe DLZ calcification. It was previously found to be associated with increased PVL or PD rates, and annulus injury only following BE-THV implantations.\(^7\)\(^9\)\(^11\)\(^12\) Previous studies also demonstrated that there is reduced rates of PVL or PD following XT compared to CV TAVI.\(^4\)\(^6\) Most of these previous studies included different grades of aortic valve calcification but did not evaluate association with DLZ calcification.

The present study is the first attempt to determine the influence of severe DLZ calcification on PVL following XT versus CV implantations. There was no significant difference in mild or more PVL between both valves. Optimal oversizing is of great importance in order to prevent PVL. It is generally accepted that CV requires a higher degree of oversizing than XT to prevent PVL.\(^4\)\(^6\) In our series, the degree of oversizing was comparable between both valves. Furthermore, no significant difference in rates of PVL was found in the excessive oversizing group (> 20% oversizing), following XT versus CV implantations.

With regard to the need for PD, previous studies reported increased rates of PD following SE-TAVI compared to BE-TAVI.\(^3\)\(^7\) Similarly, in the current study, the CV group had higher rates of PD compared to the XT group. Furthermore,
CV and XT had similar high rates of mild or more PVL. There are several possible explanations for these results. First, device positioning technique is an important factor for device success (ie, PVL or PD). XT is a relatively short device and precise positioning is mandatory for effective performance of the device post deployment. Conversely, CV is a longer device that allows for a wide range of implant depths. In CV implantations, very deep implantation results in PVL, because the covered skirt would be situated below the annulus, allowing blood to regurgitate through the uncovered portion of the stent frame. Second, it is very important to create enough radial force between the device and the aortic-valvular complex in order to avoid malposition or to prevent PVL. CV is directly influenced by the anatomical relationship between the aortic root and the LVOT angle, which may affect the ability of the nitinol frame to provide adequate radial force. Moreover, SE-valves have less radial force compared to BE-valves, which is more relevant in the setting of severe DLZ calcification. Finally, incomplete device expansion due to calcification is believed to be one of the major contributing factors for the development of PVL or the need of PD. John, et al demonstrated that the calcium of the native valve and of the LVOT are compressed between the nitinol frame of the device and the aortic wall. This factor induces gaps that in turn cause several diastolic PVL jets after CV implantations. By contrast, our previous study demonstrated that XT expansion is greater at the outflow versus the inflow, where it is relatively constrained. Moreover, the degree of expansion area of the XT at inflow level exhibited little change even though filling volume was increased. In the setting of severe DLZ calcification, these characteristics of different device designs or implantations techniques may contribute to increased PVL rates after both devices, and the higher frequency of PD in the CV group.

The present study has demonstrated that increased oversizing was not associated with decreased PVL rates after both CV and XT implantations. A previous study has shown that excessive oversizing and XT valve both predicted a larger degree of stent recoil. Accordingly, for XT prosthesis, there is an increased calcified space that remains between the aortic annular wall and the prosthesis. This space allows blood to regurgitate through incomplete apposition. Moreover, in the setting of heavy calcification, excessive oversizing was not found to reduce PVL after CV implantations. Nevertheless, further studies to determine this hypothesis are required.

Oversizing to reduce PVL must be balanced against the increased risk of annular injury. This may occur with excessive oversizing of BE-TAVI. Conversely, SE-TAVI is very rarely associated with annular rupture, when PD is not performed. Barbanti, et al demonstrated that > 20% oversizing, PD, and severe DLZ calcification predicted an increased risk of root injury during BE-TAVI. In our study, two patients with annulus injury were observed during XT procedures. Both patients had > 20% oversizing but no need for PD. Moreover, these patients had relatively large STJ and sinus of Valsalva dimensions and no commissural calcification. Therefore, excessive oversizing in the presence of severe DLZ calcification probably contributed significantly to annular injury. A previous study has shown that calcification located underneath the right coronary cusp is more frequent in cases of annular injury. Nonetheless, in both of our annular injury cases the LVOT calcification was located underneath the left coronary cusp or non-coronary cusp.

For the 6 XT patients (4.5%) that had undersized valve implantation, the reason was that the native valve dimensions were borderline for small/larger bioprosthetic valves and the operator preferred the smaller valve in order to minimize risk of annular injury in the presence of severe calcification that was especially dominant at the level of the sinus of Valsalva in these cases. With regards to the filling volume, one patient had nominal volume while another’s volume was under filling.

Furthermore, our findings showed that excessive oversizing and the degree of filling volume were not associated with decreased PVL rates after XT implantations. Therefore, for patients who have high potential risk of annulus injury in the setting of severe DLZ calcification, particularly in the case of the excessive oversizing of XT (≥ 20%), we recommend considering the use of a CV device in that CV and XT had similar rates of PVL and excessive oversizing or the degree of filling volume was not associated with decreased PVL. However, for rates of PVL that remained high, next generation SE-TAVI (ie, Lotus valve) will be required.

Limitations: The main limitation of the present study is that it represents a retrospective, single-center experience. The findings are subject to selection bias and confounders and the number of patients in both groups is not balanced. Valve type selection and sizing for THV or the need for PD were left to the operator's discretion. The association between bleeding and antiplatelet therapy following TAVI was not assessed. Future multi-center studies with larger numbers of patients and longer follow-up may further clarify this subject.

Conclusions: In the setting of severe DLZ calcification, XT and CV implantations result in similar rates of PVL. Following XT TAVI there is less need for PD. Excessive oversizing of XT carries a risk of root injury which could be further increased by the presence of DLZ calcification. Moreover, the degree of XT device filling volume or excessive oversizing of XT was not associated with rates of post-procedural PVL.

Disclosure

Conflict of interest statement: Dr. Jilaihawi is a consultant for Edwards Lifesciences, St. Jude Medical, and Venus Medtech. Dr. Makkar receives research grants from Edwards Lifesciences, Medtronic, Abbott Vascular, Cordis, and St. Jude Medical and is a proctor for Edwards Lifesciences and consultant to Medtronic.

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