

1 **Anatomical features of the aortic root in aortic stenosis and a novel**
2
3 **approach for transcatheter aortic valve implantation**
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Abstract

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6 A narrow and calcified sinotubular junction (STJ) represents a risk for ascending aortic
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8 dissection after balloon-expandable transcatheter aortic valve implantation (TAVI). The aim
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10 of this study was to assess computed tomography (CT)-based aortic root morphology in
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12 patients with aortic stenosis (AS), and to evaluate the feasibility of a two-step inflation
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14 technique that we devised for TAVI using the SAPIEN 3 in patients with a narrow and
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16 calcified STJ. We retrospectively analyzed the STJ diameter (STJD) as well the as aortic
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18 annulus diameter (AAD) and STJ calcification using CT imaging in 412 patients undergoing
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20 TAVI. We defined a "narrow STJ" as a minimum STJD that was smaller than the diameter
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22 corresponding to a 10% oversized annulus area, and a "calcified STJ" as an STJ calcification
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24 angle>90°. A "narrow and calcified STJ" was identified in 54 patients (13.1%) of patients.
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26 Among them, we performed TAVI using the two-step inflation technique with SAPIEN 3 in
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28 20 patients and compared with 11 patients that underwent the conventional inflation
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30 procedure. Two-step inflation was successfully performed without ascending aortic
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32 dissection in all 20 patients. The effective orifice area index at discharge in these 20 patients
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34 was similar to that in 11 patients who underwent the conventional inflation procedure for a
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36 "narrow and calcified STJ" [1.40 (1.20-1.51) vs. 1.33 (1.18-1.41) cm²/m², p=0.23]. Although
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38 further assessment is required, the two-step inflation technique with the SAPIEN 3 is feasible
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40 for a narrow and calcified STJ.
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52 **Keywords:** transcatheter aortic valve implantation, aortic stenosis, aortic root anatomy,
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54 sinotubular junction, calcification
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Introduction

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6 Transcatheter aortic valve implantation (TAVI) is an effective and safe therapeutic
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8 option for patients with symptomatic severe aortic stenosis [1]. When TAVI was introduced
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10 for the first time, its indication was limited to high-risk surgical patients because of
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12 procedural complications, such as aortic annulus rupture [2, 3] and coronary obstruction [4].
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14 However, the clinical outcomes have improved owing to various advances in the procedural
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16 technique, imaging modality and device technology. The SAPIEN 3 (Edwards Lifesciences
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18 Inc., Irvine, CA, USA), a newly designed balloon-expandable transcatheter heart valve
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20 (THV), has achieved low mortality and less complications such as stroke and aortic
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22 regurgitation in intermediate-risk patients [5]. However, balloon-expandable THV still has
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24 several problems because of the nature of its design. Especially in patients with a narrow and
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26 calcified sinotubular junction (STJ), balloon-expandable TAVI may cause ascending aortic
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28 dissection [2, 6-8]. Therefore, it is important to assess the anatomical features of the STJ such
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30 as its diameter and the degree of calcification prior to TAVI. However, there is little
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32 information of how precise STJ anatomical assessment should be used to establish the TAVI
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34 strategy.
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42 We recently devised a two-step inflation technique for TAVI using the
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44 balloon-expandable SAPIEN 3 valve in patients with a narrow and calcified STJ. This
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46 technique can avoid stressful contact with the STJ and allows valve expansion at the annulus.
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50 In the present study, we assessed the anatomical features of the aortic root using
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52 computed tomography (CT) in patients with aortic stenosis who underwent TAVI, especially
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54 focusing on the size and degree of STJ calcification. In addition, we assessed the feasibility
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56 of the novel two-step inflation technique in patients who had a narrow and calcified STJ.
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Methods

CT assessment of aortic root morphology

In a total of 412 patients who underwent TAVI between January 2014 and June 2017 at Sendai Kousei Hospital, preprocedural CT was performed using a 320-detector row CT system (Aquilion ONE, VISION edition, Toshiba Medical Systems, Tokyo, Japan) to assess the anatomic features of the aortic root. This study complies with the Declaration of Helsinki and was approved by our institutional ethics and committee. Written informed consent was obtained from all patients. Each morphological parameter was measured using ZIO STATION 2 PLUS, version 2.4.0.4 (Ziosoft, Tokyo, Japan), and OsiriX v.4.1.2 32-bit (OsiriX Foundation, Geneva, Switzerland). The CT measurement of the aortic root was performed based on a previous report [9]. The mean aortic annulus diameter was calculated as $(2 \times \sqrt{[\text{basal ring area in mm}^2/\pi]})$, as proposed previously [10,11]. STJ diameter was measured involving the thickness of its calcification (Figure 1A). The mean STJ diameter was calculated as the mean of the maximum and minimum diameters. The STJ area was calculated as maximum STJ diameter \times minimum STJ diameter $\times \pi / 4$. The mean STJ height was derived from the mean of the STJ heights measured in the slices at the right and left coronary ostium level. The STJ calcification angle was measured using a transverse STJ image and was summed if there were multiple calcifications (Figure 1B). The aortic valve Agatston calcium score was measured by standard Agatston methodology, with a threshold for calcium detection of 130 Hounsfield units [12]. The annular area sizing was determined as follows: $(\text{nominal THV area}/\text{annulus area}-1) \times 100$. Nominal areas of the 20-, 23-, 26-, and

1 29-mm SAPIEN 3 THVs were 309.2, 407.2, 519.2, and 649.2 mm², respectively, as provided
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3 by the manufacturer [13].
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6 7 8 **Echocardiographic measurement** 9

10 All subjects underwent standard two-dimensional B mode and Doppler transthoracic
11 echocardiography prior to the procedure and the conventional parameters were measured
12 according to the American Society of Echocardiography (ASE) guidelines [14,15].
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16 17 18 19 20 **Definition of “narrow STJ” and “calcified STJ”**

21 A “narrow and calcified STJ” was defined as the presence of both a "narrow STJ" and
22 a "calcified STJ". A "narrow STJ" was defined as a minimum STJ diameter smaller than the
23 diameter derived from a 10% oversized annulus area. This criterion was based on the concept
24 that the THV or balloon may contact the STJ when a 10% oversized SAPIEN 3 is selected,
25 according to a previous report [16]. A "calcified STJ" was defined as an STJ calcification
26 angle >90°.
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40 41 **The two-step inflation technique**

42 With "the two-step inflation technique", the SAPIEN 3 is first deployed with an
43 underfilled volume, and then post-dilation is performed for the lower half of SAPIEN 3. We
44 devised this technique as a novel TAVI strategy using SAPIEN 3 for patients with a "narrow
45 and calcified STJ". The choice of the inflation method, SAPIEN 3 sizing and the inflation
46 volume were at the operator's discretion, taking into account the preprocedural CT findings.
47 Figure 2 shows a representative case with a “narrow and calcified STJ” in which the SAPIEN
48 3 was deployed using the two-step inflation technique. Preprocedural CT demonstrated a
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1 “narrow and calcified STJ”, where the minimum diameter was 16.7 mm and the calcification
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3 angle was 212.7° (Figure 2A, B). Since the aortic annulus area was 351 mm², a 23-mm
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5 SAPIEN 3 was selected. The THV balloon was slowly inflated to avoid stressful contact with
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7 the STJ calcification, and then the SAPIEN 3 was deployed at an underfilled volume (-3 mL
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9 from nominal inflation volume) (Figure 2D). Then, the THV balloon was shifted downward
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11 and post-dilated up to a nominal inflation volume (0 mL), where the central marker was at the
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13 left ventricular edge of the SAPIEN 3 (Figure 2E). Final aortography and transesophageal
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15 echocardiography demonstrated that the SAPIEN 3 had a skirt-like shape, and neither aortic
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17 dissection nor paravalvular leakage occurred (Figure 2F, G). Transthoracic echocardiography
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19 at discharge revealed that the effective orifice area (EOA) index was 1.33 cm²/m², and the
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21 mean pressure gradient (MPG) was 7 mmHg (Figure 2H). The deployment position was
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23 approximately 2 mm between the SAPIEN 3 marker and the annulus plane to minimize the
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25 need for pacemaker implantation [17].
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35 **Definition of ascending aortic dissection**

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38 The definition of ascending aortic dissection in this study is Stanford type A aortic dissection
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40 originating notified during or after procedure.
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45 **Statistical analysis**

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47 Continuous variables were assessed for normality of distribution using the
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49 Shapiro-Wilk test; those that followed a normal distribution were reported as the mean ± SD
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51 and those that did not were reported as the median (interquartile range). For intergroup
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53 comparisons, a Student’s t-test was used for data with a parametric distribution, and a
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55 Mann-Whitney U test was used for data with a non-parametric distribution. Categorical
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1 variables were reported as a number (percentage) and compared using Pearson's chi-square
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3 test or Fisher's exact test. Correlations between two variables were assessed using simple
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5 linear regression. A p-value <0.05 was considered statistically significant. JMP® 11 for Mac®
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7 (SAS Institute, Cary, NC, USA) was used for all statistical analyses.
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In all 412 patients, the mean STJ diameter was larger than the mean aortic annulus diameter (25.8 ± 2.8 vs. 22.8 ± 2.0 mm, p<0.0001) (Figure 3A). However, the mean STJ diameter was smaller than the mean aortic annulus diameter in 22 patients (5.4%). A “narrow STJ”, as defined in the Methods section, was found in 125 patients (30.3%). There was a strong correlation between the mean aortic annulus diameter and the mean STJ diameter (r=0.61, p<0.0001) (Figure 3B). The mean STJ calcification angle was 66.0±73.5° (Figure 3C). In 121 patients (29.3%), STJ calcification was absent. The STJ calcification angle was 0–90° in 177 patients (43.0%), 90–180° in 80 (19.4%), 180–270° in 21 (5.1%), and 270–360° in 13 (3.2%). Thus, a “calcified STJ”, as defined in the Methods section, was seen in 114 patients (27.7%). A “narrow and calcified STJ” was seen in 54 patients (13.1%). There was a negative correlation between the STJ calcification angle and the ratio of the mean STJ diameter to the mean aortic annulus diameter (r=-0.24, p<0.0001) (Figure 3D).

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We compared patient characteristics, transthoracic echocardiographic parameters and CT data between patients with and without “narrow and calcified STJ”. The “narrow and calcified STJ” group showed a trend of smaller body size as compared to the control group in height (148.8±8.6 vs 151.2±8.9 cm, p=0.06), weight (50.4±11.2 vs 52.9±10.9 kg, p=0.11), and body surface area (1.4±0.2 vs 1.5±0.2 m², p=0.06). The frequency of prior open heart surgery was higher in the “calcified STJ” group than in the control group (14.9 vs 3.6 %, p<0.001). The other patient characteristics did not differ between the two groups (Table 1). Preoperative echocardiographic data showed that aortic stenosis severity and left ventricular function were similar between the two groups (Table 2). Based on the preprocedural CT data, aortic annulus area, mean aortic annulus diameter were similar between the two groups (Table 2). The Mean diameter of sinus of Valsalva was smaller in the “narrow and calcified STJ” group than in the control group (28.7±2.6 vs 30.3±3.1 mm, p=0.0005). The mean STJ diameter was smaller in the “narrow and calcified STJ” group than in the control group (23.7±1.8 vs. 26.1±2.7 mm, p<0.0001). The mean STJ height was smaller in the “narrow and calcified STJ” group than in the control group (18.6±2.2 vs. 19.4±2.6 mm, p=0.04). The STJ calcification angle in the “narrow and calcified STJ” group was 166.8±80.3°, whereas that in the control group was 50.6±59.0° (p<0.001). The aortic valve Agatston score was similar between the two groups.

Feasibility of the two-step inflation technique

Although the period of the CT assessment study with 412 patients was between January 2014 and June 2017, we started using the SAPIEN 3 in June 2016. After SAPIEN 3 was available, all 31 cases with “narrow and calcified STJ” were treated with SAPIEN 3. We performed the conventional inflation procedure for TAVI in the first 11 patients with a

1 “narrow and calcified STJ”. Thereafter, we used the two-step inflation technique in the next
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3 20 patients with a “narrow and calcified STJ”. We compared preoperative echocardiographic
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5 parameters, CT data, procedural data, and the clinical and echocardiographic data at
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7 discharge between the two-step inflation group (n=20) and the conventional inflation group
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9 (n=11). All preoperative echocardiographic and CT data were similar between the two groups
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11 (Table 3). The SAPIEN 3 size was similar between the two groups (Table 4). Annular area
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13 sizing [11.3 (4.5-15.3) vs 10.4 (-0.7-21.6)%, p=0.84] did not differ. Pre-dilation was
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15 performed in 2 patients (10.0%) in the two-step inflation group and 2 patients (18.2%) in the
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17 conventional inflation group (p=0.60). The inflation volume at the time of THV deployment
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19 was significantly lower in the two-step inflation group than in the conventional inflation
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21 group (difference from nominal volume: -1.78 ± 0.95 vs. -0.91 ± 1.04 ml, p=0.02). Post-dilation
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23 was performed in all patients in the two-step inflation group and in 7 patients (65.4%) in the
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25 conventional inflation group (p=0.004). The final inflation volume was equivalent between
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27 the two groups (difference from nominal volume: -0.08 ± 0.77 vs. -0.05 ± 1.01 ml, p=0.93).
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29 These was no postoperative mortality in the two-step inflation group, but one patient in the
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31 conventional inflation group died because of congestive heart failure (0 vs 9.1 %, p=0.35).
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33 Ascending aortic dissection did not occur in any patient in either group (Table 4). A new
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35 pacemaker implantation was required in 3 (15.0%) and 2 patients (18.2%) in the two-step
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37 inflation and conventional inflation groups, respectively (p=1.0). Echocardiographic data at
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39 discharge showed that the EOA index was similar between the two groups [(1.40 (1.20-1.51)
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41 vs. 1.33 (1.18-1.41) cm²/m², p=0.23]. In addition, the THV peak velocity (2.33 ± 0.48 vs.
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43 2.34 ± 0.31 m/s, p=1.00) and MPG (10.9 ± 4.4 vs. 10.8 ± 2.9 mmHg, p=0.95) was also similar
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45 between the groups. Aortic regurgitation of > grade 2 was present in one patient (5.0%) in the
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47 two-step inflation group and no patient (0%) in the conventional inflation group (p=1.0).
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Discussion

In the present study, we first elucidated the anatomical features of the aortic root in patients with aortic stenosis, especially focusing on size and calcification at the STJ. As a result, a “narrow STJ”, defined as a minimum STJ diameter smaller than the diameter derived from a 10% oversized annulus area, was found in 30.3% of the patients in this study. A “calcified STJ”, defined as a STJ calcification angle $> 90^\circ$, was seen in 27.7% of patients. A “narrow and calcified STJ” defined as the presence of both a "narrow STJ" and a "calcified STJ” was seen in 13.1% of patients. Next, we demonstrated the feasibility of a novel TAVI strategy, the two-step inflation technique, for patients with a “narrow and calcified STJ”.

Anatomical features of the STJ in aortic stenosis

The STJ is recognized as the interface between the aortic root and the ascending aorta. STJ calcification is predominant in the elderly and is associated with atherosclerosis [18,19]. Finkelhor et al. [20] reported that STJ calcification was observed in 18% of elderly individuals without any cardiac disorders. Colli et al. [7] used transesophageal echocardiography and reported that 78% of 103 aortic stenosis patients undergoing transapical TAVI had localized STJ calcification. In addition, complete circumferential STJ calcification was found in 18% of the patients. In contrast, our CT assessment showed that an STJ calcification angle $\leq 360^\circ$ but $>$ than 270° was present in only 3.2%. These discrepant data may be due to the difference in the imaging approaches. To our knowledge, our study is the first to assess the distribution of STJ calcification using CT.

1 The size relationship between the aortic annulus and the STJ has been controversial.
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3 Some studies reported that the STJ and aortic annulus showed a similar size in both healthy
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5 individuals and aortic stenosis patients [20,21], whereas other studies reported that the STJ
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7 was smaller than the annulus [22]. The discrepancy may be due to the difference in the
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9 imaging modalities and the methods of measurement. In our CT study, the aortic annulus
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11 diameter, which was calculated from the traced annulus area [10,11], was smaller than that of
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13 the STJ in all of the aortic stenosis patients. However, in 5.4% of patients, the mean STJ
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15 diameter was smaller than that of the aortic annulus. Additionally, we found that STJ
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17 calcification showed a negative correlation with the ratio of the mean STJ diameter to the
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19 mean aortic annulus diameter. This result suggests that STJ size may depend on STJ
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21 calcification, and that negative remodeling due to atherosclerosis may have an important
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23 influence on STJ morphology. However, further investigations are required to clarify these
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25 assumptions.
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32 **Iatrogenic ascending aortic dissection**

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35 Aortic dissection is a rare but serious complication in TAVI. A meta-analysis of 9251
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37 patients from 46 studies reported that emergent cardiac surgery due to aortic dissection
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39 during TAVI was very rare, as it occurred in only 14 patients (0.15%) [23]. However,
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41 Barbanti et al. [2] reported two cases of STJ injury after TAVI, although they provided no
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43 details. On the other hand, Yashima et al. [7] reported clear details about iatrogenic ascending
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45 aortic dissection for a narrow and calcified STJ using SAPIEN XT. An important finding in
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47 their study was that even though SAPIEN XT itself did not reach the STJ, STJ injury
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49 occurred due to the overfilling of the delivery balloon. The potential risk of interference with
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51 the STJ may be higher with the SAPIEN 3 than with the SAPIEN XT, because SAPIEN 3
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1 tends to reach the STJ for the following two reasons. First, the height of the SAPIEN 3 is
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3 taller than that of the SAPIEN XT. Second, the SAPIEN 3 is recommended to be deployed at
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5 a higher position to minimize the risk of atrioventricular block [17]. Therefore, we pay
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7 meticulous attention to this issue when we perform TAVI using the SAPIEN 3 in patients
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9 with a narrow and calcified STJ.
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13 A self-expanding THV may be preferred for a narrow and calcified STJ because it does
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15 not require excessive force to expand. In addition, even though iatrogenic dissection occurs at
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17 the ascending aorta, a self-expanding THV can seal it [24]. However, the use of a
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19 self-expanding THV is limited by the device eligibility in institutions or countries and other
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21 morphological characteristics like horizontal aorta, ascending aorta dilatation, and device
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23 access.
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30 **The two-step inflation technique**

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32 We devised the two-step inflation technique utilizing the conformability of the
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34 SAPIEN3 platform as a novel approach for patients with a narrow and calcified STJ. Using
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36 this technique, the outflow portion is relatively under expanded to accommodate a narrow
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38 and calcified STJ, and was flared at the aortic annulus. The two-step inflation technique
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40 seemed to be safe and might contribute to the prevention of STJ injury induced by direct
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42 SAPIEN 3 THV contact as well as balloon delivery at the time of THV deployment. With the
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44 two-step inflation technique, the pigtail catheter should be fully pulled back from the sinus of
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46 Valsalva before full dilation, because the catheter as well as the balloon might cause aortic
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48 dissection [25, 26].
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55 The inflation volume at the first inflation is a key factor in the two-step inflation
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57 technique. We inflate the delivery balloon very slowly so that we can stop the inflation when
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1 the delivery balloon or THV itself pushes on the STJ calcification, which can be seen on
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3 fluoroscopy. In our experience, when STJ calcification is mild to moderate, the balloon
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5 should be underfilled by -1 to -2 ml compared with the nominal inflation volume for the
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7 annulus. However, when the STJ calcification is severe and thick, -3 ml may be beneficial. At
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9 the time of post-dilation, the center marker of the delivery balloon is positioned at the inflow
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11 edge of SAPIEN 3 so that it dilates at the annulus and does not interfere with the outflow
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13 edge (Figure 2E). The stiff wire should be positioned deep inside the left ventricle and
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15 trapping in the papillary muscle should be avoided. Also, blood pressure should be lowered
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17 by rapid pacing during inflation. These efforts are important for the prevention of injury of
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19 the left ventricle and papillary muscle, because the delivery balloon is deep inside the left
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21 ventricle at the time of post-dilation.
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28 In this study, we deployed the SAPIEN 3 in patients with a “narrow and calcified STJ”
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30 and compared various parameters between 20 patients who underwent two-step inflation and
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32 11 patients who underwent conventional inflation. Our study showed that there was no
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34 significant difference in echocardiographic parameters, EOA and paravalvular leak at
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36 discharge, and pacemaker implantation between two groups, and this suggests that the
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38 two-step inflation technique is safe. Although the postoperative course of the two groups
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40 patient was not significantly different, it is important to note that that there was neither
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42 ascending aortic dissection nor postoperative death in the two-step inflation group. Although
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44 this pilot study showed the feasibility of the two-step inflation technique, evaluation using a
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46 larger sample of patients is required to establish the safety and efficacy of this technique.
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55 **Study limitations**

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1 Norio Tada is a clinical proctor for Edwards Lifesciences. All the other authors have no
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3 conflict of interest to disclose.
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Figure legends

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6 **Figure 1 A computed tomography (CT) image of sinotubular junction (STJ)**
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8 **calcification and measurement of the maximum and minimum diameter**
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10 **(A) and STJ calcification angle (B).**

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12 STJ diameter was measured involving the thickness of its calcification. Maximum and
13 minimum STJ diameter is measured as 22.5 mm and 16.7 mm, respectively (A). STJ
14 calcification angle is summed if there are multiple (45.6°, 46.2°, and 120.9°, total
15 212.7°)(B). The same case as Figure 2.

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25 **Figure 2 A representative case of the two-step inflation technique for a “narrow and**
26 **calcified STJ”.**

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31 A narrow and heavily calcified STJ is shown (A,B). There is bulky calcification above
32 the non-coronary cusp (white arrow). Aortography shows heavy calcification at the STJ on
33 the non-coronary cusp (white arrow) (C). A 23-mm SAPIEN 3 is dilated and stopped at an
34 underfilled volume of -3 mL to avoid pushing on the bulky calcification (D). The
35 transcatheter heart valve (THV) balloon is shifted downward and post-dilation is performed
36 up to nominal volume, where the central marker is at the left ventricular edge of the
37 SAPIEN 3 (E). Final aortography (F) and transesophageal echocardiography (G) shows that
38 the THV has a skirt-like shape. There is neither aortic dissection nor paravalvular leakage.
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40 Transthoracic echocardiography at discharge revealed that the effective orifice area (EOA)
41 index was 1.33 cm²/m², and the mean pressure gradient (MPG) was 7 mmHg (H).

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57 **Figure 3 Morphological characteristics of the sinotubular junction (STJ).**
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1 The mean STJ diameter was larger than the mean aortic annulus diameter (A).
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3 Relationship between the mean STJ diameter and the mean aortic annulus
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5 diameter showing a strong correlation (B). Distribution and box plot of the STJ
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7 calcification angle (C). Relationship between the STJ calcification angle and the
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9 ratio of the mean STJ diameter to the mean aortic annulus diameter showing a
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11 negative correlation (D).
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Table 1. Baseline characteristics of patients with and without a “Narrow and calcified STJ” (defined as a minimum STJ diameter that is smaller than the diameter corresponding to a 10% oversized annulus area and a calcification angle >90°)

	“Narrow and calcified STJ” group N=54	Control group N=358	p-value
Age (years)	84.6±4.3	83.4±4.1	0.11
Male gender; n (%)	16 (29.6)	111 (31.0)	0.83
Height (cm)	148.8±8.6	151.2±8.9	0.06
Weight (kg)	50.4±11.2	52.9±10.9	0.11
Body surface area (m ²)	1.4±0.2	1.5±0.2	0.06
Hypertension; n (%)	31 (57.4)	234 (65.4)	0.26
Diabetes; n (%)	10 (18.5)	70 (19.6)	0.86
Dyslipidemia; n (%)	16 (29.6)	99 (27.7)	0.76
Atrial fibrillation; n (%)	8 (14.8)	80 (22.4)	0.20
Carotid artery stenosis; n (%)	5 (9.3)	21 (5.9)	0.41
Stroke; n (%)	5 (9.3)	30 (8.4)	0.83
Prior open-heart surgery; n (%)	8 (14.9)	13 (3.6)	<0.001
Prior pacemaker; n (%)	2 (3.7)	19 (5.3)	0.62
Radiation therapy; n (%)	0 (0)	3 (1.0)	0.50
eGFR (mL /min/1.73m ²)	49.6±17.9	52.5±19.3	0.31
Creatinine (mg/dl)	1.08±0.67	1.02±0.69	0.60
Brain natriuretic peptide (pg/ml)	763.5±793.8	632.4±778.1	0.25
STS score	8.9±7.9	7.7±7.7	0.27

STJ: sinotubular junction, eGFR: estimated glomerular filtration rate, STS: Society of Thoracic Surgery

Table 2. Echocardiography and CT data in patients with and without a “narrow and calcified STJ” (defined as a minimum STJ diameter that is smaller than the diameter corresponding to a 10% oversized annulus area and a calcification angle >90°)

	“Narrow and calcified STJ” group N=54	Control Group N=358	p-value
Echocardiography data			
Aortic valve area (cm ²)	0.67±0.13	0.70±0.18	0.21
Peak aortic jet velocity (m/s)	4.56±0.75	4.66±0.88	0.43
Mean pressure gradient (mmHg)	52.5±17.7	55.4±21.0	0.32
Left ventricular ejection fraction (%)	48.0±13.5	47.6±15.1	0.85
CT data			
Aortic annulus area (mm ²)	416.1±67.4	412.6±72.2	0.74
Mean aortic annulus diameter (mm)	22.9±1.9	22.8±2.0	0.58
Mean diameter of sinus of Valsalva (mm)	28.7±2.6	30.3±3.1	0.0005
Mean STJ diameter (mm)	23.7±1.8	26.1±2.7	<0.0001
Mean STJ height (mm)	18.6±2.2	19.4±2.6	0.04
STJ calcification angle (degree)	166.8±80.3	50.6±59.0	<0.001

Aortic valve Agatston score

2825.3±2100.0

2734.3±1626.6

0.72

CT: computed tomography, STJ: sinotubular junction

Table 3. Echocardiography and CT data in the two-step inflation and conventional inflation groups

	Two-step inflation group N=20	Conventional inflation group N=11	p-value
Echocardiography data			
Aortic valve area (cm ²)	0.71 (0.58-0.83)	0.72 (0.60-0.75)	0.53
Peak aortic jet velocity (m/s)	4.45 (3.95-5.24)	4.45 (3.95-5.24)	0.49
Mean pressure gradient (mmHg)	53.0 (37.0-67.0)	42.0 (37.0-67.0)	0.26
Left ventricular ejection fraction (%)	50.0 (44.0-59.0)	48.0 (46.0-55.0)	0.59
CT data			
Aortic annulus area (mm ²)	413.8±58.3	431.7±103.0	0.53
Mean sinus of Valsalva diameter (mm)	27.9 (26.4-30.7)	29.6 (26.9-31.1)	0.42
Mean STJ diameter (mm)	23.5 (22.5-25.2)	24.0 (21.8-25.4)	0.96
Minimum STJ diameter (mm)	23.0 (22.3-25.0)	23.4 (21.4-24.7)	0.90
Mean STJ height (mm)	18.7±2.0	19.4±2.1	0.34
STJ calcification angle (degree)	152.5 (100.0-222.0)	130.0 (110.0-180.0)	0.61
Aortic valve Agatston score	2720.9±2478.5	2443.8±1684.7	0.75

CT: computed tomography, STJ: sinotubular junction

Table 4. Procedural characteristics in the two-step inflation and conventional inflation groups

	Two-step inflation group	Conventional inflation group	p-value
	N=20	N=11	
Procedural characteristics			
SAPIEN 3 size (mm)			0.38
20; n (%)	0 (0%)	0 (0%)	
23; n (%)	11 (55.0%)	6 (54.6%)	
26; n (%)	9 (45.0%)	4 (36.4%)	
29; n (%)	0 (0%)	1 (9.1%)	
Degree of annular area sizing (%)	11.3 (4.5-15.3)	10.4 (-0.7-21.6)	0.84
Pre-dilation; n (%)	2 (10.0%)	2 (18.2%)	0.60
Inflation volume at deployment (ml): difference from nominal inflation volume	-1.78±0.95	-0.91±1.04	0.02
Post-dilation; n (%)	20 (100)	7 (65.4)	0.004
Final inflation volume (ml): difference from nominal inflation volume	-0.08±0.77	-0.05±1.01	0.93
Clinical outcomes at discharge			
30-day mortality; n (%)	0 (0)	1 (9.1)	0.35

Ascending aortic dissection; n (%)	0 (0)	0 (0)	1.0
New pacemaker implantation; n (%)	3 (15.0)	2 (18.2)	1.0
Echocardiographic data at discharge			
THV peak velocity (m/s)	2.33±0.48	2.34±0.31	1.00
THV mean pressure gradient (mmHg)	10.9±4.4	10.8±2.9	0.95
Effective orifice area (cm ²)	1.99 (1.64-2.14)	1.96 (1.84-2.17)	0.84
Effective orifice area index (cm ² /m ²)	1.40 (1.20-1.51)	1.33 (1.18-1.41)	0.23
Left ventricular ejection fraction (%)	55.0 (47.0-59.3)	51.5 (42.8-59.3)	0.55
AR >2; n (%)	1 (5.0)	0 (0)	1.0

CT: computed tomography, STJ: sinotubular junction, THV: transcatheter heart valve, AR: aortic regurgitation





