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Transcatheter aortic valve replacement in patients with degenerative calcified rheumatic aortic stenosis: A 10-patient case series☆

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A B S T R A C T

Background: Transcatheter aortic valve replacement (TAVR) for patients with rheumatic heart disease (RHD) has not been well-known. This study aimed to assess characteristics and computed tomography (CT) findings of the aortic valve in old patients with RHD and to investigate the safety and efficacy in the patients who underwent TAVR.
Methods and results: Of 352 consecutive patients with severe aortic stenosis (AS) who underwent TAVR at the Sakakibara Heart Institute between 2013 and 2016, 10 patients (2.8%) were considered to have degenerative calcified rheumatic AS by transthoracic echocardiography. Young patients with rheumatic AS without any calcification were not indicated for TAVR in this study. They were likely to have previous pacemaker implantation, atrial fibrillation, anticoagulants, diuretics, reduced ejection fraction, mitral valve involvement, and high pulmonary artery pressure. CT was able to clearly visualize irregular valve thickening, commissure fusion, and a relatively small amount of calcification from the tip of the leaflet to the base of the aortic valve. Mortality at 30 days after TAVR was 0%, with a mean Society of Thoracic Surgeons Score of 7 ± 4%. Device success was 90%, and no patients met the safety endpoint at 30 days.
Conclusions: CT was able to visualize the calcified aortic valve in old patients with RHD, and we demonstrate the safety and efficacy of TAVR in this specific population. Care should be taken for procedural success in particular characteristics with marginal calcified aortic valve, anticoagulant use with low body mass index, or concomitant mitral valve disease.

1. Introduction

Rheumatic heart disease (RHD) is the cardiac sequela of acute rheumatic fever, an immune-mediated, multisystem inflammatory disease that follows group A *Streptococcal* infection characterized by leaflet thickening, commissural fusion, calcification, and restricted leaflet motion on heart valves [1]. Although its prevalence has been steadily decreasing in industrialized countries, an estimated 34 million people worldwide have RHD, resulting in 340,000 deaths and 10 million disability-adjusted life-years lost per year [2].

Over the past decades, transcatheter aortic valve replacement (TAVR) has emerged as a less-invasive alternative to surgical valve replacement, and there is a tremendous survival advantage and symptom benefit for patients with degenerative aortic stenosis (AS) [3]. However, despite potential high-surgical risk due to comorbidities in patients with rheumatic AS, such as atrial arrhythmia, thromboembolism, heart failure due to mitral or tricuspid valve dysfunction, and subsequent cachexic status, TAVR has not been aggressively performed because of potential improper anchorage of the transcatheter heart valve due to lack of calcium in the aortic valve [3]. Even in recent national registries, the TAVR experience in patients with RHD has not been described; therefore, safety and efficacy data are scarce [4–13].

The purpose of this study was 1) to assess characteristics and computed tomography (CT) findings of the aortic valve in old patients with RHD and 2) to investigate the safety and efficacy in the patients who underwent TAVR.

2. Methods

2.1. Study population

The treatment was initially determined according to the following: 1) presence of symptoms, 2) New York Heart Association classification ≥II, 3) a mean gradient

Abbreviation: AS, aortic stenosis; CT, computed tomography; RHD, rheumatic heart disease; STS, Society of Thoracic Surgeons; TAVR, transcatheter aortic valve replacement.
☆ Each author takes responsibility for all aspects of liability and freedom from bias of the data presented and their discussed interpretation.
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>40 mm Hg or jet velocity >4.0 m/s, or 4) aortic valve area <1 cm^2 (<0.6 cm^2/m^2). Patients with failed surgical bioprosthesis in the aortic position, young patients with pure rheumatic AS without any calcification on aortic valve, and patients on dialysis were excluded. All cases were reviewed by a multidisciplinary heart team consisting of cardiac surgeons, interventional cardiologists, and imaging specialists and deemed to be high risk or inoperable. The Society of Thoracic Surgeons (STS) risk score for predicted risk of mortality was calculated in each patient. All information was retrospectively obtained from patients' medical records or telephone interview. Therefore, there was follow-up and accountability of all patients. Informed consent was obtained from each patient. The study was performed in accordance with the ethical principles set forth in the Declaration of Helsinki and was approved by the Human Investigation Committee of Sakakibara Heart Institute.

2.2. Transthoracic echocardiography and transesophageal echocardiography

All patients underwent standard 2-dimensional B-mode and Doppler transthoracic echocardiography (TTE) before the procedure, and conventional parameters were measured according to American Society of Echocardiography guidelines [14,15]. RHD was defined by the presence of any definite evidence of mitral- or aortic-valve regurgitation seen in two planes by Doppler echocardiography, accompanied by the following morphologic abnormalities of the valve: restricted leaflet mobility (particularly doming of leaflets mainly evaluated by the long-axis view), commissural fusion, and focal or generalized valvular thickening with or without calcification mainly evaluated by short-axis view. For a definite diagnosis of RHD, these features had to be identified concordantly by each echocardiographer, all of whom were experienced in the diagnosis and treatment of RHD [14,16]. Transesophageal echocardiography was performed when the valve etiology could not be adequately assessed with TTE.

2.3. CT data analysis

Analysis was based on preoperative multislice CT images routinely acquired for procedure planning on a dual-source CT scanner (Siemens Healthcare, Germany) with a slice thickness of 1 mm and 40 mL of intravenously administered contrast agent. All analyses were overseen and confirmed by a single expert reader (N.I.). For annular and atrioventricular dimensions, curved multiplanar reconstruction analyses were performed using software specifically customized for valve analysis (3mensio valves version 7.0 software, 3-mensio Medical Imaging BV, Bilthoven, the Netherlands). Thickness, commissure fusion, and distribution of calcification on aortic valves were reviewed and confirmed by two- and three-dimensional CT.

2.4. Endpoint and other criteria

The primary endpoint was device success defined as the absence of procedural mortality, correct positioning of a single prosthetic valve, and intended performance of the prosthetic valve. Procedural complications were defined according to the Valve Academic Research Consortium-2 Criteria [17]. The complications at 30 days included all-cause mortality, all stroke, life-threatening bleeding, acute kidney injury (Acute Kidney Injury Network stage 2 or 3), coronary obstruction requiring intervention, major vascular complications, and valve-related dysfunction requiring a repeat procedure. TAVR was performed as previously described [3].

2.5. Statistical analysis

Continuous variables were expressed as mean ± standard deviation and categorical variables as the number and percentage. All analyses were performed using SPSS version 25.0 (IBM, Armonk, NY, USA).

3. Results

Of 352 consecutive patients with severe AS who underwent TAVR at the Sakakibara Heart Institute between November 2013 and July 2016, 10 patients (2.8%) were diagnosed or had been diagnosed before the mitral valve surgery with RHD by TTE.

Patient demographics and clinical characteristics at baseline are shown in Table 1. Patients were likely to have previous pacemaker implantation, atrial fibrillation, anticoagulant use, diuretic use, low ejection fraction, mitral valve involvement, and high pulmonary artery pressure, while no patients had previous myocardial infarction or bypass surgery. Five of 10 patients had at least mild mitral regurgitation due to rheumatic change of the mitral valve, and three patients had previous mitral valve replacement with mechanical valve due to RHD (Table 1). Only one patient (case 10) did not have mitral valve involvement; however, the patient had typical doming of the leaflet (†) with three commissural fusions (*) on aortic valve on TTE, and a relatively small amount of calcification (Agatston score of 2202 Agatston Unit) from the tip of the leaflet to the base of the aortic valve on CT (Fig. 1). Overall, on echocardiographic findings in the aortic valve, doming of leaflets, irregular thickening/calcification in the base, and at least one fused commissure were confirmed in all patients (Table 3). On CT findings, irregular valve thickening/calcification and commissure fusion could also be confirmed in all patients with higher resolution than those with TTE, and the average Agatston score was 2061 (1233 to 3718) with various distribution of the calcification on the aortic valve including the tip of the valve (Fig. 1). Notably, nine patients could not recall any history of acute rheumatic fever.

Table 1
Baseline patient characteristics.

Characteristic	($n = 10$)
Age, years	83 ± 6
Women, %	7 (70.0)
Body mass index (kg/m^2)	21 ± 3
NYHA classification III/IV, %	5 (50.0)
STS score, %	7 ± 4
Clinical frailty scale (1–9)	4 ± 1
Diabetes mellitus, %	2 (20.0)
Hypertension,%	8 (80.0)
Dyslipidaemia, %	2 (20.0)
Previous myocardial infarction, %	0 (0)
Previous bypass surgery, %	0 (0)
Peripheral artery disease, %	3 (30.0)
Previous stroke, %	2 (20.0)
Previous pacemaker implantation, %	3 (30.0)
Atrial fibrillation, %	7 (70.0)
COPD (moderate/severe), %	0 (0)
Haemoglobin level, g/dL	11 ± 1
eGFR, mL/min/1.73 m^2	49 ± 16
Albumin level, g/dL	3.7 ± 0.4
NT-pro BNP, pg/mL	3198 ± 2382
Antiplatelet	3 (30.0)
Anticoagulant	7 (70.0)
Beta-blocker	5 (50.0)
Diuretics	8 (80.0)
Transthoracic echocardiography	
Ejection fraction, %	50 ± 10
Aortic valve area, cm^2	0.7 ± 0.2
Mean gradient, mm Hg	52 ± 15
Mitral valve involvement	9 (90.0)
Systolic pulmonary artery pressure, mm Hg	33 ± 10

Values are mean ± SD, n (%) or median (interquartile range). COPD = chronic obstructive pulmonary disease; eGFR = estimated glomerular filtration rate; MR = mitral regurgitation; NYHA = New York Heart Association; STS = Society of Thoracic Surgeons.

Mortality at 30 days after TAVR was 0%, with a mean STS score of 7 ± 4%. Procedural outcomes are shown in Table 2. Device success was 90%; case 7 subsequently had 29 mm SAPIEN 3 valve after 29 mm Evolut R deployment failure due to difficulty anchoring for calcification, shown in Table 3. Although case 9 required cardiopulmonary bypass during TAVR due to cardiogenic shock, the patient was recovered fully and was discharged to home without any cerebral dysfunction. No patients met the safety endpoint at 30 days.

Eight patients had balloon-expandable valves, and the others had self-expandable valves. Case 1 and case 7 required >20% oversizing for anchoring due to a small amount of calcification (Table 3). In case 6, a 29-mm SAPIEN 3 valve was initially considered the best option by CT annular area measurement. However, bulky calcification on the left ventricular outflow tract and angiogram during balloon valvuloplasty suggested a smaller valve, and a 26-mm SAPIEN 3 valve was finally deployed with an additional 1 cc, resulting in acceptable paravalvular leak without annular rupture. Two other patients (case 2 and case 10) had deployment with additional 1 cc for safety, even though oversizing was acceptable according to CT measurements.

In Fig. 2, the valve appears expanded evenly relative to the sinus of Valsalva and relatively circular after deployment of the valve regardless of commissure fusion in case 3 with an Evolut R valve and case 8 with a SAPIEN 3 valve, although underexpansion was appreciated at the right coronary cusp due to heavy calcification in case 3.

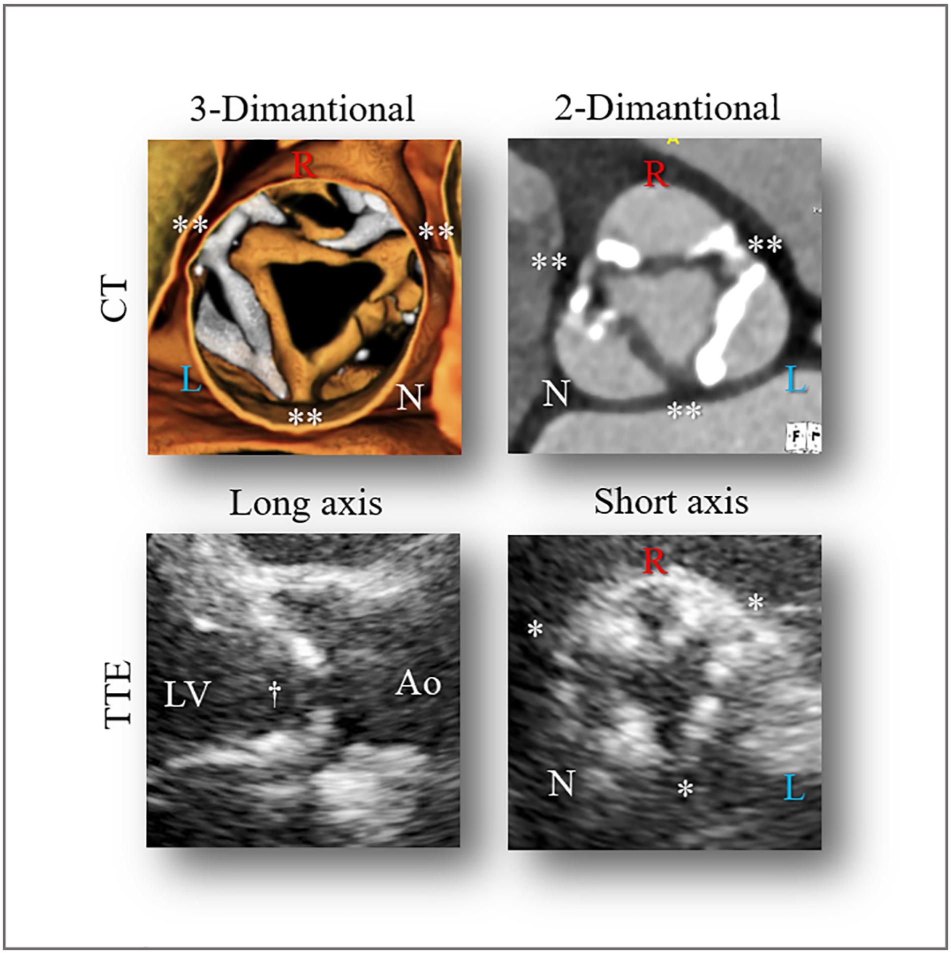

Fig. 1. Representative images of rheumatic heart disease case (case 10). Irregular valve thickening and commissural fusions can be seen by computed tomography with higher resolution than those with echocardiography (**). The three-dimensional computed tomography image is a mirror image of the two-dimensional computed tomography image. Ao: aorta; CT: computed tomography; L: left coronary cusp; LV: left ventricle; N: noncoronary cusp; R: right coronary cusp; TTE: transthoracic echocardiography.

4. Discussion

The purpose of this study was to assess characteristics and CT findings of the aortic valve in old patients with RHD and to investigate the safety and efficacy in the patients who underwent TAVR. CT was able to clearly visualize the calcified aortic valve in patients with RHD. The patient population in the present study was slightly different from those with pure degenerative AS; however, outcomes were excellent, which suggests feasibility of TAVR for degenerative calcified rheumatic AS.

Table 2
Procedural outcomes.

Outcome	(n = 10)
Transfemoral approach, %	7 (70.0)
Procedure time, min	102 ± 42
Radiation time, min	18 ± 7
Contrast media, mL	89 ± 10
Length of stay after TAVR, days	12 ± 8
Device success, %	9 (90.0)
Early safety at 30 days, %	10 (100)
Mortality, %	0 (0)
All stroke, %	0 (0)
Life-threatening bleeding, %	0 (0)
Acute kidney injury (AKIN stage 2 or 3), %	0 (0)
Coronary obstruction requiring intervention, %	0 (0)
Major vascular complication, %	0 (0)

Values are mean ± SD, n (%) or median (interquartile range). TAVR = transcatheter aortic valve replacement.

CT was able to clearly visualize the calcified aortic valve in old patients with RHD. Fig. 1 shows a great example of degenerative calcified rheumatic AS. CT nicely demonstrates fused commissures (**) and an irregular thickened valve (care should be taken that the three-dimensional CT image is a mirror image of the two-dimensional CT, shown in Fig. 1). Echocardiography has superior temporal resolution and provides superior data on rheumatic aortic valve leaflet motion such as doming, whereas CT has superior spatial resolution and can improve the understanding of the morphology such as commissural fusion, valvular thickening, or distribution of the calcification [18]. Furthermore, Agatston score and three-dimensional CT allow us to recognize the distribution and degree of the calcification of the aortic valve precisely. In the present study, the Agatston score of the aortic valve was obviously lower than that in typical TAVR patients previously reported. However, various distribution of the calcification (from tip to base) and the mean age of this population predominantly >75 years suggest that this population also has degenerative characteristics in the aortic valve [19,20]. Typical rheumatic AS has morphological changes that involve the valve leaflets, free edges, and commissures with fibrosis, cusp retraction, scarring, and severe calcification with time but spares the base of the leaflets, whereas degenerative disease always involves the base. This indicates that this population most likely had a combination of degenerative changes and rheumatic abnormality (or alternatively may represent end-stage degeneration of the rheumatic process, although it seems extremely unlikely due to biological and epidemiological reasons). The use of a combination of echocardiography and CT may be useful to unravel the main mechanism of the AS.

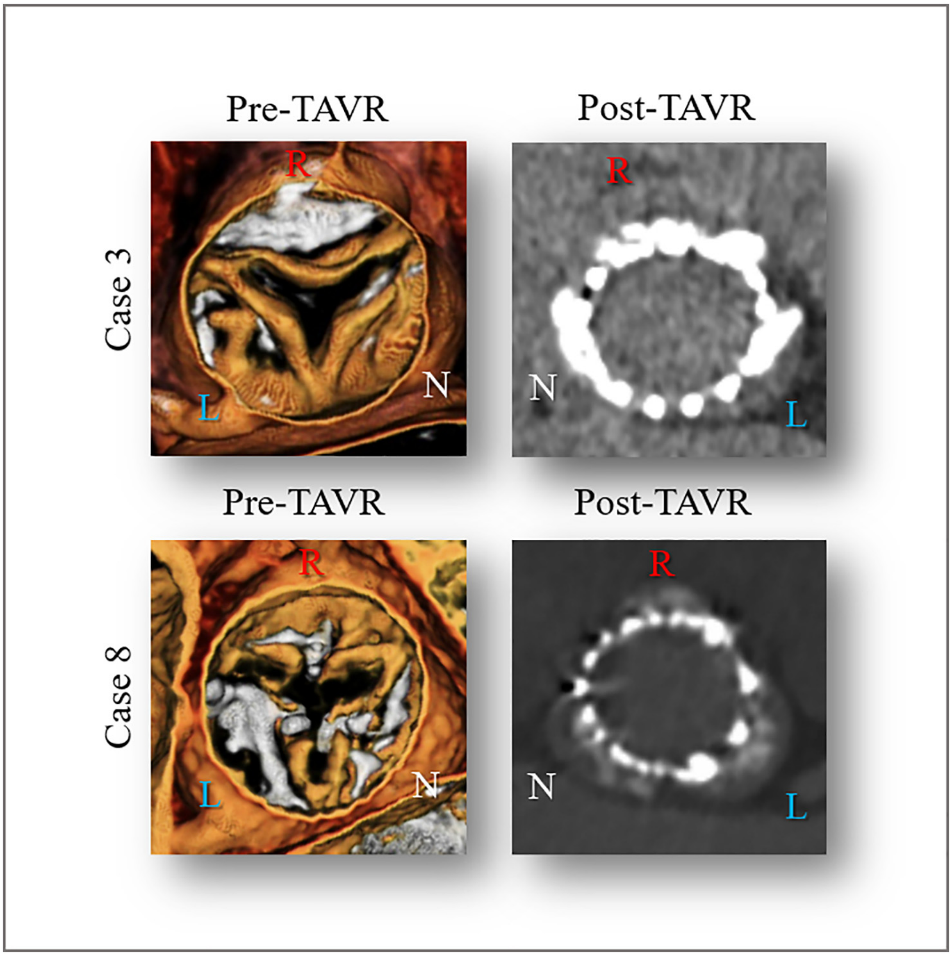

Fig. 2. Representative images of transcatheter valve in rheumatic heart disease. The SAPIEN 3 valve in case 8 appears expanded evenly regardless of commissural fusion, while the bottom of the Evolut R valve in case 3 appears expanded, oval, and underexpanded due to calcification, not fusion or thickened valve.

Nonetheless, this is the first study showing characteristics of aortic valve in old patients with RHD by CT in TAVR patients. Considering the higher resolution in CT than that in echocardiographic imaging, CT potentially has the capability to diagnose RHD in the aortic valve as well as mitral valve [18]. Nonetheless, precise preprocedural CT assessment makes TAVR a safer procedure, particularly in this heterogeneous population [21].

The patient population in the present study was slightly different from the population with pure degenerative AS in previous studies [3–8]. Lower body mass index and more frequent anticoagulant use are considered risk factors for bleeding. Greater pulmonary artery pressure and reduced ejection fraction are considered risk factors for heart failure following the procedure. The mechanical valve in the mitral position possibly impinges the left ventricular outflow tract during valve deployment, which is still unpredictable and challenging [22,23]. Furthermore, RHD is an uncommon cause of isolated aortic valve disease, occurring more frequently as mixed aortic and mitral valve disease. Severe mitral regurgitation might reduce the forward flow (and gradient) across the aortic valve and lead to underestimation of the severity of AS [2]. Finally, marginal calcification on the aortic valve potentially embolizes or dislocates TAVR valves [24]. Although the patients might not have severe atherosclerosis (no patients with a history of previous myocardial infarction and bypass surgery were included in the present study), rheumatic fever usually during childhood with or without their notice can affect the mitral and/or aortic valve for a long time, likely resulting in comorbidities such as atrial fibrillation or cachexia/frailty, making outcomes following TAVR worse and complicated in addition to comorbidities previously mentioned [2,25]. On the other hand, the vast majority of the world population afflicted with rheumatic AS is typically younger and has multivalvular lesions, mixed lesions, and aortic valve morphology dissimilar to the current study population [10–13].

These differences require paying attention to this specific population during the TAVR procedure; however, device success and 30-day outcomes were excellent, demonstrating safety and efficacy of TAVR in patients with degenerative calcified rheumatic AS [26]. Considering the mechanism of the transcatheter heart valve, TAVR is considered a reasonable option in patients with rheumatic AS if the valve is calcified for proper anchorage, while great care should be taken if the valve is not calcified enough, although the patients are considered at high surgical risk and transcatheter therapy may be only the option to treat them. Slightly more oversized deployment using a balloon-expandable valve than usual deployment to the pure degenerative valve might prevent device dislocation/embolization depending on the oversize of the valve. However, it remains unclear which type of TAVR device (balloon-expandable or self-expandable) has a more stable anchorage in a less calcified aortic valve [10–13]. In two cases of postprocedural CT, the valve appears expanded evenly and relatively circular after valve deployment in addition to the postprocedural pressure gradient shown in Table 3, suggesting TAVR valves function well even in the aortic valve with rheumatic changes. Unlike raphe on the bicuspid valve, fusion due to rheumatic change seems like softer tissue if it is not calcified [27].

In a previous surgical series in Japan reported just 15 years ago, approximately 30% of AS cases in elderly patients has rheumatic change as well as degenerative change [28]. Even if we take into account the decrease in prevalence of RHD in Japan, it is relatively reasonable to think that approximately 3% of this study's population still had degenerative calcified rheumatic AS recently [2]. If the next generation TAVR valve does not require much calcification for valve anchoring, degenerative calcified rheumatic AS described in the present study will be smoothly indicated for TAVR using both CT and TTE assessment. Nonetheless, RHD remains a leading noncommunicable disease of the young, suggesting that focusing on this population will be still important in the future [2,29].

5. Limitations

This study has several important limitations. First, this study was limited by its retrospective nature and was performed at a single center. Second, this study included a small number of patients. Therefore, broad generalization of the findings cannot be supported. We have presented the study in terms of preliminary results that suggest that their findings may apply to a broader TAVR population. Third, the present study did not evaluate patients who were excluded for TAVR because of no or few calcifications on the aortic valve.

6. Conclusions

Our study offers some important conclusions. Herein, CT was able to clearly visualize the calcified aortic valve old in patients with RHD, which can be called “degenerative calcified rheumatic AS”, and we demonstrate that TAVR in this population was safe and efficient. However, care should be taken for procedural success with particular characteristics, such as marginal calcified aortic valve, anticoagulant use with low body mass index, or concomitant mitral valve disease.

Supplementary data to this article can be found online at https://doi.org/10.1016/j.ijcard.2018.11.090.

Conflict of interest

Tetsuya Tobaru, MD, PhD, is a proctor for Edwards Lifesciences and Medtronic. The remaining authors state that they have no conflicts of interest to declare.

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