### Comparison of Aortic Annulus Dimension After Aortic Valve Neocuspidization With Valve Replacement and Normal Valve

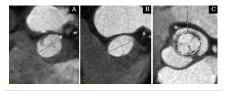
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Aortic valve replacement (AVR) remains the standard surgical intervention for aortic valve disease and is preferred by many surgeons, despite its associated clinical issues. The clinical efficacy of aortic valve neocuspidization (AVNeo) with glutaraldehyde-treated autologous pericardium, the Ozaki procedure, has recently been reported. Although it is presumed to preserve the normal aortic annulus motion, changes to the aortic annulus during the cardiac cycle after AVNeo remain unclear.

From March to December 2014, aortic annular dimensions were measured for 23 patients; the sample included 8 patients who had undergone AVNeo, 10 patients with normal aortic valves, and 5 patients who had undergone AVR. Measurements were recorded using electrocardiographygated multidetector computed tomography. Data were analyzed using automated aortic root analysis software. Postoperative peak pressure gradients for the AVNeo and AVR groups were compared.

No statistically significant differences in annulus variation were observed between patients who had undergone AVNeo and those with normal aortic valves. Annular area was larger during systole than during diastole in both groups. Postoperative peak pressure gradients were significantly lower in the AVNeo group than in the AVR group.

The results of the present study demonstrated that aortic annular dimensions after AVNeo are similar to the dimensions of normal aortic valves. This was evidenced using electrocardiography-gated multidetector computed tomography, previously reported as the most reliable method, to evaluate annulus



Measurement of annular dimensions: (A) AVNeo, (B) normal aortic valve, and (C) AVR.

#### **Central Message**

Natural aortic annulus expansion is preserved following AVNeo and it will increase the likelihood of good hemodynamics.

#### Perspective statement

Aortic valve neocuspidization (AVNeo) has substantial utility for the treatment of aortic valve disease as it provides lower postoperative peak pressure gradients than AVR and does not require anticoagulation management. Multidetector computed tomography was used to demonstrate normal aortic annulus motion after AVNeo. This result will likely provide greater insight into flow dynamics after AVNeo.

motion during the cardiac cycle. Lower postoperative peak pressure gradients might underlie the observed changes. These advantages will help in rectifying AVR defects.

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### INTRODUCTION

Valvular heart disease treatment accounts for 10%-20% of all cardiac surgical procedures performed in the United States, with

aortic valve replacement (AVR) accounting for approximately twothirds of all heart valve operations.<sup>1</sup> AVR remains the standard surgical intervention for aortic valve disease. However, anticoagulation (due to the use of mechanical valves) and the durability of prosthetic valves remain substantial clinical issues. To overcome these issues, aortic valve repair may be considered; however, its use is currently limited to patients with aortic valve regurgitation (AR). Accordingly, there is a substantial clinical need for a method that does not require anticoagulation management and is suit-

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able for a wide spectrum of aortic valve diseases, including aortic valve stenosis (AS).

Good short- and mid-term results without anticoagulation were reported for aortic valve reconstruction (aortic valve neocuspidization [AVNeo]) with glutaraldehyde-treated autologous pericardium.<sup>2</sup> The reported method entailed the replacement of 3 cusps with glutaraldehyde-treated autologous pericardium based on the distance between the commissures of each cusp.<sup>3</sup> It is suitable for patients with AS and has the advantages of increasing the maximum valve orifice area and preserving the natural motion of the aortic annulus, as pericardial grafts are sewn directly to the aortic annulus. This method thus confers lower postoperative peak pressure gradients than those conferred by AVR.<sup>2</sup> However, the actual change to the annulus during the cardiac cycle after AVNeo is yet to be reported. We consider evaluating this change to be of clinical importance.

Transcatheter AVR (TAVR) has recently become the standard procedure for patients considered ineligible for conventional surgical valve replacement. However, paravalvular AR is associated with increased mortality, predominantly as a result of valve undersizing.<sup>4-6</sup> Accordingly, accurate annulus measurements are crucial for ensuring appropriate valve size. Multidetector computed tomography (MDCT) is more reliable than transesophageal echocardiography (TEE). Further, reproducible annulus measurements play an increasingly important role in pre-TAVR evaluations.<sup>7-9</sup>

The aim of the present study was to use MDCT to evaluate changes to the aortic annulus during the cardiac cycle after AVNeo.

#### PATIENTS AND METHODS

#### Study Population and Design

All patients underwent AVNeo between December 2012 and April 2014. The AVNeo group comprised 4 women and 4 men aged between 63 and 77 years who did not have renal dysfunction (estimated glomerular filtration rate [eGFR], <45 mL/min per 1.73 m<sup>2</sup>). Several previous studies have identified a baseline eGFR <45 mL/ min per 1.73 m<sup>2</sup> to be associated with an increased risk of contrast-induced nephropathy.<sup>10,11</sup> We therefore excluded patients with an eGFR below baseline. No significant AR was observed with postoperative ultrasound cardiography (UCG) in the AVNeo group. Patients underwent AVR using porcine aortic-stented valves between April 2014 and December 2014. The AVR group comprised 3 women and 2 men aged between 69 and 83 years who did not have renal dysfunction. All AVR procedures were performed by the same surgeon using horizontal mattress suturing.

Patients underwent MDCT for coronary artery evaluation preoperatively and postoperatively, and UCG showed neither AS nor AR. All the patients who underwent MDCT postoperatively also underwent coronary artery bypass grafting. The normal aortic valve group comprised 2 women and 8 men, aged 54-84 years. Computed tomography imaging was performed 3-12 months postoperatively for the AVNeo group, 3-5 weeks postoperatively for the AVR group, and either preoperatively or approximately 2 weeks postoperatively for the normal aortic valve group.

The statistical power was set as power =  $1-\beta$  = 80%, and sensitivity as  $\alpha$  = 5% to enable detection of difference of average annular diameter based on area (Darea) in the groups between AVNeo and normal, and between AVNeo and AVR. Power analysis consequently set the required number of patients at 8 patients per group in the comparison of Darea between AVNeo and Normal, and at 5 patients in the comparison of Darea between AVNeo and AVR.

All patients provided written informed consent, and the present study was approved by the institutional review board for human research at Kanazawa University.

#### **MDCT** Image Acquisition

MDCT was performed using a 64-slice scanner (Definition Flash, Siemens Healthcare, Erlangen, Germany). All evaluations were performed with  $128 \times 0.625$  mm<sup>2</sup> collimation, a gantry rotation time of 280 ms, and a scan pitch of 0.17. The tube current was 1100 mA with 120kV tube voltage. Contrast enhancement was achieved using  $1.25 \times$  (body weight  $\times 0.5$ ) + 20 mL of iopamidol (Iopamiron: 370-80; Bayer Schering Pharma, Osaka, Japan). Additional beta-blockers were not administered to any patient. Images were reconstructed (slice thickness = 0.75 mm; increment = 0.7 mm; B36f kernel) at every 10% of the cardiac cycle.

#### **MDCT** Image Analysis

Commercially available automated aortic root analysis software was used (syngo, CT Cardiac Function-Valve Pilot, Siemens Healthcare, Erlangen, Germany) with a retrospective electrocardiography (ECG)-gating technique (Fig. 1). The software detects the annulus plane by connecting the 3 lowest insertion points of the valve leaflets and performing automated luminal planimetry at this level (Fig. 1A-D). Although the utility of semiautomated analysis software has been reported,<sup>12,13</sup> automated analysis software remains to be fully validated. For semiautomated analysis, datasets were automatically evaluated to identify anatomic landmarks and automatically delineate and manually adjust aortic annulus contours. We used semiautomated analysis for the AVNeo and normal aortic valve groups. One patient in the AVNeo group required major correction (equivalent to manual reconstruction) because of an incorrect plane level.

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