



## Research paper

# Dynamism of the aortic annulus: Effect of diastolic versus systolic CT annular measurements on device selection in transcatheter aortic valve replacement (TAVR)



Darra T. Murphy<sup>a,\*</sup>, Philipp Blanke<sup>a</sup>, Shalan Alaamri<sup>a</sup>, Christopher Naoum<sup>a</sup>, Ronen Rubinshtein<sup>c</sup>, Gregor Pache<sup>d</sup>, Bruce Precious<sup>a</sup>, Adam Berger<sup>a</sup>, Rekha Raju<sup>a</sup>, Danny Dvir<sup>b</sup>, David A. Wood<sup>b</sup>, John Webb<sup>b</sup>, Jonathon A. Leipsic<sup>a</sup>

<sup>a</sup> Department of Radiology, St Paul's Hospital and University of British Columbia, Vancouver, BC, Canada

<sup>b</sup> Department of Cardiology, St Paul's Hospital and University of British Columbia, Vancouver, BC, Canada

<sup>c</sup> Cardiology Department, Lady Davis Carmel Medical Centre, Haifa, Israel

<sup>d</sup> Division of Cardiovascular Radiology, University Hospital Freiburg, Freiburg, Germany

## ARTICLE INFO

## Article history:

Received 19 February 2015

Received in revised form

28 April 2015

Accepted 9 July 2015

Available online 26 July 2015

## Keywords:

Transcatheter aortic valve replacement  
TAVR

Transcatheter aortic valve implantation

TAVI

Aortic annulus

MDCT

Multidetector CT

Computed tomography

## ABSTRACT

**Background:** Annular dimensions, including cross-sectional area, perimeter and subsequently derived diameters, are subject to dynamic changes throughout the cardiac cycle. There is ongoing controversy as to whether perimeter measurement changes between systole and diastole are too small to impact on valve sizing.

**Objectives:** To assess both the variability of aortic annular dimensions throughout the cardiac cycle across a range of sub-annular calcification using computed tomography (CT) and the impact of this variability on device size selection for balloon-expandable valves in a large, all-comer multi-center cohort.

**Methods:** ECG-gated CT data of 507 patients (mean  $81 \pm 7.5$  years, 60.1% male) were analyzed in this retrospective, multicenter analysis. Aortic annulus dimensions were assessed on pre-specified systolic and diastolic phases by planimetry, yielding both area and perimeter. Contour smoothing was employed to avoid artificial increase in perimeter values by uneven contours. The extent of subannular calcification was graded semi-quantitatively and assessed in relation to the degree of annular dynamism. Hypothetical device sizing was undertaken to assess the impact of using systolic and diastolic measurements on valve selection.

**Results:** Mean annular dimensions were larger during systole than diastole (area:  $474.4 \pm 87.4 \text{ mm}^2$  vs.  $438.3 \pm 84.3 \text{ mm}^2$  or 8.23%,  $p < 0.001$ ; perimeter:  $78.5 \pm 7.2 \text{ mm}$  vs.  $75.9 \pm 7.2 \text{ mm}$  or 3.36%,  $p < 0.001$ ). The magnitude of annular area and perimeter change (systolic minus diastolic measurement) was greater among patients without calcification compared to patients with grade 3 calcification. Using diastolic rather than systolic data for device sizing resulted in a change of the recommended valve size in nearly half of patients for both annular area and perimeter.

**Conclusions:** The systematic differences between systolic and diastolic annular measurements for cross-sectional area and perimeter have implications for device sizing with potential for valve under-sizing if diastolic annular dimensions are employed.

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\* Corresponding author. Department of Radiology, St. Paul's Hospital, 1081 Burrard St, Vancouver, BC, V6Z 1Y6, Canada.

E-mail addresses: [dmurphy@providencehealth.bc.ca](mailto:dmurphy@providencehealth.bc.ca) (D.T. Murphy), [phil.blanke@googlemail.com](mailto:phil.blanke@googlemail.com) (P. Blanke), [drshalan@gmail.com](mailto:drshalan@gmail.com) (S. Alaamri), [chris.naoum@gmail.com](mailto:chris.naoum@gmail.com) (C. Naoum), [ronenrub@clalit.org.il](mailto:ronenrub@clalit.org.il) (R. Rubinshtein), [gregor.pache@universitaets-herzzentrum.de](mailto:gregor.pache@universitaets-herzzentrum.de) (G. Pache), [bprecious@dal.ca](mailto:bprecious@dal.ca) (B. Precious), [adam.berger@unsw.edu.au](mailto:adam.berger@unsw.edu.au) (A. Berger), [rekharaju@hotmail.com](mailto:rekharaju@hotmail.com) (R. Raju), [danny.dvir@gmail.com](mailto:danny.dvir@gmail.com) (D. Dvir), [david.wood@vch.ca](mailto:david.wood@vch.ca) (D.A. Wood), [webb@providencehealth.bc.ca](mailto:webb@providencehealth.bc.ca) (J. Webb), [jleipsic@providencehealth.bc.ca](mailto:jleipsic@providencehealth.bc.ca) (J.A. Leipsic).

## 1. Introduction

Evaluation of aortic annular dimensions with multidetector computed tomography (MDCT) prior to transcatheter aortic valve replacement (TAVR) has been shown to improve clinical outcome compared to assessment by 2D-echocardiography and can be considered standard of care.<sup>1–9</sup> Several studies have shown that

accurate sizing has important implications to avoid paravalvular leak (PVL) and annular rupture.<sup>7,10–12</sup> Commonly, the aortic annular plane is defined by the most basal attachment points of all 3 cusps,<sup>13</sup> which can be identified and segmented on cardiac CT data sets, usually followed by planimetric assessment of the annular contour yielding area or perimeter. However, the aortic root is subject to dynamic changes in annular dimensions and morphology throughout the cardiac cycle due to annular compliance and deformation.<sup>14–17</sup> This typically results in a larger annular morphology found during systole. While it is generally agreed that the cross-sectional area (CSA) of the annulus changes dynamically, there is conflicting data on the amount of cyclical change in the annular perimeter and the effect small changes in perimeter might have on device selection.<sup>16–18</sup>

Given the continued debate regarding the cyclical changes in annular perimeter we sought to further investigate CT-derived annular dimensions. Our aims included determination of cyclical changes in measured annular dimension across a large multicenter international cohort, assessment of the relative changes in annular area and perimeter across varying degrees of sub-annular calcification and evaluation of the impact of diastolic assessment on device selection.

## 2. Material and methods

### 2.1. Patient selection

This retrospective study had institutional review board approval and was compliant with the Helsinki Declaration. Pooled consecutive MDCT examinations from a total of 507 patients with severe aortic stenosis being evaluated for potential TAVR were included. Consecutive clinical CT data sets were obtained from three centers: St Paul's Hospital, Vancouver, Canada (2010–2013;  $n = 116$ ); University Hospital Freiburg, Germany (2013;  $n = 79$ ); Lady Davis Carmel Medical Centre, Haifa, Israel (2011–2013;  $n = 87$ ) as well as Corelab cases from subjects enrolled in the prospective safety and performance study of the Edwards Sapien 3 THV (2013–2014;  $n = 225$ ). CT imaging studies that did not contain both diastolic and systolic data were excluded from analysis. All studies were performed between 2010 and 2014 on various MDCT platforms with a minimum of 64-slice capacity.

### 2.2. Annular analysis

All measurements were performed at St Paul's Hospital, Vancouver using Aquarius InTuition (Version 4.4.11.82, TeraRecon, Foster City, CA). Annular segmentation was performed in accordance with the Society for Cardiovascular CT (SCCT) consensus document<sup>19</sup> and as described previously.<sup>3,20</sup> Single systolic and diastolic phases were selected for annular assessment (Fig. 1). Phase selection was made with the goal of generating optimal image quality to facilitate confident annular assessment and was typically in the range 25–35% for systolic data and 65–80% for diastolic data. Annular dimensions were assessed by means of planimetry yielding long axis (maximum) and short axis (minimum) diameters, cross sectional area and perimeter. A smoothing algorithm was used whereby the software application fits the contour with splines of a selected arc length. We chose an arc length of 5 mm to avoid an artificial increase in perimeter by contour irregularities as described previously.<sup>21</sup>

The presence, distribution and extent of annular and sub-annular calcification was semi-quantitatively graded on a four point scale<sup>11,22</sup>: grade 0: no calcification; grade 1 (mild): one nodule of calcium extending <5 mm in any dimension and covering <10% of the perimeter of the LVOT; grade 2 (moderate): 2 nodules

of calcification or 1 extending >5 mm in any direction or covering >10% of the perimeter of the LVOT; and grade 3 (severe): multiple nodules of calcification or single focus extending >1 cm in length or covering >20% of the perimeter of the LVOT.

### 2.3. Valve selection

Hypothetical valve sizing was performed for the Sapien XT balloon-expandable valve using a table previously published<sup>4</sup> and calculated in all patients for both systolic and diastolic measurements with a goal of not under-sizing. The sizing regimen consists of non-overlapping ranges proposing a definite valve size, with interposed ranges allowing for selection of neighbour valve size referred to as 'grey-zones'. These ranges for both area and perimeter are presented in Table 1. Diastolic and systolic measurements were cross-tabulated with recommended valve sizes and grey zones for both cross-sectional area and perimeter.

### 2.4. Statistical analysis

Statistical analysis was performed using Prism v6.0 (GraphPad Software Inc., La Jolla, CA). Continuous variables are reported as mean  $\pm$  standard deviation and categorical variables as frequencies (percentages). Paired analyses between systolic and diastolic measurements were performed using paired student t-tests and Wilcoxon matched-pairs signed rank tests as appropriate. Bland-Altman plots were generated to assess for measurement bias between systolic and diastolic measurements. Mann-Whitney  $U$  tests were performed to assess for statistical differences in area and perimeter change (systolic measurement minus diastolic measurement) between groups of increasing sub-annular calcium grade (described above) as appropriate. A  $P$  value <0.05 was considered statistically significant.

## 3. Results

### 3.1. Annular measurements

MDCT examinations were analyzed in 507 patients (mean  $\pm$  SD age,  $81 \pm 7.5$  years, range: 49–97 years; 60.1% male). Systolic and diastolic annular measurements are presented in Table 2, including a sub-analysis across the range of annular calcification grades (grade 0:  $n = 280$ ; grade 1:  $n = 121$ ; grade 2:  $n = 75$ ; grade 3:  $n = 31$ ). The mean annular cross sectional area for all patients ( $n = 507$ ) was  $438.3 \text{ mm}^2 \pm 84.3 \text{ mm}^2$  in diastole and  $474.4 \text{ mm}^2 \pm 87.4 \text{ mm}^2$  in systole representing an increase in annular area of  $36.1 \pm 19.6 \text{ mm}^2$  ( $P < 0.001$ ), or 8.23%. The mean annular perimeter was  $75.9 \text{ mm} \pm 7.2 \text{ mm}$  in diastole and  $78.5 \text{ mm} \pm 7.2 \text{ mm}$  in systole representing an increase in annular perimeter of  $2.55 \pm 1.60 \text{ mm}$  ( $p < 0.001$ ) or 3.36%. Bland-Altman plots confirmed a bias towards larger measurement for both area and perimeter when systolic measurements were acquired (Fig. 2). Differences between systolic and diastolic annular measurements were maintained among patients with higher sub-annular calcium severity grades (0–3) (Fig. 3), although the magnitude of change appeared to decrease with increasing sub-annular calcium (Fig. 4). Mean area and perimeter change were greater among patients with grade 0 calcium compared to patients with grade 3 calcium (area:  $37.5 \pm 19.8 \text{ mm}^2$  vs.  $29.8 \pm 16.9$ ,  $p = 0.02$ ; perimeter:  $2.65 \pm 1.61 \text{ mm}$  vs.  $1.99 \pm 1.23 \text{ mm}$ ,  $p = 0.03$ ).

### 3.2. Effect on valve selection

Cross tabulation of cross-sectional area measurements for the

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