Repeatability of aortic annulus measurements on pre-procedure CT scans for transcatheter aortic valve implantation (TAVI)

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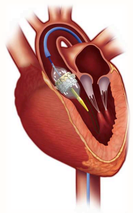
Purpose

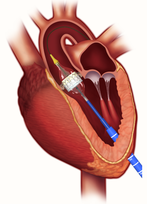
- Determine measurement precision of several proposed CTA measurements of the aortic annulus for TAVI screening:
  - Calculated elliptical valve area based on short and long axis diameters
  - Area based on free-form contour of annulus
  - Area of best-fit ellipse

Introduction

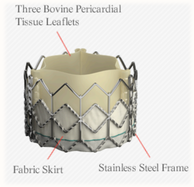
- Transcatheter aortic valve implantation (TAVI) is offered to patients suffering from critical aortic stenosis (AS) who are at high risk for surgical valve replacement.[1]
- Less invasive alternative to surgery that involves accessing the aortic valve either retrograde transarterially or anterograde transapically. The prosthetic valve is inserted into the native stenotic valve using a balloon catheter. It will function like a normal valve and correct blood flow will be restored in the patient.



transfemoral



transapical



http://newheartvalve.com/hcp/tavr-overview#sthash.Yjwsi9YE.oOiLDnYk.dpbs
(downloaded 2013-11-20)

	Valve Size	
Sizing Criteria	23 mm	26 mm
Annular Diameter (TEE)*	18-22 mm	21-25 mm
Annular Diameter (CT)	19-23 mm	22-26 mm
Annular Area (CT)	283-415 mm²	380-531 mm²

* FDA-approved package insert criteria

- Initial FDA approval was based on transesophageal echo (TEE) measurements of the aortic annulus diameter
- Recent literature supports CT as the gold standard[2,3] and suggests that CT diameter measurements are slightly greater than TEE measurements
- Pre-surgical CT scan is necessary to measure the size of the aortic valve annulus for the purpose of choosing the correct device size.[4,5] The correct size valve will reduce the risk of complications:
  - Implant too small: paravalvular leakage or device migration
  - Implant too large: valve dysfunction or catastrophic aortic annulus rupture
- Several methods of measuring the aortic annulus have been proposed, but the repeatability of these has yet to be determined:
  1. Long and short axis diameter
  2. Area based on free-form contour
  3. Best-fit ellipse area

Methods

- Retrospective study of 45 randomly selected patients with severe aortic stenosis who underwent TAVI screening CTA at UW between Nov. 1, 2011 and July 31, 2013.

CTA Acquisition & Reconstruction

- 64-slice scanner (VCT, GE Healthcare, Waukesha, WI)
- Retrospective ECG gating *without* tube current modulation
- Fluoro-trigger on ascending aorta
- 150 mL iopamidol 370 injected at 5 mL/sec (volume required for both the cardiac CTA and the immediately following CTA of the abdomen/pelvis for assessment of iliofemoral arteries)
- 100 mL saline bolus immediately following contrast injection to flush contrast from veins
- 1.25 mm slice thickness, reconstructed at 0.625mm intervals
- ~10sec acquisition time during suspended respiration
- Reconstructed at 10 phases of the cardiac cycle with a 32cm field of view

CTA Analysis

- Measurements were performed using Vitrea 3D software (Vital Images, Minnetonka, MN) by a medical student (SS) after initial training on 15 additional randomly selected studies that were not included in the subsequent analysis
- Studies were de-identified and measured in a randomized order
- Repeat measurements were made at least 2 weeks following initial measurements in a separately randomized order to ensure blinding to the initial measurements
- Measurements were made on systolic phase images
- The annular plane on a double-oblique multiplanar reformat was identified as follows:
  1. Coarse adjustments: Coronal and sagittal oblique reformats were rotated so that the crosshair representing the annular plane was just below the insertion of the aortic valve leaflet hinge points
  2. Fine adjustments: The double-oblique angle of the annular plane was adjusted so that all of the valve leaflets entered the image simultaneously while scrolling from caudal to cranial
  3. The first image caudal to the valve leaflets was used for the measurements
- 4 measurements were made (Figure 1)
  1. **Long axis diameter** } Used to calculate the area of an ellipse having these diameters
  2. **Short axis diameter**
  3. **Area based on free-form contour of annulus**
  4. **Area of best-fit ellipse**

Statistical Analysis

- Bland-Altman analysis was used to determine the repeatability of the measurements
- Student's paired t-test was used to assess for any systemic differences between the repeated measurements.

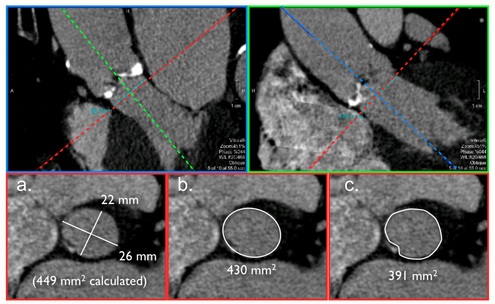


Figure 1. Aortic Annulus Measurements
a) Long and short axis diameter
b) Best-fit elliptical area
c) Free-form area (any calcium was excluded from measurements)

References

1. Stone M, et al, Annals of Thoracic Surgery 6(94):1791-95 (2012)
2. Tops LF, et al, JACC: Cardiovascular Imaging 1(3):321-330 (2008)
3. Ng ACT, et al, Circulation: Cardiovascular Imaging 3:94-102 (2010)
4. Gurvitch R, et al, Am Coll Cardiol Intv 3(11):1157-65 (2010)
5. Kasel AM, et al, JACC: Cardiovascular Imaging 6(2):249-262 (2013)

Results

- There were no statistically significant differences between 1st and 2nd measurements (95% confidence intervals of the bias on Bland-Altman analysis include 0)
- Measurement variability was wide for all 3 measurement methods, as evidenced by the wide 95% limits of agreement on the Bland-Altman plots (Figure 2).

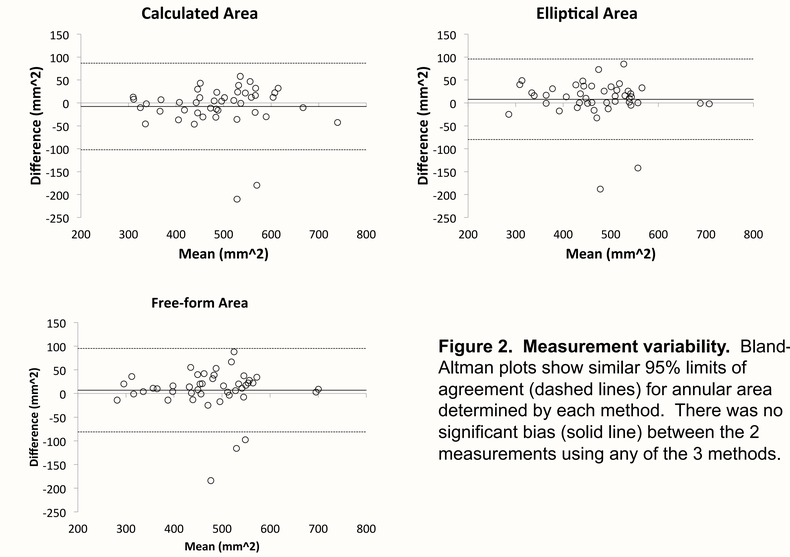


Figure 2. Measurement variability. Bland-Altman plots show similar 95% limits of agreement (dashed lines) for annular area determined by each method. There was no significant bias (solid line) between the 2 measurements using any of the 3 methods.

- The area calculated from the diameter measurements was greater than the area measured from either a best-fit ellipse or a free-form contour ($p<0.001$ for both). There was no difference in best-fit ellipse and free-form contour areas ($p=0.09$).

		Repeated measurements	
	Mean ± SD	Bias *mean [95% CI]*	95% Limits of Agreement
Calculated Area *	490 ± 95 mm²	-8 [-22, 7] mm²	± 95 mm²
Best-Fit Ellipse Area	471 ± 88 mm²	8 [-6, 21] mm²	± 88 mm²
Free-form Area	475 ± 91 mm²	7 [-7, 13] mm²	± 88 mm²

* Significantly larger than other methods of calculating area

Conclusions

- Aortic annular area calculated from long and short axis dimensions resulted in 3-4% larger values than directly measured areas using either free-form contour or best-fit ellipse.
- The measurement variability for all 3 methods was similar and was relatively large – over 50% of the range of allowable sizes for both 23mm and 26mm valves.
- It is possible that this measurement variability differs between readers with different amounts of experience. Future work will evaluate inter-reader variability by comparing measurements made by readers with differing levels of experience.
- We recommend that the measurement precision of the specific readers making these clinical measurements be included when reporting the aortic annulus area.

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