MDCT FOR TAVR: WHERE WE ARE

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Disclosures

Speaker’s bureau: GE Healthcare and Edwards LifeSciences

Grant Support- CIHR, GE Healthcare

Advisory Board- GE Healthcare, Edwards LifeSciences, Vital Images

Equity Stakeholder- TC3
Transcatheter Aortic-Valve Replacement for Inoperable Severe Aortic Stenosis

Hazard ratio, 0.41 (95% CI, 0.30–0.58)
P<0.001

No. at Risk
TAVR 179 115 100 89 64
Standard therapy 179 86 49 30 17

Makkar et al. ACC 2012, NEJM
We have good results using echo!
Who Needs MDCT?
PARTNER Cohort B: Paravalvular Regurgitation

No changes over time

N = 179

30-Day
- Severe: 12%
- None/trace: 52%
- Mild: 35%
- Moderate: 1%

6 months
- Severe: 7%
- None/trace: 40%
- Mild: 53%
- Moderate: 10%

1 Year
- Severe: 2%
- None/trace: 45%
- Mild: 43%
- Moderate: 10%

Two-Year Outcomes after Transcatheter or Surgical Aortic-Valve Replacement

Susheel K. Kodali, M.D., Mathew R. Williams, M.D., Craig R. Smith, M.D.,
Lars G. Svensson, M.D., Ph.D., John G. Webb, M.D., Raj R. Makkar, M.D.,
Gregory P. Fontana, M.D., Todd M. Dewey, M.D., Vinod H. Thourani, M.D.,
Augusto D. Pichard, M.D., Michael Fischbein, M.D., Ph.D., Wilson Y. Szeto, M.D.,
Scott Lim, M.D., Kevin L. Greason, M.D., Paul S. Teirstein, M.D.,

D  Severity of Total Aortic Regurgitation: None or Trace, Mild,
or Moderate to Severe

P<0.001 by log-rank test

<table>
<thead>
<tr>
<th>Severity</th>
<th>No. at Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>None or trace</td>
<td>125</td>
</tr>
<tr>
<td>Mild</td>
<td>162</td>
</tr>
<tr>
<td>Moderate to severe</td>
<td>34</td>
</tr>
</tbody>
</table>

Months after Implantation
What we know about PV Leak

- Two main causes of PAR include under sizing of the transcatheter heart valve (THV) relative to the aortic annular size and incorrect device positioning (either too high or too low relative to the annular plane).

- Treatment of severe PAR due to THV under sizing is challenging and typically unsuccessful.

Aortic Annulus

Annulus Sizing

The aortic annulus is a complex 3 dimensional structure

Previous anatomical studies established that the aortic annulus is a 3-pronged coronet rather than a circular structure

It has three anchor points at the nadir of each aortic cusp

The annulus is commonly oval-shaped. Reported in approximately 50% of patients evaluated for TAVR. The mean difference between coronal and sagittal measurements was 3.0 ± 1.9 mm. Any single diameter cannot adequately characterize the annulus "size" due to its elliptical non-circular configuration.

MDCT Provides Reproducible Measurements of the Annulus that provide a granular assessment of root geometry
Advantages to MDCT methods

- Greater reproducibility
- Less sensitive to minor changes in obliquity
Creating the Basal Ring

diameter = (min. + max.)/2

diameter = perimeter/π

diameter = 2 x √(area/π)
Example of Incorrect Plane – Too Low

Oblique Coronal

Double Oblique Axial

Oblique Sagittal

3D
Example of Incorrect Plane – Wrong Orientation

- Oblique
- Coronal
- Axial
- Oblique
- Sagittal
- Double
- Oblique
- Axial
- 3D
### Aortic Annulus Diameter Determination by Multidetector Computed Tomography

Reproducibility, Applicability, and Implications for Transcatheter Aortic Valve Implantation

Inter-reader reliability as measured by ICC*, estimates and 95% CI for 3 readers (n=50).

<table>
<thead>
<tr>
<th></th>
<th>Coronal</th>
<th>Sagittal oblique</th>
<th>Short axis basal ring</th>
<th>Long axis basal ring</th>
<th>3-chamber</th>
<th>Basal Ring Average Diameter</th>
<th>Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.78 (0.67, 0.85)</td>
<td>0.54 (0.39, 0.69)</td>
<td>0.71 (0.59, 0.81)</td>
<td>0.72 (0.61, 0.82)</td>
<td>0.70 (0.58, 0.81)</td>
<td>0.82 (0.72-0.88)</td>
<td>0.87 (0.81-0.92)</td>
<td></td>
</tr>
</tbody>
</table>

Gurvitch et al. JACC interventions Nov 2011
Reproducible Measurements across 3 readers from different centers and 120 patients

<table>
<thead>
<tr>
<th>MDCT annular measurement</th>
<th>ICC</th>
<th>95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean diameter</td>
<td>0.87</td>
<td>0.79 - 0.90</td>
</tr>
<tr>
<td>Area</td>
<td>0.86</td>
<td>0.65 - 0.90</td>
</tr>
<tr>
<td>Long diameter</td>
<td>0.77</td>
<td>0.71 - 0.83</td>
</tr>
<tr>
<td>Short diameter</td>
<td>0.70</td>
<td>0.49 - 0.82</td>
</tr>
</tbody>
</table>
Reproducibility throughout the Cardiac Cycle

systolic – 20% of RR

27.1 mm x 21.6 mm
Area: 4.61 cm²

77.4 mm

diastolic – 60% of RR

27.8 mm x 16.2 mm
Area: 3.62 cm²

Leipsic et al Radiology in press
Maximum and Minimum Annular Diameter
Area Measurements Can Predict Significant PV Leak
Incidence of PV Leak

Willson et al. JACC April 3 2012
78 year old female severe aortic stenosis
Mean diameter of 24.0 mm and Area 5.18 cm²

23mm: 4.15 cm², Area increase: 28%
26mm: 5.31 cm², Area increase: 28%
29mm: 6.61 cm², Area increase: 25%
Moderate PV Leak post Implant
23mm: 4.15cm², Area increase: 28%
26mm: 5.31cm²
29mm: 6.61cm², Area increase: 25%
MDCT Can Provide Reproducible and Robust Sizing Recommendations
# Vancouver MDCT Sizing Guidelines

<table>
<thead>
<tr>
<th>Annular Area (mm²)</th>
<th>26mm SAPIEN XT THV</th>
</tr>
</thead>
<tbody>
<tr>
<td>23mm</td>
<td>4.15cm²</td>
</tr>
<tr>
<td>26mm</td>
<td>5.31cm²</td>
</tr>
<tr>
<td>29mm</td>
<td>6.61cm²</td>
</tr>
<tr>
<td>Area increase</td>
<td>28%</td>
</tr>
<tr>
<td></td>
<td>25%</td>
</tr>
<tr>
<td>520</td>
<td>2.1</td>
</tr>
<tr>
<td>530</td>
<td>0.2</td>
</tr>
</tbody>
</table>
Implications on Sizing

- CT guidelines: the aortic annulus would be over sized by a mean of 13.9±8.0% (range 1.3 to 29.8%) and no aortic annuli would be undersized.

- TEE guidelines with clinical judgement: the annulus was over sized on average by 9.4±17.4% (range: -21.5% to 65.9%, p=0.01).

- 12% (10/120) of THVs were over sized by more than 30%.

- 33.3% (40/120) of annuli were undersized (THV area < annular area) with 20% mod/severe PAR.
Cross-Sectional Computed Tomographic Assessment Improves Accuracy of Aortic Annular Sizing for Transcatheter Aortic Valve Replacement and Reduces the Incidence of Paravalvular Aortic Regurgitation

Hasan Jilaihawi, BSc (Hons), MBChB,* Mohammad Kashif, MD,* Gregory Fontana, MD,† Azusa Furugen, MD, PhD,* Takahiro Shiota, MD,* Gerald Friede, BS, MS,* Rakhee Makhija, MD,* Niraj Doctor, MBBS,* Martin B. Leon, MD,‡ Raj R. Makkar, MD*

Table 5
Comparison of Outcomes Related to Prosthesis Sizing With TEE- and CT-Guided Approaches

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>All Studied Patients (n = 136)</th>
<th>2D TEE-Guided Annular Sizing (n = 96)</th>
<th>Cross-Sectional CT-Guided Annular Sizing (n = 40)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>PV AR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>41 (30.1)</td>
<td>23 (24)</td>
<td>18 (45)</td>
<td>0.001</td>
</tr>
<tr>
<td>Trivial or mild</td>
<td>71 (52.2)</td>
<td>52 (54.1)</td>
<td>19 (47.5)</td>
<td></td>
</tr>
<tr>
<td>Mild-moderate</td>
<td>9 (6.6)</td>
<td>8 (8.3)</td>
<td>1 (2.5)</td>
<td></td>
</tr>
<tr>
<td>Moderate</td>
<td>12 (8.8)</td>
<td>10 (10.4)</td>
<td>2 (5)</td>
<td></td>
</tr>
<tr>
<td>Moderate-severe</td>
<td>3 (2.2)</td>
<td>3 (3.1)</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>PV AR &gt; mild</td>
<td>24 (17.6)</td>
<td>21 (21.9)</td>
<td>3 (7.5)</td>
<td>0.045</td>
</tr>
<tr>
<td>Need for bail-out valve-in-valve</td>
<td>1 (0.7)</td>
<td>1 (1)</td>
<td>0</td>
<td>0.52</td>
</tr>
<tr>
<td>Annular rupture</td>
<td>1 (0.7)</td>
<td>1 (1)</td>
<td>0</td>
<td>0.52</td>
</tr>
<tr>
<td>Prosthesis instability (rocking)</td>
<td>1 (0.7)</td>
<td>1 (1)</td>
<td>0</td>
<td>0.52</td>
</tr>
<tr>
<td>Peri-procedural mortality</td>
<td>4 (3)</td>
<td>3 (3.2)</td>
<td>1 (2.5)</td>
<td>0.82</td>
</tr>
</tbody>
</table>
Why not size with perimeter?
Deformation Dynamics and Mechanical Properties of the Aortic Annulus by 4-Dimensional Computed Tomography

Insights Into the Functional Anatomy of the Aortic Valve Complex and Implications for Transcatheter Aortic Valve Therapy

Ashraf Hamdan, MD,*† Victor Guetta, MD,* Eli Konen, MD,† Orly Goitein, MD,† Amit Segev, MD,* Ehud Raanani, MD,‡ Dan Spiegelstein, MD,‡ Ilan Hay, MD,* Elio Di Segni, MD,*‡ Michael Eldar, MD,* Ehud Schwammenthal, MD, PhD*

Tel Hashomer, Israel
## Dynamism of the Perimeter - The Ongoing Debate

<table>
<thead>
<tr>
<th></th>
<th>Absolute change</th>
<th>p</th>
<th>Relative change</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>CSA</td>
<td>72.9±22.6mm²</td>
<td>&lt;0.001</td>
<td>18.2±6.1%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Perimeter</td>
<td>5.4±1.5mm</td>
<td></td>
<td>7.3±2.1%</td>
<td></td>
</tr>
<tr>
<td>$D_A$</td>
<td>2.0±0.6mm</td>
<td>&lt;0.001</td>
<td>8.7±2.8%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>$D_P$</td>
<td>1.7±0.5mm</td>
<td></td>
<td>7.3±2.1%</td>
<td></td>
</tr>
</tbody>
</table>

In Press JACC Interventions
Limitations of Perimeter Measurements
Coronary Ostial Height
CT Screening Can Reduce your Vascular Access Complications
Vascular complications have been reported and are largely attributable to the large device size and significant atherosclerosis. Initial iliofemoral assessment with single plane angiography in the cath lab.
MDCT allows assessment of a greater breadth of pathologies and anatomical structures.

- Minimal luminal diameter
- Vessel tortuosity
- Burden and pattern of calcification
- Extent of atherosclerosis
- Other high-risk features including dissections and complex atheromas

Thorough and complete three-dimensional assessment of the iliofemoral system.
Iliofemoral Access- What We Know

Circumferential and/or horseshoe calcification in association with small caliber vessels or stenotic segments is considered a contraindication to a transfemoral approach

may not allow the artery to expand to accommodate the large-profile delivery catheter

They also may increase the risk of arterial dissection or perforation

Currently, alternative transapical or tranaxillary approaches should be considered in these patients
85 yo female- tortuous non-calcified iliofemoral arteries
Heavily Calcified Access Small vessels
Identifies High Risk Features
Transfemoral Aortic Valve Implantation

New Criteria to Predict Vascular Complications

Kentaro Hayashida, MD, PhD, Thierry Lefèvre, MD, Bernard Chevalier, MD, Thomas Hovasse, MD, Mauro Romano, MD, Philippe Garot, MD, Darren Mylotte, MD, Jhonathan Uribe, MD, Arnaud Farge, MD, Patrick Donzeau-Gouge, MD, Erik Bouvier, MD, Bertrand Cormier, MD, Marie-Claude Morice, MD

Massy, France

<table>
<thead>
<tr>
<th>Variables</th>
<th>≥1.05 (n = 55)</th>
<th>&lt;1.05 (n = 72)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any vascular complication</td>
<td>23 (41.8%)</td>
<td>12 (16.7%)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>VARC Major</td>
<td>17 (30.9%)</td>
<td>5 (6.9%)</td>
<td>0.001</td>
</tr>
<tr>
<td>VARC Minor</td>
<td>6 (10.9%)</td>
<td>7 (9.7%)</td>
<td>0.827</td>
</tr>
<tr>
<td>Femoral artery complication</td>
<td>15 (27.3%)</td>
<td>9 (12.5%)</td>
<td>0.035</td>
</tr>
<tr>
<td>Iliac artery complication</td>
<td>11 (20.0%)</td>
<td>2 (2.8%)</td>
<td>0.002</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>11 (20.0%)</td>
<td>5 (6.9%)</td>
<td>0.033</td>
</tr>
<tr>
<td>30-day mortality</td>
<td>10 (18.2%)</td>
<td>3 (4.2%)</td>
<td>0.016</td>
</tr>
</tbody>
</table>

Values are n (%). p Values in **bold** are statistically significant.

Abbreviations as in Tables 2 and 3.
<table>
<thead>
<tr>
<th>Variable</th>
<th>No vascular complication n = 58</th>
<th>Vascular complication n = 8</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Minimal lumen diameter (mean)</td>
<td>7.0</td>
<td>6.2</td>
<td></td>
</tr>
<tr>
<td>Minimal lumen diameter &lt; sheath diameter, n (%)</td>
<td>23 (40%)</td>
<td>7 (83%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Moderate or severe calcification, n (%)</td>
<td>9 (15%)</td>
<td>5 (42%)</td>
<td>0.04</td>
</tr>
</tbody>
</table>

Toggweiler et al. JACC Jan 2012
17% of patients screened with CT declined for procedure in 2010
Angle of Deployment

The need for multiple aortograms to define this optimal orientation increases procedural time, contrast use, and radiation exposure.

CT offers the potential to reduce the need for multiple angiograms and to provide guidance in advance of the procedure.
ANGLE OF DEPLOYMENT

We aim to find angiographic projections representing perpendicularity to the native valve plane in 3 axes:

1) AP cranial-caudal without RAO or LAO angulation
2) straight RAO to LAO as needed without cranial or caudal angulation
3) LAO 30° with cranial or caudal angulation as needed.

These axes were chosen based on the preferred working angles in the catheterization lab.
Predict Co-axial Angle of Deployment
CT to Assist Valve Deployment

Connect the Dots
Line of Perpendicularly - Predicted Angles
MDCT vs 3-D Angio CT for Angle Prediction

Binder et al. TCT 2011, Circ Interventions April 2012
Post TAVR Follow Up with CT
Assessment of Positioning - Expansion and Circularity
Computed tomography evaluation- 22 patients minimum 3 years post

**NO VALVE MIGRATION:**
Distance from left main
3.0 ± 3.6mm vs 1.9± 3.7mm, p=0.24

**STENTS REMAIN CIRCULAR**

NO VALVE FRACTURE

Self Expandable Valves: Geometry

Higher eccentricity and incomplete expansion compared with balloon expandable valve *

<table>
<thead>
<tr>
<th>Circularity</th>
<th>Long – short diameter</th>
</tr>
</thead>
<tbody>
<tr>
<td>100% 28/28</td>
<td>1.1mm</td>
</tr>
<tr>
<td>50% 15/30</td>
<td>2.3mm</td>
</tr>
<tr>
<td>33% 10/30</td>
<td>3.2mm</td>
</tr>
<tr>
<td>13% 4/30</td>
<td>4.4mm</td>
</tr>
</tbody>
</table>

CONCLUSION

TAVR therapy has seen rapid advancements over the last 5 years

MDCT can evaluate

3D annular and aortic root morphology and dimensions

MDCT measures of the annulus are predictive of PAR and can provide more granular and reproducible annular sizing

Assessment of iliofemoral access

Procedural planning- angle prediction and left main height assessment