I, Rebecca T. Hahn, MD DO NOT have a financial interest/arrangement or affiliation with one or more organizations that could be perceived as a real or apparent conflict of interest in the context of the subject of this presentation.

1. Have a complete understanding of the procedure and device
2. Full in-service for both interventionalist and imager
3. Have a complete understanding of the important anatomy and how to image it
   a. 2D and 3D Imaging Essential
   b. 3D echo to guide most procedures
      i. Simultaneous multi-plane imaging
      ii. Real-time 3D
      iii. 3D assessment of EOA (regurgitant or stenotic)
4. Understand how to communicate effectively with your interventionalist or surgeon
New TAVI Systems - Transfemoral
- Direct Flow
- Sadra
- St. Jude
- AorTx
- HLT
- EndoTech
- ABPS PercValve

Transcatheter Aortic Valve Design

Pre-Implant Decisions:
1. Appropriate Device and Size
2. Risk of Complications and Procedural Planning

Landing Zone Anatomy

Balloon Rupture
Paraventricular Hematoma
Incidence, Predictors, and Outcomes of Aortic Regurgitation After Transcatheter Aortic Valve Replacement: Meta-Analysis and Systematic Review of Literature

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Leny Georg Simonsen, MD, PhD,† Paolo A. Lyon, MD, Clin Ficiere, MD, PhD,§
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Debra Capodanno, MD, PhD,§ Corrado Tronci, MD, PhD, and Abeer Lab, MD,†
Antonio Colombo, MD,†Sonja R. Kogula, MD,

25 studies reported on predictors of post-TAVR AR.
Predictors include (r = 0.47, p < 0.001)
1. Implantation depth
2. Valve undersizing
3. Agatston calcium score

The scalloped configuration of the hingelines of the leaflets leave fibrous interleaflet triangles or trigones between the sinuses.
The virtual annulus marks the hinge points of the cusps (Blue Line).
The maximum diameter of the annulus bisects a trigone on one side, and a cusp on the other side (Yellow arrow).
When equal cusps are imaged in LAX view, the AVOT and annular diameters may be underestimated.
Use of biplane imaging to align the annulus

- The annulus is approximately perpendicular to the long-axis of the aorta.

Because the trigone between the L and N coronary cusps is imaged, be careful NOT to measure the calcification of the trigone (red arrow).

Measuring the Annulus: Acoustic Shadowing

Low Window

Sagittal Plane
Coronal Plane
1. The annulus is oval or elliptical
2. The sagittal plane (long-axis imaging plane) is the minimum diameter and the coronal plane is the maximum diameter
3. In systole, the annulus becomes less elliptical
4. Three D measurements (CT, MRI and 3D Echo) of mean diameter, perimeter or area, correlate well

Altiok E. et al. Heart 2011;97:1578-1584

Both MSCT and 3D TEE demonstrated an elliptical aortic annular/LVOT geometry before TAVI, leading to significant underestimations of their “true” cross-sectional areas when assuming a circular geometry.
After TAVI, the “new effective” aortic annulus assumes the smaller circular internal dimensions of the deployed prosthetic valve.
Near circular geometry of the deployed prosthetic valve resulted in no significant differences between the calculated circular versus planimetered annular areas.

Ng ACT et al Circ Cardiovasc Imaging. 2010;3:94-102

In the in vitro model, CMR measurements were the most accurate for assessing the actual dimensions.
MSCT and 3DE are reasonable alternatives with the understanding that they can slightly overestimate and underestimate annular dimensions, respectively.
Using post-TAVR paravalvular AR moderate or greater (10.6% incidence) as the variable:

- Average cross-sectional diameter by CT offered a high degree of discrimination (area under the curve = 0.82, 95% CI: 0.73 to 0.90, p < 0.0001)
- Mean cross-sectional diameter by 3D-TEE was of intermediate value (area under the curve = 0.68, 95% CI: 0.54 to 0.81, p = 0.036).

1. Transverse and sagittal and coronal planes are oriented:
   - All planes intersect at the center of the opened valve.
   - Sagittal and coronal planes aligned parallel to the long axis of the ascending aorta.

2. The orthogonal planes are rotated to identify the most caudal attachments of the aortic valve leaflets (hinge points):
   - Transverse plane is repositioned to the level of the hinge points.

3. The orthogonal planes are repeatedly rotated (the turnaround rule) to ensure that the hinge points of the aortic valve leaflets are transected by the transverse plane.

Minimum 19.6 mm
Maximum 24.4 mm
Area= 376 mm²
The largest AUC to detect >mild PVR were for 3DE AveAnnP cover index (0.772) and 3DE AveAnnA cover index (0.769) Hahn RT et al. J Am Soc Echocardiogr 2013;26:1044-1052.

3D Echo Annular Measurements
- 3DE could allow more accurate measurement of the annulus for more accurate THV sizing and can be performed intra-procedurally.
- A new sizing algorithms using both the 3DE maximum dimension and perimeter-derived average annular diameter should be developed.

<table>
<thead>
<tr>
<th>Area</th>
<th>&gt;10.5-11.1% oversize</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perimeter</td>
<td>&gt;2.9-5.3% oversize</td>
</tr>
</tbody>
</table>

3DE: 26 mm

Hahn RT et al (unpublished)

Intra-procedural Monitoring and Guidance

Risk Assessment
- Aortic Annulus
- Aortic Valve Morphology/Ca
- Aortic Root and LVOT
- Aortic root morphology
- Ectopic calcification
- Sigmoid septum
- Wire position
- Mitral/Valve apparatus
- Left Ventricular size and function
- Balloon Aortic Valvuloplasty
- Positioning and deployment of THV
- Aortic valve, root and LVOT morphology

Hemodynamic Emergencies
- Aortic/AV trauma
- Peri-aortic hematoma
- Aortic dissection
- Aortic dissection
- Annular rupture
- Pericardial tamponade
- Mitral valve compromise
- Left main coronary occlusion
- Severe aortic regurgitation
- Mitral regurgitation
- Paravalvular regurgitation
The SAPIEN heart valve relies on native valve calcium to securely anchor to the annulus. Despite this beneficial aspect of calcium, at times the extent and distribution of calcium can impair procedural success. Uneven distribution of calcium causing asymmetry of valve opening increases the risk of:
1. THV dysfunction from asymmetric deployment
2. Paravalvular leakage

Obliteration of the SOV, often associated with diffuse calcification (e.g., porcelain aorta)
- Severe obliteration is defined as a difference between the SOV and sinotubular junction (STJ) diameters of < 5 mm (normal range: 5 – 10 mm).
- Severe obliteration of the SOV is associated with coronary artery obstruction and aortic rupture/dissection.

Note both size and calcification of the STJ.

Balloon Rupture
• 31 patients with aortic root rupture (20 with annular rupture and 11 with peri-aortic hematoma) and compared them to 31 matched controls.

• Patients with aortic root rupture had:
  – Higher degree of subannular/left ventricular outflow tract calcification
  – Higher frequency of ≥20% annular area oversizing (79.4% vs. 29.0%, p<0.001)
  – Higher frequency of Balloon post-dilatation (22.6% vs. 0.0%, p=0.005).

• In conditional logistic regression analysis for the matched data the significant variables:
  – Moderate/severe left ventricular outflow tract/subannular calcifications (Odds Ratio [OR]: 10.92, 95% Confidence Interval [CI]: 3.23 to 36.91, p<0.001)
  – Prosthesis oversizing ≥20% (OR: 8.38, 95% CI: 2.67 to 26.33, p<0.001) were associated with aortic root contained/non-contained rupture.

“Watermelon Seeding”: THV moves superiorly during balloon inflation

For a 23 mm SAPIEN valve, 5.6 mm – 7 mm will rest above the level of the aortic annulus.

For a 26 mm SAPIEN valve, 6.8 mm – 8.5 mm will rest above the level of the aortic annulus.

Increased Risk of Coronary Occlusion: <10 mm for 23 mm valve
<11 mm for 26 mm valve
Coronary Obstruction occurred more frequently in the left coronary artery (83.3%) and could be successfully treated percutaneously in 91.3% of cases.

Possible Risk Factors:
- The height of the left main above the annulus was on average 10.3 mm (range 7 to >12 mm), however approximately 60% of occlusions occurred with a coronary height of >10 mm.
- No cases of coronary obstruction related to the struts of the TAVR
- Aortic root diameter (echo) = 27.8 ± 2.8 mm
- Sex: 83% of the patients were women

Note: there may be a slightly higher rate of coronary obstruction after balloon-expandable (0.4%) versus self-expandable (0.2%) valve implantation.

“Whereas no specific formal recommendation for sinus of Valsalva width and coronary ostia height is provided for the implantation of the Edwards valve, a recommendation of a sinus of Valsalva width 27 mm (for the 26-mm CoreValve) or 28 mm (for the 29-mm CoreValve) mm and a coronary height 14 mm is provided by the manufacturer for the implantation of the CoreValve system.”

Ribaiio HB et al. Circulation. 2013;128:244-253
Asymmetric Calcification around the Left Main Coronary Artery

Left Main = 11.5 mm
LCC = 15.5 mm
Aortogram during BAV - LM patent

No flow seen on echo

Balloon aortic valvuloplasty

Valve deployment

Watch LM

For Annulus Size 21 to 22 mm

<table>
<thead>
<tr>
<th>Select 23 mm Edwards SAPIEN valve if:</th>
<th>To mitigate risk:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe annular calcification</td>
<td>Annular rupture</td>
</tr>
<tr>
<td>Narrow root OR Bulky leaflets and low coronary ostia</td>
<td>Coronary obstruction</td>
</tr>
<tr>
<td>Narrow or calcified sinotubular junction OR Dynamic sigmoid septum</td>
<td>Valve movement during deployment</td>
</tr>
<tr>
<td>Mitral valve calcification</td>
<td>Mitral valve perforation</td>
</tr>
<tr>
<td>Porcelain aorta OR effaced SOV or Calcified STJ</td>
<td>Aortic rupture or dissection</td>
</tr>
</tbody>
</table>

- If none of above conditions, 26 mm Edwards SAPIEN valve can be considered

[Intra-procedural Imaging]

[Intra-procedural Imaging]

[Intra-procedural Imaging]
Changes in the severity of MR may indicate compromise to the mitral apparatus from stiff wires or cannulas. Increase in blood pressure. Severe AR.

Catheter Entanglement

Immediate THV deployment

Acute Severe AR with Hypotension
The final location after implantation was significantly higher than in the final stage of rapid pacing: 16.7±16.3% of device height below the plane of the lower sinus border versus 32.6±13.8%, p<0.001, resulting in device shortening.

Operator-independent device-center upper movement during final deployment was 2±1.43 mm, range: -0.3 to 4.6 mm.

Device movement was asymmetrical, occurring more in the lower part of the device than in its upper part (3.2±1.4 mm vs. 0.75±1.5 mm, p<0.001), resulting in device shortening.

Multivariate analysis revealed that moderate and severe aortic valve calcification had 49% higher upward movement than mild calcification (p=0.03), and aortic sinus volume was negatively correlated with movement size (r = -0.35, p < 0.005).

Concentration: 50% above and 50% below the basal attachment of the leaflets

Suggestion: Final location of the middle region of implanted device will be 1 to 2 mm higher than the plane of the most basal part of the aortic sinuses (which the author believes is 1-2 mm below the hinge-point of the leaflets).
Intra-procedural Imaging for TAVR

Severe Central AR

Manipulation of wire/catheter “bring down” the cusp
Immediately following THV deployment
Tortuous aorta with kinked sheath resulted in stored tension, resulting in delayed transmission of catheter manipulation.

Immediately following Post-dilatation
Post THV deployment resulted in unstable position and severe AI.
Performed valve-in-valve* to correct central aortic insufficiency

*No testing has been performed to determine the long-term durability in this configuration.

The hemodynamic performance of the prosthesis within the aortic annulus may depend on:
- Ascending aorta anatomy
- LVOT or annulus shape
- Degree of contact with the aortic annulus
- Degree of calcification and thickness of the aortic valve leaflets, and the ability of the nitinol stent to provide a radial force.

Sherif et al. JACC 2010;56 (20):1623–9

The depth of delivery is the distance from the native aortic annular margin on the side of both the noncoronary cusp (NCC) and the left coronary cusp (LCC) to the most proximal edge on the corresponding side of the deployed stent-frame.

The LVOT-AO is the angle between the axis of the first 4 cm of the ascending aorta and the left ventricular outflow tract (LVOT) axis.

Sherif et al. JACC 2010;56 (20):1623–9
Multivariate analysis, greatest chance of significant AR with
- Greater angle (odds ratio: 1.24, p = 0.001)
- Depth of the device in relation to the noncoronary cusp is ~10 mm (odds ratio: 1.1, p = 0.024).
- Deeper or shallower implantation → AR
- A predictive model was generated,
  - If 2x \( \angle \text{LVOT-AO} + (\text{depth to noncoronary cusp - 10})^2 \geq 50 \)
  - Likelihood of occurrence of significant AR could be predicted with a sensitivity of 85% and a specificity of 87%.

Sherif et al. JACC 2010;56 (20):1623–9
Intra-procedural Echocardiography

- Intra-procedural
- Complications of Wires/BAV
- Positioning of Device
- Deployment

**Intra-procedural Echocardiography**

- Rapid assessment of device position and function

**Intra-procedural Echocardiography**

- Rapid assessment of complications
  - Device complication
  - Hemodynamic instability

Acute hypotension with BP 90/40 mmHg

Rapid assessment of complications

Device complication

Hemodynamic instability
Intra-procedural Monitoring and Guidance

Risk Assessment
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Thank you