TRICUSPID VALVE REPAIR: IMAGE GUIDANCE WITH TEE

Rebecca Hahn, MD
Professor of Medicine
Columbia University

Disclosures

• Core Lab Director for multiple tricuspid device trials for which I receive no direct compensation:
• Other Disclosures:
  • GE Medical: Speaker / Speaker's Bureau
  • Philips Healthcare: Speaker / Speaker's Bureau
  • Abbott Structural: Speaker / Speaker's Bureau
  • Gore and Associates: Consultant, Advisor
  • Boston Scientific: Speaker / Speaker's Bureau
TEE

**ASE/SCA Guidelines and Standards**

Guidelines for Performing a Comprehensive Transesophageal Echocardiographic Examination: Recommendations from the American Society of Echocardiography and the Society of Cardiovascular Anesthesiologists

Rebecca T. Hahn, MD, FASE, Chair, Theodore Abraham, MD, FASE, Mark S. Adams, RDMS, FASE, Charles J. Boss, MD, FASE, Justin R. Gia, MD, FASE, FASE, Roberto M. Lang, MD, FASE, Scott T. Reves, MD, FASE, Jack B. Shamee, MD, FASE, Samuel C. Sia, MD, FASE, William Stewart, MD, FASE, and Michael H. Percard, MD, FASE, New York, New York, Baltimore, Massapequa, Missouri, Atlanta, Chicago, Illinois, Charleston, South Carolina, London, Ontario, Canada, Cleveland, Ohio

(J Am Soc Echocardiogr 2013;26:921-64)

Keywords: Transesophageal echocardiography, Comprehensive examination

http://www.onlinejase.com/article/S0894-7317(13)00562-2/fulltext

---

**Probe Levels**

Four Levels of Imaging for the Tricuspid Valve:
1. Mid-esophageal
2. Deep-esophageal
3. Shallow Transgastric
4. Deep Transgastric

3D Modalities:
1. Simultaneous Multiplane
2. Real Time 3D
3. Full Volume 3D
4. Zoom 3D
5. Color 3D

New Level for Tricuspid Valve Imaging:

Deep Esophageal

Hahn RT et al. JASE 2013;26:921-64
### Optimal Imaging for the Tricuspid Valve

<table>
<thead>
<tr>
<th>Four Levels of Imaging</th>
<th>Five probe manipulations:</th>
<th>Five 3D Modalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Mid-esophageal</td>
<td>1. Advancing and</td>
<td>1. Simultaneous</td>
</tr>
<tr>
<td>2. Deep-esophageal</td>
<td>withdrawing the probe</td>
<td>Multiplane</td>
</tr>
<tr>
<td>3. Shallow Transgastric</td>
<td>2. Turning probe</td>
<td>2. Real Time 3D</td>
</tr>
<tr>
<td>4. Deep Transgastric</td>
<td>(clockwise to the right</td>
<td>3. Full Volume 3D</td>
</tr>
<tr>
<td></td>
<td>chest, counterclockwise</td>
<td>4. Zoom 3D</td>
</tr>
<tr>
<td></td>
<td>to the left chest)</td>
<td>5. Color 3D</td>
</tr>
<tr>
<td></td>
<td>3. Anteflexion and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>retroflexion (large</td>
<td></td>
</tr>
<tr>
<td></td>
<td>“wheel”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4. Right and left flexion</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(small “wheel”)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5. Mechanical rotation of</td>
<td></td>
</tr>
<tr>
<td></td>
<td>the multi-plane probe</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(0-180°)</td>
<td></td>
</tr>
</tbody>
</table>

### Probe Articulation

<table>
<thead>
<tr>
<th>Retroflexion</th>
<th>Anteflexion</th>
<th>Right Flexion</th>
<th>Left Flexion</th>
<th>Left+Ante</th>
<th>Right+Ante</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /></td>
<td><img src="image6.png" alt="Image" /></td>
</tr>
</tbody>
</table>

Hahn RT J Am Soc Echocardiogr 2013; 26:921-64
Grasping view for P-S

Slight ante-flexion

Slight retro-flexion
**ME 4Ch View (0-40 degrees)**

- Septal
- Anterior
- Posterior
- Pacing Wire

Pacing wire in A-S commissure

**ME Short-Axis at Base/RV Inflow-outflow**: 

- Septal
- Anterior
- Posterior
- Pacing Wire

Anteflexe Retroflexed
ME Short-Axis at Base/RV Inflow-outflow SWEEP:

- Septal-Posterior Commissure
- Septal-Posterior Tips
- Septal-Anterior Commissure
- Septal-Anterior Tips

Understanding the Commissural View

- A-S Anterior Commissure
- A-S Central
- A-P or A-S Commissure
**140-180 degree view (Long Axis)**

- Grasping view for A-S (slight anteflex or higher esophageal view)
- Grasping view for P-S (slight retroflex or deeper esophageal view)

---

**Deep Esophageal (GE junction)**

1. Eliminates LA from view
2. Closer to TV
### Transgastric Views of the RV and TV

<table>
<thead>
<tr>
<th>Imaging Plane</th>
<th>3D Model</th>
<th>2D TEE Image</th>
<th>Acquisition Protocol</th>
<th>Structures Imaged</th>
</tr>
</thead>
<tbody>
<tr>
<td>Transgastric Views</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>30°, TEE RV-PA View</td>
<td>[Image]</td>
<td>[Image]</td>
<td>Right atrium (LA), Right ventricle (RV), Right ventricular outflow tract, Tricuspid Valve (TV)</td>
<td>Pulmonary Valve</td>
</tr>
<tr>
<td>60°, TEE RV-PA View</td>
<td>[Image]</td>
<td>[Image]</td>
<td>Right atrium, Right ventricle, Right ventricular outflow tract, Tricuspid Valve</td>
<td>Pulmonary Valve</td>
</tr>
</tbody>
</table>


### Transgastric Inflow-Outflow

- **Used to position Clip under valve and for clip arm perpendicularity**
Transgastric SAX 0-50 degrees

All 3 leaflets imaged

Deep Transgastric

Sepal
Anterior
Posterior

Sepal
Anterior
Posterior
Caveat to Leaflet Identification

3D en face view

- KEY CAVEAT:
  - Three-dimensional valve
  - Highly variable anatomy

- Leaflet identification MUST be confirmed with 3D en face view

3D TV ACQUISITION

ACQUISITION

A
Use biplane views to check that the tricuspid valve annulus is centered within the acquisition plane

B
Rotate to the right atrial enface view

PRESENTATION

E
Standard tricuspid valve view from the right ventricular perspective

D
Standard tricuspid valve view from the right atrial perspective

C
Rotate 90° to place the IAS at the 6 o’clock position
Multi-beat acquisition EVEN IN AFIB
May be still be accurate for the systolic time interval

Percutaneous Approaches for Tricuspid Regurgitation
Transcatheter Tricuspid Solutions

Approaches:
1. Superior vena cava
2. Inferior vena cava
3. Transapical
4. Transatrial

Anatomic Target
1. Leaflet
2. Annulus
3. IVC
4. Valve

Annular Devices
Procedural Steps

• Right Internal Jugular Access
• Two 14F Sheaths
• Hook around wire delivery to deliver 1st pledget (anchor)
• Repeat wire delivery steps to deliver 2nd pledget (anchor)
• Cinch pledgets together to obliterate the posterior leaflet and deliver lock on atrial side

Note: Investigational Device
Tricuspid Wire Delivery Catheter shaft in the correct position in the TV orifice with tip pointed toward the outside
Intra-procedural TEE
1st Tricuspid Wire Delivery Catheter Re-positioning

During radiofrequency deployment, catheter moved.
Position now too posterior (not at septal-posterior commissure).
Wire Delivery Catheter Positioning: Transgastric

Posterior Septal Location

3D: Visualize Wire Catheter Position

*Increase Gain:* to visualize leaflets

*Decrease Gain:* to visualize the catheter (exclude the leaflets)

Depth: Distance from leaflet insertion point or hinge to the wire catheter or crossing wire

2D: Visualize Wire Catheter Depth

Intra-procedural TEE

Pledget Deployment
Intra-procedural TEE

Second Wire Re-Position x2

Ideal Distance between pledgeted sutures: 2.4-2.8 cm

Distance 2.7 cm

Intra-procedural TEE

Cinching--Plicating
**Post-procedural TEE**

**Parameter**

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tricuspid Annular Area</td>
<td>7.6 cm²</td>
</tr>
<tr>
<td>Tricuspid Valve Area</td>
<td>6.5 cm²</td>
</tr>
<tr>
<td>Tricuspid EROA</td>
<td>0.43 cm²</td>
</tr>
<tr>
<td>Tricuspid Regurgitant Volume</td>
<td>40 cc</td>
</tr>
<tr>
<td>Forward Stroke Volume</td>
<td>77 cc</td>
</tr>
<tr>
<td>PASP (mmHg)</td>
<td>58 mmHg</td>
</tr>
</tbody>
</table>
**Baseline**

3D Annulus: 13.9 cm²
3D EROA: 0.99 cm²

**Post-Trialign**

3D Annulus: 7.6 cm²
3D EROA: 0.43 cm²

---

**Early Feasibility Study of a Transcatheter Tricuspid Valve Annuloplasty**

Hahn RT et al. J Am Coll Cardiol 2017;69:1795–806
SCOUT I
- ClinicalTrials.gov Identifier: NCT02574650
- A prospective, single-arm, multi-center study, enrolling symptomatic patients with chronic functional tricuspid regurgitation and whom left-sided valve surgery is not planned.
- The study will include up to 30 subjects from up to 6 sites in the US.
- Follow-up evaluations will be conducted through 2-years post implantation.

SCOUT II
- ClinicalTrials.gov Identifier: NCT03225612
- A prospective, single-arm, multi-center study, enrolling symptomatic patients with chronic functional tricuspid regurgitation.
- The study will include up to 60 subjects from up to 15 sites in Europe and the United States.
- Follow-up evaluations will be conducted through 5 years post implantation.
MitraClip for Tricuspid Regurgitation Procedural Steps

1. Identify the location of the target jet
   - Comprehensive baseline imaging primarily utilizing 3D
2. Confirm 2D imaging planes for imaging the clip procedure
3. Position the guide catheter
4. Orient the clip arms
5. Cross the TV annulus and re-align the clip arms
6. Grasp leaflets
7. Perform full post-clip assessment
   - Mean gradient
   - Planimetered EOA (3D)
   - Residual TR (3D)

Note: Off-label Use

Step 1: Identify the location of the jet

Largest jet between the posterior and septal leaflets
Baseline

Step 2: Confirm 2D imaging plane for leaflet clipping
3D Bicaval View
- Device Straddle and Steering

Step 3: Position Guide Catheter

En face view
Step 4: Orient Clip Arms

Step 5: Grasp Leaflets
Step 6: Post-Clip Assessment
Second Clip

Unable to image clip arms and leaflets
Clip perpendicular to Imaging Plane

Flexi-slice
Advantages

2D Imaging planes off-axis

2D imaging Planes aligned with Clip Arms
How To Align Clip Arms

TTE Imaging: Apical 4Ch View
Grasping and Perpendicularity
FORMA Tricuspid Valve Therapy System (Edwards Lifesciences)

- **Spacer**
  - Positioned within regurgitant orifice
  - Provides surface for native leaflets to coapt
  - 12, 15 and 18mm sizes
  - Advanced from left subclavian vein

- **Rail**
  - Tracks Spacer into position
  - Anchored at RV apex and subclavian vein

Note: Investigational Device

Case 1: Final Position

Total Residual EROA = 0.74 cm²
The FORMA Trial
Early Feasibility Study of the Edwards FORMA Tricuspid Transcatheter Repair System

N=30
Adult subjects with clinically significant, symptomatic, tricuspid regurgitation who are at high surgical risk for standard tricuspid repair or replacement as assessed by the Heart Team

Primary Endpoint 30 days
All-Cause Mortality

6 Month and 1, 2, 3 Year
Clinical and Imaging Echo FUP

The SPACER Trial
Repair of Tricuspid Valve Regurgitation using the Edwards Tricuspid Transcatheter Repair System

N=78
Adult subjects with clinically significant, symptomatic, tricuspid regurgitation who are at high surgical risk for standard tricuspid repair or replacement as assessed by the Heart Team

Primary Endpoint 30 days
All-Cause Mortality

6 Month and 1, 2, 3 Year
Clinical and Imaging Echo FUP

The Future:
Transcatheter Tricuspid Valve Replacement
Components Specifications

- Temperature Shape Memory NiTiNi Tapered Stent (Inflow=30mm/Outflow=40mm)
- Height profile 21 mm, Truncated Cone configuration with a Diffuser effect.
- Annular Winglets for secure anchoring of annulus and tricuspid valve leaflet.
- Chemically Preserved Xenogeneic Pericardium.

The larger sized valves are ideal for the dilated Tricuspid Valve. (TV 48 ± 4mm Ø)

Note: Investigational Device

Gate Valve
Transcatheter Valved Stent Replacement Technology

Delivery System & Introducer Sheath

Delivery System
- Capsule profile: 35F
- Proximal Shaft: 24F
- Steerable distal shaft length: 2.5 cm
- Usable Length: 40 cm
- Steering control knob for coaxial alignment
- Controlled Release Knob to avoid jumping during device deployment

Introducer Sheath
- Sheath OD: 42F
- Sheath is radiopaque
- Triple valve for hemostasis
Pre-procedural CT planning
Tricuspid annular area by 3D imaging

Systolic phase: 44 x 54 mm
Diastolic phase: 44 x 49 mm

Decision: 48 vs 52 mm valve

Access
Plan for transcatheter tricuspid valve replacement with a 48mm NaviGate tricuspid valve bioprosthesis

**TR Quantitation**

- **EROA by PISA** = $0.63 \text{cm}^2$ and calculated regurgitation volume = $70.4 \text{cc}$
- **3D Quantitation**: annular area = 13.8 $\text{cm}^2$ calculated diastolic stroke volume = 156 $\text{cc}$, regurgitation volume = 106.8 $\text{cc}$, EROA = $0.96 \text{ cm}^2$
- **3D Quantitation**: annular area = 15.38 $\text{cm}^2$ (dimensions = 4.45cm by 4.28cm) calculated diastolic stroke volume = 173.8$\text{cc}$, regurgitation volume = 120.7$\text{cc}$, EROA = $1.08 \text{ cm}^2$
- **3D color Doppler EROA** (averaged over 11 frames) = $0.91 \text{cm}^2$ calculated regurgitation volume = 101.6$\text{cc}$.
- **3D TV EOA** = 7.50$\text{cm}^2$
New Grading Scheme for Severe TR

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>Massive</th>
<th>Torrential</th>
</tr>
</thead>
<tbody>
<tr>
<td>VC (tricuspid)</td>
<td>&lt;3 mm</td>
<td>3.5-5 mm</td>
<td>7-13 mm</td>
<td>14-20 mm</td>
<td>≥21 mm</td>
</tr>
<tr>
<td>EROA (PISA)</td>
<td>&lt;20 mm²</td>
<td>20-39 mm²</td>
<td>40-59 mm²</td>
<td>60-79 mm²</td>
<td>≥80 mm²</td>
</tr>
<tr>
<td>3D VCA or quantitative EROA²</td>
<td>&gt;75-94 mm²</td>
<td>&gt;95-114 mm²</td>
<td>&gt;95-114 mm²</td>
<td>&gt;115 mm²</td>
<td></td>
</tr>
</tbody>
</table>

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
²3D VCA and quantitative Doppler EROA cutoffs may be larger than PISA EROA.


Severe

Massive

Torrential

Massive tricuspid incompetence

Simultaneous Echo and Fluoro Guidance is KEY

Temporary pacing achieved with Confida wire in left ventricle and pacing electrodes mounted on wire
Positioning the Transatrial Puncture

**Atrial Poke:** Distance 7.5 cm

- **Poor Position (non-coaxial)**
- **Good Position (coaxial)**

Balloting the Atrium

Positioning of stiff guidewire into right ventricle over a pigtail catheter, and through transatrial incision

**Case 6: Columbia University 10/2017**

Initial valve deployment with RCA injection

Retracting the capsule:
Exposing Ventricular Tines
Trivial central and trivial paravalvular regurgitation

Peak/mean transtricuspid gradient = 1.5 and 0.3 mmHg
New tricuspid therapies
TRANSCATHETER TECHNOLOGIES

<table>
<thead>
<tr>
<th>Mechanism</th>
<th>New Technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Annuloplasty (Direct and Indirect)</td>
<td>TriAlign, Cardioband, 4Tech, Millepede, Pasta</td>
</tr>
<tr>
<td>Leaflet Devices</td>
<td>Forma, MitraClip, PASCAL</td>
</tr>
<tr>
<td>Stented Valves in IVC/SVC</td>
<td>Trinity/Sapien, TriCentro</td>
</tr>
<tr>
<td>Valve Replacement</td>
<td>Navigate</td>
</tr>
</tbody>
</table>