In 1967, Braunwald advised a conservative approach to TR. It was thought that appropriate correction of the left-sided valve disease would probably result in a decrease or even abolition of functional TR.


Severe TR is associated with a poor prognosis, independent of age, direct cause, systolic function, RV size, and dilation of the inferior vena cava.


Of the 883 patients that did not undergo TV surgery, the 5-year survival rate was 75%.


Surgical mortality of TVR ≈ 3.4x higher compared to other single valve open procedure


Why is the Tricuspid Valve "The Forgotten Valve"?

In 1967, Braunwald advised a conservative approach to TR. It was thought that appropriate correction of the left-sided valve disease would probably result in a decrease or even abolition of functional TR.

### Residual TR following TV Repair

**Key point:**
Eliminating secondary TR is difficult with suboptimal results no matter which repair technique is used!

- Moderate TR
- Low TR
- No TR

Other anatomic levels (subvalvular, papillary muscle, and right ventricular) contributing to TR/pathophysiology are currently unaddressed.

---

### Etiologies of TR

<table>
<thead>
<tr>
<th>Morphologic Classification</th>
<th>Disease Subgroup</th>
<th>Specific Abnormality</th>
</tr>
</thead>
<tbody>
<tr>
<td>Primary Leaflet Abnormality</td>
<td>Acquired Disease</td>
<td>Degenerative myxomatous</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Rheumatic</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Endocarditis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Carcinoid</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Endomyocardial fibrosis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Trauma</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Iatrogenic (Pacing leads, RV biopsy)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Other (eg. ischemic papillary muscle rupture)</td>
</tr>
<tr>
<td></td>
<td>Congenital</td>
<td>Ebstein's anomaly</td>
</tr>
</tbody>
</table>

- 146 consecutive patients with functional mitral regurgitation
- Pre-procedural TR (moderate/severe, n = 47 and none/mild, n = 99)

---

### Primary TR: Flail Tricuspid Valve post-Biopsy

- 1-year outcomes and predictors of mortality after MicroClip therapy in contemporary clinical practice results from the German transcatheter mitral valve interventions registry

- Multivariable analysis, significant predictors of 1-year mortality were:
  - NYHA class IV (HR 1.62, P < 0.01)
  - Anemia (HR 2.44, P = 0.01)
  - Previous aortic valve intervention (HR 2.13, P = 0.002)
  - Serum creatinine > 1.5 mg/dL (HR 1.77, P = 0.002)
  - Peripheral artery disease (HR 2.12, P = 0.001)
  - Left ventricular ejection fraction < 30% (HR 2.59, P = 0.01)
  - Severe tricuspid regurgitation (HR 2.81, P = 0.001)
  - Procedural failure (HR 4.38, P < 0.001)*

*Defined as operator-reported failure, conversion to surgery, failure of clip placement, or residual post-procedural severe mitral regurgitation.
Very severe TR (with significant malcoaptation of the leaflets) may have laminar flow.

**Primary TR: Carcinoid**

- Very severe TR (with significant malcoaptation of the leaflets) may have laminar flow.

**Etiologies of TR**

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<tr>
<td>Secondary</td>
<td>Left heart disease</td>
<td>LV dysfunction or valve disease</td>
</tr>
<tr>
<td></td>
<td>Right ventricular dysfunction</td>
<td>RV ischemia</td>
</tr>
<tr>
<td></td>
<td>Pulmonary Hypertension</td>
<td>RV volume overload, RV cardiomyopathy (e.g. ARVD)</td>
</tr>
<tr>
<td></td>
<td>Right atrial abnormalities</td>
<td>Chronic lung disease, Pulmonary thromboembolism, Left-to-right shunt</td>
</tr>
</tbody>
</table>

**Pathophysiology of Functional TR**

- Etiologies:
  - Left Heart Disease
  - Primary RV disease
  - Hypertensive pulmonary disease
  - Atrial Fibrillation
  - [iatrogenic not included]

- Phases of development:
  - Phase 1: dilatation of RV resulting in tricuspid annular (TA) dilatation with or without TR
  - Phase 2: progressive dilatation of RV and TA result in malcoaptation of leaflets and TR
  - Phase 3: progressive dilatation/distortion of RV result in further TR dilatation and marked tethering of leaflets

**Primary TR: Rheumatic**

- 3D of the TV is oriented with the interatrial septum located inferriorly.

**“Outcomes” based on Echocardiographic Measurements**

- Prophylactic intervention with significant annular dilatation is defined by a diastolic diameter ≥2.5 cm (1-2) or ≥2.2 cm/m² (2) in the four-chamber transthoracic view was associated with improved echo reduced TR progression, improved RV remodeling, and improved functional outcomes.

Outcomes based on Echocardiographic Measurements

- Significant annular dilatation is defined by a diastolic diameter \( \geq 40 \text{ mm} \) or \( >23 \text{ mm/m}^2 \) in the four-chamber transthoracic view
  - Dreyfus J et al
  - Normal: 3.4±0.46 cm (median, 3.2; 95% CI [3.37–4.17]) and 1.85±0.23 cm/m² (median, 1.86; 95% CI [1.36–2.42])
  - TA enlargement defined as \( >42 \text{ mm} \) or \( >23 \text{ mm/m}^2 \) (n = 66 normal volunteers) which is supported by other studies


Approach to FTR: Staging

Stage 1: No or mild TR
- TA <40mm
- Tenting height
- Tenting area

Stage 2: Mild or mod TR
- TA >40mm
- Tenting height
- Tenting area
- Loss of apposition

Stage 3: Severe TR
- TA >40mm
- Tenting height
- Tenting area
- Loss of coaptation
- Annuloplasty
- Annuloplasty with leaflet augmentation


Dreyfus G et al. JACC 2015;65:2331–6

Staging based on 3 Criteria
1. Severity of TR
2. TA diameter
3. Leaflet coaptation

Staging based on 3 Criteria
1. Severity of TR
2. TA diameter
3. Leaflet coaptation

Predictors of Recurrent TR post-TV Repair:
- Tenting height \( \geq 2.96 \) and tenting area \( \geq 23 \text{ cm}^2 \) \( n = 216 \)
- Tenting volume \( \geq 20 \text{ cm}^3 \) \( \text{cm}^3 \)

Tentings height


Assessment of functional tricuspid regurgitation using 320-detector-row multislice computed tomography

A tethering height of greater than 7.2 mm emerged as a likely cutoff value for the recurrence of TR or more after TAP (sensitivity, 72%; specificity, 100%).

The Journal of Thoracic and Cardiovascular Surgery 2014 147, 312-320
DOI: (10.1016/j.jtcvs.2012.11.017)

Why we need Transcatheter Solutions

- Need options for patient with high surgical risk
  - Who have already had left heart valve intervention
    - Surgical
    - Transcatheter (TAVR and MitroClip)
  - Who have naive chests but significant co-morbidities
- Need low risk options to allow EARLIER intervention (phase 2)

3D Echo

RV Strain

Pooled data (though heavily weighted by a single vendor) suggest that global longitudinal RV free wall strain < -20% (i.e., <20% in absolute value) is likely abnormal

Tricuspid Regurgitation Severity

Reoperations after tricuspid valve repair

- Between 1976 and 2002, 74 patients with a mean age of 53.8 +/- 12.2 years underwent valve reoperations for dysfunction of previous tricuspid valve repair
- Hospital mortality (30-day or within first admission) was 35.1%

### TR Severity

<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
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<tbody>
<tr>
<td><strong>Central jet area</strong></td>
<td>&lt; 5 cm²</td>
<td>5–10 cm²</td>
<td>&gt; 10 cm²</td>
</tr>
<tr>
<td><strong>Vena contracta</strong></td>
<td>Not defined</td>
<td>Not defined</td>
<td>&lt; 7 mm</td>
</tr>
<tr>
<td><strong>CW jet density</strong></td>
<td>Soft</td>
<td>Dense</td>
<td>Dense</td>
</tr>
<tr>
<td><strong>CW jet contour</strong></td>
<td>Parabolic</td>
<td>Variable</td>
<td>Triangular, early peaking</td>
</tr>
<tr>
<td><strong>Hepatic vein flow</strong></td>
<td>Systolic dominance</td>
<td>Systolic blunting</td>
<td>Systolic reversal</td>
</tr>
<tr>
<td><strong>IVC</strong></td>
<td>Normal</td>
<td>Normal</td>
<td>Dilated, diastolic septal flattening</td>
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<td><strong>RA</strong></td>
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<td>Normal or mild</td>
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*The Nyquist limit was controlled at 45 to 65 cm/s for JARAA ratio < 0.7.*

**Color Doppler Flow Mapping (at least 2 orthogonal planes)**

Zoghbi WA et al. JASE 2003;16:777-802

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### Hepatic vein flow

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**Color Doppler Flow Mapping (at least 2 orthogonal planes)**

Zoghbi WA et al. JASE 2003;16:777-802
Tricuspid Regurgitation Quantification

**In Functional TR: PISA Correction Factors**

**Correction 1**
- Systematic underestimation of flow rate due to flattening of the isovelocity contours close to the orifice which can be corrected by multiplying the calculated flow rate by $V_p/V_a$.
- Nyquist velocity was 58 cm/sec at a scanning depth of 16 cm.

**Correction 2**
- Funnel-shaped inlet leading to the orifice will constrain the isovelocity contours and a coefficient smaller than 2πr will be needed to yield accurate flow estimates. A correction that has been validated is to multiply 2πr by $\alpha/180$, where $\alpha$ is the angle subtended by the valve leaflets.

**PISA for TR**

$$ROA = \frac{2\pi^2 V_a}{V_p - V_a} \times \frac{\alpha}{180}$$

$V_a$ = aliasing velocity, $V_p$ = peak velocity, $\alpha$ = angle of the tented leaflets

**TR Sevency**

<table>
<thead>
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<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>PISA radius (shift to 28 cm/s)</td>
<td>&lt;0.5 cm</td>
<td>0.6-0.9 cm</td>
<td>&gt;0.9 cm</td>
</tr>
<tr>
<td>PISA EROA</td>
<td>&lt; 20 mm²</td>
<td>20-39 mm²</td>
<td>&gt;40 mm²</td>
</tr>
</tbody>
</table>

The shape of the tricuspid regurgitant orifice is often elliptical or stellate which may result in significant underestimation of the ROA by this method.

**Limitations of Single measurement**

**ROA**

**Timing of Peak Velocity**

**TR Quantitation**

<table>
<thead>
<tr>
<th></th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
</tr>
</thead>
<tbody>
<tr>
<td>3D Vena Contracta*</td>
<td>Not defined</td>
<td>Not defined</td>
<td>&gt;36 mm²</td>
</tr>
</tbody>
</table>

*The Nyquist limit was controlled at 45 to 65 cm/sec for 3D TRAO and 45 cm/sec for 2D TRAO.

The cutoff for 3D VCA (0.36 cm²) was similar to the cutoff for mean of 2D and 3D methods (0.35 cm²), although the latter had better sensitivity and specificity.
Volumetric Method

Can measure TV annulus or orthogonal planes or 3D planimetry
- Annular Area x TVTI = Tricuspid Diastolic Volume (both forward and regurgitant volume)
- LVOT forward stroke volume
- Regurgitant volume = Diastolic SV - Forward Systolic SV

Limitations
- Quantitation of regurgitation has relied upon the use of PISA and VC, however:
  - The shape of the regurgitant orifice is highly variable, from circular to crescent-shaped
    - PISA measurements which assume a hemispheric shape, will typically underestimate the true regurgitant orifice of an ellipse or crescent.
  - The timing of regurgitant flow is dynamic.
  - Direction and location of regurgitant flow may significantly influence the measurement of both PISA and VC, particularly in the setting of eccentric jets with constrained proximal flow regions.
  - Multiple jets effect the PISA radius since flow from the LV to the LA is determined by the total EROA.

Annular Area x TVTI = Tricuspid Diastolic Volume (both forward and regurgitant volume)
- LVOT forward stroke volume
- Regurgitant volume = Diastolic SV - Forward Systolic SV

Doppler Measurements of TR Severity

Hahn RT (submitted for publication Circ CV Imag)

Doppler Measurements of TR Severity


Percutaneous Approaches for Tricuspid Regurgitation
RV and RA Anatomy

Conduction System

From a Bicaval View

Transcatheter Tricuspid Solutions

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

Anatomic Target
1. IVC
2. Leaflets
3. Annulus
**MitraClip For Functional TR**

**Internal Jugular Approach**

**Common Femoral Approach**

Presented by Brij Maini at TCT 2015

---

**Transatrial intrapericardial tricuspid annuloplasty (TRA IPT A)**

(A) Braided suture (packaging and spool), transatrial intrapericardial tricuspid annuloplasty (TRA IPTA) implant and delivery device. (B) TRA IPTA implant loaded onto delivery device. The suture is housed within the hollow TRA IPTA implant with a pre-tied Roeder sliding knot. (C) The system is advanced into the pericardium through the right atrial appendage. (D) The nitinol delivery device ensures that the system opens into a loop inside the pericardium and reaches the atrioventricular groove. (E) The delivery device is withdrawn. (F) The implant is tightened.

Rogers, T et al. J Am Coll Cardiol Intv 2015;8:97–99

---

**Off-label Use of MitraClip**

**Baseline TR**

~70–80 implanted around the world

Presented by Brij Maini at TCT 2015

---

**Transatrial intrapericardial tricuspid annuloplasty (TRA IPT A)**

---

**Top Down: Tricuspid Clip**

Courtesy of Robert Schueler
University of Bonn, Germany

---

**Cardioband MR**

Mitral Valve View

FlexiSlice

Courtesy of Robert Schueler
University of Bonn, Germany
Early Feasibility Trials in the US

4Tech TriCinch System

1. Assessment of the right side of the heart....

Courtesy of Philippe Blanke
2. Tricuspid Annulus
Non-planarity—Annular Dimensions

3. Prediction of Fluoroscopic Angulation
Coplanar view to facilitate Coaxial Deployment

4. Caval veins
Quantification of anatomical dimensions and orientation

Edwards FORMA Repair System
Designed to restore leaflet coaptation
FORMA Repair System consists of:
- Spacer
  - Positioned into the regurgitant orifice
  - Creates a platform for native leaflet coaptation
- Rail
  - Tracks Spacer into position
  - Distally and proximally anchored

Hospital outcomes:

- Death
  - 0%
- Paravalvular leakage
  - 0%
- Leaflet damage
  - 0%
- Vascular or access site complications
  - 0%
- Pneumonia
  - 0%
- Hospitalization length (days)
  - Median: 4 (IQR: 3-5)
Figure 1. Right atrial angiogram to demonstrate relations of the TV on fluoroscopy.

Left, Frame from the AP projection of the RV in systole. The TV is in closed position. Right, Lateral projection with RV in diastole and TV in open position.
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
**Trialign Device**

Step 1: Wire Delivery

Step 2: Pledget Delivery

Step 3: Second Wire Delivery

Step 4: Plication and Lock

---

**Sweep of Posterior Annulus for Trialign**

---

**CT Planning for Trialign**

Posterior Wall View

1st Tricuspid Wire Delivery Catheter

‡ - Likely TWDC 1st CW
† - 2nd TWDC

†‡ - Likely TWDC 1st CW
† - 2nd TWDC

---

**Intra-procedural TEE**

* During radiofrequency deployment, catheter moved
* Position now too posterior (not at septal-posterior commissure)

---

**CT Planning**

Posterior wall view

Posterior-posterior implant location

Ideal Distance between pledgeted sutures: 2.4-2.8 cm

Distance 2.7 cm

---

**Intra-procedural TEE**

Second Wire Re-Position x3

Ideal Distance between pledgeted sutures: 2.4-2.8 cm

Distance 2.7 cm

---
SCOUT
- Percutaneous or secondary TR
- No previous Tricuspid repair or replacement
- No PTA valve stenosis or regurgitation ≥ moderate
- LVEF ≥ 35%
- Must have PAP ≤ 60 mmHg
- Right Ventricle TAPSE ≥ 13 mm
- Tricuspid annular diameter ≥ 40 mm and ≤ 55 mm
- ECHO
  • No other valve stenosis or disease requiring intervention ≤ 30 days
  • LVEF ≥ 25% within 2 weeks of implant
  • PAP < 2/3 of systemic pressure via TTE within 45 days
  • No moderate or greater Tricuspid stenosis
  • No right sided intracardiac mass, thrombus or vegetation
  • Tricuspid valve/right heart anatomy suitable for the study device:
    - Native tricuspid annulus area < 2.63 cm² (12 mm device)
    - Sub-valvular structures/anatomy that would preclude from proper anchor or coaptation device placement, positioning and retrieval

FORMA
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  • Tricuspid valve/right heart anatomy suitable for the study device:
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    - Sub-valvular structures/anatomy that would preclude from proper anchor or coaptation device placement, positioning and retrieval

Task | Purpose | Imaging
--- | --- | ---
Pre-procedural Planning | Assess tricuspid valve morphology and function | • Determine device size and function
 | - TVOA | • TEE (2D and 3D) | • Modeling
 | - EROA and Reg Vol | | |
Intra-procedural guidance | Guide wire delivery and device placement prior to release | • Device location and stability function
 | - Valvular function | • TEE (2D and 3D) and 
 | | - ANSI/JCE | 
Post-procedural Assessment | Assess tricuspid valve morphology and function | • Confirm residual lesions
 | | | • TEE (2D and 3D)