Percutaneous Tricuspid Valve Therapies: The Next Frontier?
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The Ohio State University Structural Heart Disease Course
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Outline

- Is the Tricuspid Valve Relevant?
- Data and Guidelines for TV Interventions
- A Role for Percutaneous Therapies?
- Developing Approaches
- Case
Middle child of adult valvular heart disease

Surgical tricuspid valve repair historically avoided
  ▪ Fix left sided heart disease, may improve

High morbidity and mortality
  ▪ Organ dysfunction
  ▪ Right heart failure
  ▪ Pulmonary hypertension

Is the Tricuspid Valve Relevant?

- Arbulu et al., 1991 J Thorac Cardiovasc Surg
  ▪ 53 patients (IVDA) with right sided endocarditis
  ▪ Valvulectomy without replacement
    ▪ 16 (30%) died, 6 within 45 days
    ▪ 6 (11%) later with valve replacement due to refractory right sided heart failure

Some tolerate, so do not…
Tricuspid Valve Disease is Different…

<table>
<thead>
<tr>
<th>Functional TR (90%)</th>
<th>Primary TR (10%)</th>
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</thead>
<tbody>
<tr>
<td>Pulmonary arterial hypertension (75%)</td>
<td>Ebstein’s anomaly</td>
</tr>
<tr>
<td>Left heart disease</td>
<td>Pacemaker/ICD/EMB</td>
</tr>
<tr>
<td>Congenital conditions, surgeries</td>
<td>Endocarditis</td>
</tr>
<tr>
<td>RV infarction, cardiomyopathies</td>
<td>Rheumatic heart disease, carcinoid</td>
</tr>
<tr>
<td>Left to right shunt (ASD, VSD, APV)</td>
<td>Myxomatous degeneration</td>
</tr>
<tr>
<td>Pulmonary stenosis</td>
<td>Connective tissue disease</td>
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<tr>
<td></td>
<td>Drugs (anorectic)</td>
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</tbody>
</table>

Multiak 2007; Stuge 2006, Rogers and Bolling 2010

Tricuspid Regurgitation and Mortality

5,233 patients, TTE at VAMC, 4-year follow up

<chart>

Independent of PA pressures, LV or RV function

Nath et al., JACC 2004
Tricuspid Repair During Left Sided Surgery?

Moderate or greater TR present in up to 50% of those undergoing MV surgery

- Surgery for ischemic MR, incidence of mod TR
  - 25% < 1 yr
  - 50% < 3 yrs
  - 75% > 3 yrs

- >90% “isolated TR” occurs after left-valve surgery
- Reoperation has operative mortality 10-25%

Tricuspid Repair or Ring?

Coincident tricuspid disease should be addressed, and generally with a ring rather than isolated surgical repair

Recurrent TR

Long-term survival

Observational study, n = 702, 85% functional, left-heart surgeries with moderate-severe TR

Rogers and Biling, 2009; Stab et al., 1999; Kim et al, 2009; Mangoni et a., 2001

Tang et al., 2006, Circulation
Class I Indication: Severe, functional TR at the time of left-sided surgery regardless of symptoms

Class IIa Indication: Functional TR with predominant annular dilation at the time of left-sided surgery regardless of symptoms

Class IIa Indication: Symptomatic, severe primary TR at the time of left-sided surgery
Estimated prevalence is 1.6 million in US
More than 50% patients with surgical MR have mod-severe TR
More than 40% acquire moderate-severe TR after mitral valve surgery

Tricuspid Regurgitation and Mortality

5,233 patients, TTE at VAMC, 4-year follow up

Severe TR: 50% survival at ~2-yrs (47 days)
Independent of PA pressures, LV or RV function
Estimated prevalence is 1.6 million in US
More than 50% patients with surgical MR have mod-severe TR
More than 40% acquire moderate-severe TR after mitral valve surgery

The State of Affairs
Are Percutaneous Therapies, Worth Exploring?

- TR is common, and concomitant severe TR exists in most with surgical MR
- TR often develops or progresses in most patients after MV surgery
- If untreated has negative prognostic impact, and re-operation has high mortality

**Guidelines**
- TV repair is recommended during left sided surgeries, not commonly undertaken
  - Minimizing cardiopulmonary bypass time, general anesthesia is desirable
  - Managed medically, referred typically after right heart failure and organ dysfunction

- A large number of patients might benefit from safe, less invasive TV therapy
- Concept of “early” repair, before right heart failure or organ dysfunction
- No approved percutaneous devices
Strategies for Percutaneous Intervention

**Cinch, Coapt, or Re-construct**

**Cinch (Annular Reduction)**
- Cerclage
- Plication
- Tensioning

**Re-Construct**
- Valve-in-valve
- SVC-IVC Valves

**Coapt**
- MitraClip
- Forma Anchor

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**Strategies for Percutaneous Intervention: Cinch**

**TriAlign (MitrAlign)**

**TriCinch (4Tech)**

*Early CE Mark Trials*
Strategies for Percutaneous Intervention: Cinch

TriAlign (MitrAlign)
- N = 15 patients
- Severe TR, HF, non-surgical
- Implant success 100%
- No proc deaths, major comp
- 30-d 3/15 had detachment
- NYHA, 6MW improved

TriCinch (4Tech)
- n = 3
- Severe TR, HF, non-surgical
- Implant success 100%
- No proc deaths, major comp
- Durable at 6 months
- NYHA, 6MW improved

Early US feasibility (SCOUT)

*Early CE Mark Trials

Strategies for Percutaneous Intervention: Coapt

MitraClip (Abbott)

Forma Anchor (Edwards)*

~3:1 AS:PS

*Early US feasibility

~ Nickening et al. 2017; Campelo-Parada et al. 2015

~ Hahn et al. 2017; Fortech, TVT 2015

~THE OHIO STATE UNIVERSITY MEDICAL CENTER

~O H I O S T A T E U N I V E R S I T Y
Strategies for Percutaneous Intervention: Coapt

MitraClip (Abbott)
- N = 64 patients
- Severe TR, HF, non-surgical
- Implant success 97%
- ≥1 grade reduction 91%
- No proc deaths, major comp
- 3 in-hospital deaths (5%)
- NYHA, 6MW improved

Forma Anchor (Edwards)*
- First in man 2015; n = 13
- Severe TR, HF, non-surgical
- Implant success 92%
- ≥1 grade reduction 100%
- No proc deaths, major comp
- No in-hospital deaths
- NYHA, QOL improved

~3:1 AS:PS

*Early US feasibility

Percutaneous Valve “Replacement”

Native: Caval Valves
- IVC and/or SVC
- IVC caliber, landing zone
- Limited experience
- NYHA marginally improves
- Dedicated devices forthcoming

Tricuspid Ring: VIV
- 64 year old female…

HOVER (US)
TRICAVAL (Europe)
64 year old female…

- Rheumatic Heart Disease
  - 1982: Mitral valve replacement (Porcine)
  - 1991: Mitral valve replacement (Mechanical)
  - 1994: Mitral valve replacement (Mechanical)
  - 1997: Mitral valve replacement (Mechanical), Aortic valve replacement (Mechanical), Tricuspid valve #34 Physio ring and Mitral valve cadaveric homograft in the tricuspid position

- Congestive cirrhosis, MELD 11, Childs-Pugh Class A

- NYHA IV, repeated paracenteses
Conclusion

- Tricuspid valve disease inconsistently treated
  - Transcatheter approaches are developing, feasible, and procedurally safe
  - May permit us to address many residual questions
    - Patient selection
    - Timing
    - Appropriate trial endpoints
Thank You

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