DEFINE-PCI

- **CONDITION:** Coronary Artery Disease
- **PI:** Emmanouil Brilakis, MD
- **CONTACT INFO:** Amy McMeans | amy.mcmeans@allina.com | 612-863-3895

**DESCRIPTION:** This is a prospective, single-arm, multi-center, non-significant risk pilot study. Consented subjects with CAD who undergo physiologic lesion assessment with iFR<0.90 in at least 1 coronary artery are eligible for participation. After successful PCI to all culprit lesions based on angiographic assessment of the treating physician, a blinded post-PCI iFR and iFR pullback will be performed.

**CRITERIA LIST/QUALIFICATIONS:**
- Present with stable angina, silent ischemia or non-ST-elevation ACS
- Pre-PCI iFR performed in all vessels intended for PCI
- No acute STEMI within the past 7 days
- No Chronic Total Occlusion (CTO) of study vessel or prior CABG

- **SPONSOR:** Phillips Volcano
The Not-so-Forgotten Valve: Latest Advances in Tricuspid Valve Interventions

Jonathan G. Schwartz, MD
Advanced Structural & Congenital Heart Disease Interventional Fellow

5 February 2018

Disclosures

- Nothing to disclose
- Off-label, compassionate use, and trial-only device use will be discussed
Objectives

- Traditional/historical review of TR, therapeutic options
- Review tricuspid anatomy and pathophysiology
  - Focus: TR; tricuspid stenosis & Ebstein’s anomaly saved for another day
- Novel transcatheter therapies
  - Percutaneous repair: Trialign/SCOUT trial (Mitralign), TriCinch (4Tech)
  - Annuloplasty: Cardioband (Edwards)
  - “Leafletplasty”: Tricuspid clip/TRILUMINATE study (Abbott)
  - Annular Spacer: FORMA (Edwards)
  - Valve replacement: TTVR, caval (CAVI), v-in-v, v-in-ring

“Treat other valves & tricuspid disease resolves, or manage with diuretic therapy alone”

Percutaneous therapies

Not-so-Forgotten Valve

- **2017 ACC/AHA Focused Update**
  - No major updates related to TR

- **2017 ESC/EACTS Guidelines for the Management of Valvular Heart Disease**
  - Echo: ideal technique for assessment
  - CMR: preferred for RV size, function

- **Indications**
  - Avoid irreversible RV dysfunction
  - Secondary TR: repair should be performed “liberally”

- **Repair**
  - Preferred to replacement

- **Percutaneous therapies**
  - No recommendations

---


---

### Not-so-Forgotten Valve

#### Recommendations on primary tricuspid regurgitation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery is indicated in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Surgery is indicated in asymptomatic patients with severe isolated primary tricuspid regurgitation without severe RV dysfunction.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Surgery should be considered in asymptomatic or mildly symptomatic patients with severe isolated primary tricuspid regurgitation and progressive RV dilatation or deterioration of RV function.</td>
<td>IIa</td>
<td>C</td>
</tr>
</tbody>
</table>

#### Recommendations on secondary tricuspid regurgitation

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery is indicated in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.</td>
<td>I</td>
<td>C</td>
</tr>
<tr>
<td>Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation in the absence of annular dilatation when previous left-sided valve surgery has been documented.</td>
<td>IIa</td>
<td>C</td>
</tr>
<tr>
<td>Surgery may be considered in patients undergoing left-sided valve surgery with mild or moderate secondary tricuspid regurgitation in the absence of annular dilatation when previous right-sided heart failure has been documented.</td>
<td>IIb</td>
<td>C</td>
</tr>
</tbody>
</table>

Background

- TR: Relatively common
  - 70% of adults have at least some TR\(^1\)
  - Brief, follows valve closure, low signal strength
  - Abnormal: usually functional w/RV overload
    - Annular dilation
    - Leaflet tethering
    - VA study: 15.7% of pts had TR > moderate, 8% with primary valve pathology\(^2\)
  - Frequently asymptomatic, often only detected on echo

---

Background

- Functional TR
  - Most common – normal leaflets, chords
  - Dilation of RA/RV, annulus\(^1\), with leaflet tethering\(^2\)
    - Mechanism not fully defined
  - Associations
    - PH, AF\(^3,4\), LV dysfunction, mitral disease
  - Comorbid conditions: induce PH, RV dilation
    - Left HF, MS/MR, primary pulm disease, L to R shunting, Eisenmenger syndrome, PS, hyperthyroidism
  - RV disease: infarction, cardiomyopathies

---

Background

- Valvular abnormalities
  - Uncommon – <10% of pts with severe TR
  - Direct injury: ppm, ICD, biopsy
  - Chest trauma
  - IE (IVDU), rheumatic fever, carcinoid syndrome
  - Ebstein’s, CTD (Marfan)
  - Ischemic
  - Myxomatous (up to 40% of pts with MVP)
  - Marantic: SLE, RA
  - Drug-induced: fen-phen, pergolide


“ Forgotten” valve?

- Pathophysiology
  - Compliant RA → no major hemodynamic consequences w/mild-mod/sev TR
  - RHF symptoms can develop once TR is severe
    - RV systolic dysfunction, decreased CO
    - Elevated CVP → renal dysfunction, unrelated to etiology of lesion or CO
  - Hepatosplenomegaly, ascites, renal dysfunction

- Evaluation
  - Echocardiography
    - Normal vs. abnormal motion
    - RV, RA dilation (unless acute)
    - Severe TR: vena contracta width >0.7cm, systolic flow reversal in hepatic veins

Updates to TR Evaluation

- **Proposed new criteria for TR grading**
  - Qualitative parameters lead to underdiagnosis
  - Severe: VC≥0.7cm, EROA≥0.4cm², regurg volume≥45mL
  - End-stage pts enrolling in trials currently

<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 (dilatation)</td>
<td>&lt;3 mm</td>
<td>3-6.9 mm</td>
<td>7-13 mm</td>
<td>14-20 mm</td>
<td>≥21 mm</td>
</tr>
<tr>
<td>EROA (m²)</td>
<td>&lt;20 mm²</td>
<td>20-39 mm²</td>
<td>40-79 mm²</td>
<td>60-79 mm²</td>
<td>≥80 mm²</td>
</tr>
<tr>
<td>3D VCA or quantitative EROA</td>
<td>75-94 mm²</td>
<td>95-114 mm²</td>
<td>≥115 mm²</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

  - Cutoffs based on grading for mild, moderate TR
  - Will aid in demonstrating grade reductions in TR

- **Cardiac MR**
  - Quantitative assessment of regurgitant volume, regurgitant fraction, RV volumes & EF, associated LV/mitral disease


Tricuspid Regurgitation

- **Prognosis**
  - Severe TR: independent predictor of mortality
    - VA study: 1 yr survival = 64% with severe TR, regardless of PASP or LVEF
    - LVEF ≤ 35%: severe TR indep. predictor of mortality
    - Isolated TR: jet area independent determinant of mortality

- **Management**
  - Symptoms, signs of HF
  - TR severity
  - Presence, extent of associated abnormalities
    - PH, annular dilation, comorbid valvular disease

Tricuspid Regurgitation

- **Therapeutic options**
  - Medical management, counseling, surgery
  - Novel options: percutaneous therapies
  - Underlying causes: mitral disease, CHF

- **Medical management**
  - Often will not consider intervention until all other valves are addressed
  - HF: edema often unresponsive to diuretic therapy
  - PH: therapy can reduce functional TR
  - Correction of MS, chronic thromboembolic PH can lead to improvement in TR

1. Nishimura RA et al. JACC 2014;63(22):e57.

---

Tricuspid Surgical Repair/Replacement

- **Review of guidelines: ACC/AHA**
- **Dependent upon whether left-sided valvular surgery is indicated**

1. Nishimura RA et al. JACC 2014;63(22):e57.
Tricuspid Surgical Repair/Replacement

• Special notes:
  • Primary/functional severe TR does not always improve following left-sided valvular surgical therapy
  • TA dilation diameter >40mm (echo), 21mm/m², or >70mm (intraoperative)
  • Evidence of right heart failure

1. Nishimura RA et al. JACC 2014;63(22):e57.

Tricuspid Surgical Repair/Replacement

• Isolated tricuspid surgery
  • Not well established/agreed upon; AHA/ACC and ESC guidelines similar, slight differences
  • ACC/AHA: Severe TR + symptoms unresponsive to medical therapy, prior to RV dysfunction¹
    Severe congestive hepatopathy
  • ESC: Isolated primary severe TR + symptoms, without RV dysfunction²
  • Asymptomatic TR: uncertain path
    • AHA/ACC: progressive moderate+ RV dilation¹
    • ESC: progressive RV dilation/RV dysfunction²
  • ?Helpful in pericardiotomy pts for constrictive pericarditis

1. Nishimura RA et al. JACC 2014;63(22):e57.
Tricuspid Surgical Repair/Replacement

Rationale: At time of left-sided surgery

- Prevent/improve HF sx
  - No data showing survival benefit...\(^1\)
- Mild-mod TR expected to progress in 25% of pts undergoing left-sided valve surgery\(^2\)
- Pre-op TR predictor of post-op mortality\(^3\), late post-op TR has increased mortality rate\(^4\)
- Risk factors for persistence/progression: annular dilation, RV dysfunction/remodeling, leaflet tethering height, PA HTN, AF, nonmyxomatous MR, ppm/ICD across tricuspid valve\(^2\)
- TR repair does not add appreciable risk to mitral surgery; reop after left-sided surgery: 10-25% perioperative mortality risk\(^2\)

References:

Tricuspid Surgical Repair/Replacement

Rationale: isolated tricuspid surgery

- Control regurg, improve/prevent symptoms
- Surgery can improve functional capacity (observational)\(^1\)
- Survival impact unknown; no statistical difference shown in propensity-matched trial\(^2\)

Repair vs. replacement

- Repair generally favored: ease, speed
- Recurrent TR post-repair substantial, reop mortality risk is high
  - Similar operative mortality for repair vs. replacement, survival rates to 10 years similar\(^3\)

References:
Tricuspid Surgical Repair/Replacement

- Surgical therapies
  - Prosthetic annular ring, band (most durable)
  - Biologic annuloplasty repair: De Vaga procedure (suture A-P annulus), Peri-Guard annuloplasty
  - Kay Bicuspidization (pliate posterior leaflet)
  - More complex procedures
- Operative mortality rates: 6-14%
  - Most pts w/concomitant surgery on other valves
  - 5-yr survival 64-72%, 10-yr survival: 44-47%1
  - Conflicting data: prosthetic ring vs. suture repair – lower risk of post-op TR2,3


Tricuspid Surgical Replacement

- Surgical Replacement
  - High operative mortality rates: 10-33%1,4, lower in modern literature2
  - Most pts w/concomitant valve surgery, or reop
  - 5-yr survival: 60-74%, 10-yr survival: 37-58%
  - Conflicting data abound; operative mortality rates as low as 1.4%, 5-yr survival 95%4
  - Mechanical vs. bioprosthesis: patient-specific
  - ESC: favor large bioprosthesis over mechanical
  - Small series reporting homograft use5

Tricuspid Surgical Repair/Replacement

- Timing, risk stratification of intervention
  - Isolated tricuspid surgery: controversial
  - Trial: benefit in operating on symptomatic TR before development of RV end-systolic area ≥ 20cm², or Hgb ≤ 11.3 g/dL
    - Death, readmission at 32 months
  - Risk stratification models
    - STS does not include TV surgery alone, or with MV surgery
    - Others...
- Endocardial ppm, ICD leads
  - Impingement, tethering, perforation, chordae entanglement – address first!
    - Higher mortality rate than TR pts w/o leads
  - Alternative methods of pacing possible


Tricuspid Surgical Repair/Replacement

- Clearly, struggling with:
  - When to intervene
  - Durable therapies
  - Procedures carry high risk
- Tackling TR from a different angle...
Transcatheter Tricuspid Therapies

- Increased attention from IC community\(^1\)
- All are preclinical, early feasibility, or first-in-man evaluations
- Challenge: many patients have torrential TR; complete elimination of TR impossible
- Current clinical experience still very limited
  - Standardized, uniform definitions of efficacy do not exist
  - Impossible to directly compare devices
  - Patients have advanced disease – can be challenging to demonstrate benefit (similar to early TAVR experience)


Tricuspid Anatomy

- Thorough understanding needed for percutaneous intervention
- Complex apparatus, closely linked structures working (or not) in harmony – similar to MV
- Adjacent structures serve as useful anatomic markers for intervention
  - Achieve better results
  - Avoid complications
Tricuspid Anatomy

• Thorough understanding needed for percutaneous intervention
• Complex apparatus, closely linked structures working (or not) in harmony
• Adjacent structures serve as useful anatomic markers for intervention
• Achieve better results
• Avoid complications
• Echo: anatomical, functional assessment
• CT increasingly utilized
• Spatial resolution, multiplanar/3D interface
• MR is gold standard of RV assessment; limited use currently


Tricuspid Anatomy

• Most anterior valve
  • Oriented vertically, oval orifice, larger than mitral valve
  • Annulus changes under varying loading conditions
  • Fibrous annulus, leaflets, papillary muscles, chords
  • Trileaflet: septal, anterior, posterior
    • Anterior is largest, may be notched
    • Posterior usually smallest, often scalloped
    • Can be up to 6 leaflets – supernumerary and/or commissural cusps
  • Marked variability in papillary muscles
  • Coronary sinus ostium lies in between IVC orifice and septal portion of tricuspid annulus
  • RCA in AV groove, close to annulus; great variability

Tricuspid Regurgitation

- FTR: Continuum, dynamic process; extremely dependent on heart loading conditions
- Annular dilation
  - Develops laterally along RV free wall, both anterior and posterior directions
  - Annulus loses its 3D shape, becomes more circular and flat
  - Significant dilation: >35mm diameter in diastole
- Leaflet tethering
- RV pressure, volume overload
- RV remodeling: risk increases once irreversible

PH: assess with RHC for reversibility, use Fick


Timing of Transcatheter Interventions

- Functional TR (fTR) with left-sided disease
  - Dilated vs. nondilated annulus
- Isolated atrial annular dilation
  - Rare, low-risk, easily repairable
  - Operate prior to RV dilation, PH onset
- Isolated fTR after left heart surgery
  - Sickest patients, longstanding RV overload, several comorbidities
  - Replacement more likely
  - Intervene when symptoms develop, or when RV enlargement/dysfunction noted
Considerations for Percutaneous Therapy

- **Anatomy:** enormous (nl circumference: 12cm, area 11cm$^2$)
  - Dedicated technologies will be ideal
  - RVOT obstruction is rare
- **Fragile leaflet tissue** (esp. vs. mitral tissue)
- **Complex anatomy, rarely calcific**
  - Fixation mechanisms important
  - Lower pressures – more durable fixation?
- **Adjacent structures**
  - Bundle of His, AV node, AV septum, CS os, RCA
- **3D echo, CT very helpful given complex anatomy**
- **Heart positioning make echo imaging more difficult**
  - Anterior leaflet, shadowing
- **Leaflet tethering may require combined procedure**
- **RV failure a concern in severe PH, RV dysfunction**

Considerations for Percutaneous Therapy

- **Uniform definition of achievable endpoints do not exist at present**
  - Patient subgroups, treatment approaches vary
  - Paul's slide here
Interventional Imaging

<table>
<thead>
<tr>
<th>Modality</th>
<th>Pre-procedural Planning</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICE</td>
<td>1. Navigation of devices</td>
</tr>
<tr>
<td></td>
<td>2. Guidance to the target zone and fine positioning of devices</td>
</tr>
<tr>
<td></td>
<td>3. Discerning annulus from leaflets</td>
</tr>
<tr>
<td>Fluoroscopy</td>
<td>1. Identification of catheters, guidewires, and other metallic devices</td>
</tr>
<tr>
<td></td>
<td>2. Rough navigation to the target zone</td>
</tr>
<tr>
<td>Angiography</td>
<td>1. Anatomic relationship of RCA</td>
</tr>
<tr>
<td>CT scan</td>
<td>1. TV remodeling parameters (TA shape, localization of commissures, accurate TA measures)</td>
</tr>
<tr>
<td></td>
<td>2. Anatomic relationship of RCA</td>
</tr>
<tr>
<td></td>
<td>3. Semiquantitative evaluation of the tissue quality adjacent to the TA</td>
</tr>
<tr>
<td></td>
<td>4. Vascular map and IVC sizing</td>
</tr>
</tbody>
</table>

- Pre-procedural planning
  - Selection of candidates, procedure/device
  - Define TR mechanism
  - Characterize TV morphology
  - Analyze anatomic relationships between TV apparatus and nearby structures
  - Determine size of SVC, IVC

- Candidates
  - High/prohibitive surgical risk, fTR, normal leaflet morphology/excursion, annular dilation, no RV remodeling, non-severe PH

1. Rudski LG et al. JASE 2010;23(7):685.
Interventional Imaging

A word about fusion imaging

Fluroscopy + echocardiography: EchoNav (Philips)

- Aligns fluoroscopic, 2D/3D TEE images in space and time
- Can aid in device localization and guidance, characterizing anatomic relationships, localize origin of regurgitant jet

Limited by restricted motion of c-arm


Percutaneous Tricuspid Therapies

- Percutaneous Tricuspid Repair
  - Trialign (SCOUT trial), Mitralign
  - Tricinch (4Tech)
- Annuloplasty: Cardioband (Edwards)
- "Leafletplasty": Tricuspid clip/TRILUMINATE study (Abbott)
- Annular Spacer: FORMA (Edwards)
- Valve replacement: TTVR, caval (CAVI), v-in-v, v-in-ring

Percutaneous Tricuspid Repair

- **Trialign system**: replicate Kay bicuspidization procedure
- **Pledgeted sutures** within TA along length of posterior leaflet
- **8Fr delivery system**, jugular vein approach
- **Plication lock device** brings 2 sutures together
- Numerous reports of successful use
- **Echo guidance**, sub-annular positioning
- **Early Feasibility trial (SCOUT)** completed US enrollment: reduction in annular size, EROA, improved NYHA, MLHFQ, 6m walk test all improved
- **CE mark trial (SCOUT II)** enrolling in Europe


**SCOUT trial at MHI**

- **Currently enrolling at US**
- **Inclusion criteria:**
  - Age ≥18, ≤85 years
  - NYHA II-IV
  - Symptomatic despite GDMT, pt on diuretics at minimum
  - LVEF ≥35%
  - TA diameter ≥40mm (or 21mm/m²), ≤55mm (or 29mm²)
- **Exclusion criteria:** Prior TV intervention, severe CAD, PCI within 30d, chronic steroids, life expectancy <12 months
Percutaneous Tricuspid Repair

- **TriCinch System**: replicate Kay bicuspidization procedure (4Tech)
  - Cinches annulus at antero-posterior commissure
  - Permanent corkscrew implant with self-expanding IVC stent in hepatic region (applies tension)
  - 24F sheath, 18F delivery system
  - Corkscrew inserted into annulus at AP commissure (close monitoring of RCA needed), attached to stent
  - Pull test checks cinching, repeated echo assessment after each degree of cinching
  - Cinching maintained by nitinol IVC stent
  - Can deliver under moderate sedation if ICE used
  - Initial reports favorable, some complications
    - Next gen: intrapericardial anchor
  - PREVENT trial completed enrollment in Europe


---

Percutaneous Tricuspid Annuloplasty

- **Cardioband transcatheter system**: (Edwards)
  - Currently indicated for treatment of secondary/functional MR (CE mark)
  - Direct annuloplasty system, transvenous approach, beating heart deployment
  - Deployed along posterior MV annulus, adjusted under TEE guidance
  - Polyester sleeve with anchors, premounted contraction wire
  - Cinching tool: proportional reduction between anchors
  - Reduces MR, improves HF symptoms and exercise capacity, no deaths reported
  - Several investigators modified procedure for functional TR
    - Reduced regurgitant volume, orifice area 50-70%, mean RAP
  - TRI-REPAIR-CE now enrolling in Europe

Percutaneous Tricuspid Annuloplasty


Percutaneous Tricuspid Annuloplasty

- **Anatomic challenges**
  - Annulus: close proximity to RCA
  - Access: limited
    - Transapical: Thin RV wall
    - Transfemoral: acute angle between TV and IVC
    - IJ/SVC: ergonomically awkward in cath lab
  - Large annular diameters: prostheses nearly 2x size of aortic devices
  - Imaging difficulties, lack of standards
- **Complete vs. incomplete annuloplasty**
  - More experience with incomplete thus far
  - Efficacy, durability?
"Leafletplasty"

- MitraClip system: Tricuspid Clip
- >300 procedures performed worldwide
- Step-by-step descriptions published
- Address HF, MR prior to TV clipping (RHC)
- RV failure, severe PH excluded from trials
- 97% success rate, 91% reduction in TR by at least 1 grade
- No major complications
- NYHA class improved at d/c
- 6m walk times improved at 30d
- TRIUMPH I study enrolling now
- TRIClip system EFS
- MHI: 1st implant worldwide

Case Review

• Case files of the MHI
  • 86M CAD s/p CABG (’94, LIMA-LAD and rSVG-D1), severe AS s/p SAVR (’03, St. Jude) + rSVG-OM, severe MR, severe TR with TA dilation and noncoapting leaflets, permanent AF s/p ppm, HTN, HLP, restrictive lung disease
    - TMVR with MitraClip 6/2017
    - Persistent symptoms, severe TR remains
    - PPM lead exchanged for CS lead (7/2017)
    - Considered for TRILUMINATE, screened out
  • Compassionate use commercial MitraClip system (NOT a study patient)

Case Review

• Pre-procedure TTE, TEE
Case Review

- Intra-procedure TEE
TRILUMINATE study at MHI

- Currently enrolling, 1 of 2 sites in US
- Inclusion criteria:
  - >18 years of age
  - Adequately treated for CAD, MR, HF for at least 30d
  - NYHA II (w/severe TR), III, IV
  - No indication for left-sided/pulm valve correlation
  - Heart team in agreement for percutaneous approach
  - Moderate+ TR by TTE, TEE, valve anatomy suitable for implantation (ECL confirmation)
- Exclusion criteria: PASP>60mmHg, prior TV procedure, MR≥3+, RV lead preventing clip

Annular spacer: The FORMA Repair System

- Goal: occupy the effective regurgitant orifice
- Left subclavian vein approach, 20 vs. 24 Fr
- Anchor with attached 42mm foam-filled spacer device, fully removable percutaneously
- 2 sizes available: 12mm, 15mm; fully adjustable
- Determined by VC width per TEE measurement
- Pre-procedural CT necessary – RV anatomy
- Intra-procedural 2D/3D TEE, fluoroscopy
- Leaflets coapt against device
- Multiple successful implants, no complications

Tricuspid Annular Spacer

- Functional status improvement at 30d, durable at 1 year\(^1\)
  - NYHA class improved in 86%, increases in 6m walk distance and KCCQ scores
  - Less edema, decreased diuretic doses, decreased BNP
  - 1 pt: device thrombus – subtherapeutic INRs; resolved 2mo after INR therapeutic
  - Decreased HF hospitalizations in all pts
  - TR improved at least 1 grade in all but 1 pt, residual moderate TR noted in most
- Unclear if anticoagulation needed in absence of AF
- Can be used in pts with leads in RV

1. Perlman G et al. JACC CI 2017;epub.

Caval Valve Implantation (CAVI)

- Orthotopic: valve implanted in anatomically correct position in TV annulus – more likely to result in complete correction of TR
  - Necessary to achieve clinical improvement?
  - Highly variable, less resistance for fixation vs. AoV
  - Large diameters req. enormous leaflet heights to avoid prolapse into RA
- Heterotopic: attractive alternative
  - Straightforward implantation, lower risk of structural damage at implantation
  - No interference with existing leads

Caval Valve Implantation (CAVI)

- First human implant: 2010\(^1\), first small series with Sapien XT in 2013\(^2\), others coming...
  - IVC positioning/cavoatrial junction; safe, feasible, hemodynamically effective
- Still unclear which approach is best, for which patients
- Proper caval valve function: pulsatile blood flow, systolic flow reversal in caval veins
  - CAVI likely primarily effective in pts with preserved RV function
- Uppermost IVC does not dilate significantly = ideal CAVI landing zone
- SVC-RA Inflow massively dilates
  - Anchoring is difficult, if not impossible


Caval Valve Implantation (CAVI)

- Diameters typically exceed current commercially available aortic devices
  - Pre-stenting employed to partially compensate
- Devices: Sapien XT, Sapien 3, TricValve (P&F)
- Trial or compassionate use only
- BEV: SVC/IVC diameter must be ≤30mm, TricValve: 35mm
- TricValve: 2 self-expanding bovine prostheses, PTFE skirt
- 27Fr delivery system
- Subgroup of pts only, does not address TR
  - Mean IVC pressure remains elevated...

Transcatheter Tricuspid Valve Replacement

• Degenerated surgical ring repair, bioprosthetic TV replacement
• Small case series detail successful uses of transcatheter aortic devices (V-in-V, V-in-ring) – off-label use
• 8 years post-surgical TV ring repair: >33% have 3-4+ TR1
• Re-op rare for isolated TR – high-risk, poor outcomes
• Valve-in-ring: largest series 22 patients2
• Reasonable results – no TS or TR, “most” with improved NHYA, no mortality
• 75% had PVL, 78% in the “open”/medial aspect of incomplete surgical ring
• Follow-up procedures in ~half of those with PVL
• Not all rings respond similarly – incomplete rings deform inconsistently with round prostheses; innovation coming…


Transcatheter Tricuspid Valve Replacement

• Prior surgical bioprosthetic TVR: longevity

Transcatheter Tricuspid Valve Replacement

- GATE Tricuspid Atrioventricular Valved Stent

- Transjugular, transatrial approach
- Implanted in 3 patients to date
- Close monitoring of RCA – wiring recommended
- TEE, fluoroscopic guidance; ICE can be useful
- May be useful for both fTR and degenerative TV disease
- Less concern for anchoring, RVOT obstruction – unlike TMVR devices
- CMR, TEE useful for PVL assessment post-procedure
- First experiences yet to be published


Summary

Guesses?

— Transported to a surreal landscape, a young girl kills the first person she meets and then teams up with three strangers to kill again.
Final Thoughts

- Large populations exist with fTR with advanced multivalvular heart disease
  - Increasing as we have more effective therapies
- Transcatheter techniques to repair/replace the TV are a burgeoning frontier in structural heart interventions
  - Subpopulations may lead to multiple approved, widely-utilized devices
  - As left heart valvular disease is treated, the tricuspid space serves as the remaining conquerable realm
- Preemptive tricuspid therapies for native TR – too far off for current technology at present, which is attempting to establish technical feasibility

Patient selection criteria, echo parameters, device-specific anatomic selection factors, objective clinical and echo outcomes need standardization and full/open reporting\(^1\)

- Most tricuspid devices: modest TR amelioration by echo
  - Consider: inoperable patients, chronicity & severity of TR, annular dilation
  - Extreme end of TR spectrum, prohibitive surgical risk, failed medical therapies
  - Torrential TR to severe TR seems to show meaningful improvements
    - Most data: not powered to show this
- Randomized trials lacking...but coming soon
- Multiple promising technologies!

\(^1\) Kapadia S et al. Circ 2017;135:1815.
Special Thank You...

• Dr. Paul Sorajja
• Dr. Mario Goessl
• Dr. Richard Bae
• Dr. Karol Mudy
• Marcus Burns, DNP
• Lynelle Schneider, PA-C
• Kate Jappe, RN
• Sara Olson, RN
• MHIF & research team members
• Cath lab & Clinic nurses + staff
• The patients!