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John and Paul

Old

New
Transcatheter Tricuspid Therapy

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Disclosures

- **Consulting or Advisory Board**: Abbott Structural, Anteris, Boston Scientific, Medtronic, TriFlo, Vdyne, WL Gore
- **Institutional Research**: Abbott Structural, Boston Scientific, Edwards Lifesciences, Medtronic
- **National P.I.**: SUMMIT MAC, EXPAND II, HighLife (U.S.), TRILUMINATE II Pivotal, VDyne
Tricuspid Regurgitation
Reasons for Neglect

Survivors of other CV disease
Long indolent period with late RV failure
Severity easily underestimated

2020 ACC/AHA Guidelines
Tricuspid Regurgitation

- L-sided surgery, severe TR (I)
- Severe primary or secondary TR on GDMT (IIA)
- L-sided surgery, annular dilatation, RHF, mod TR (IIA)
- Asx severe primary TR with abnormal RV (IIB)
- Symptomatic severe TR with prior surgery (IIB)

No Class I recs for isolated TR
Survival with Tricuspid Regurgitation
Community Population (n=1,095)

10-year survival, 14%

Isolated TR survival

How Will Transcatheter Therapy Change Tricuspid Regurgitation?
Primary and Secondary TR
Goal is to Restore or Recreate Coaptation

Flex to TV, same as SGC
Placement increases S/L movement \(\sim 4x\)
Height management

TriClip G4 IDE System
Specifically Designed for TR
TriClip G4 IDE System

No 30-day mortality, stroke, CV surgery in EFS

First-in-human TRILUMINATE Cases
August 28, 2019
Symptomatic, severe TR, intermediate or greater risk of mortality with TV surgery, anatomically eligible on GDMT

Randomize 1:1 (N=450) Ability to reduce TR to Moderate or less? Single Arm (N=100)

TriClip Repair Medical Therapy

1-yr Primary Endpoint Death, TVS, HF hosp., KCCQ

Death, KCCQ

TRILUMINATE Pivotal Trial
Worldwide Leadership

Incredible work of MHI and MHIF
TRILUMINATE Pivotal Trial
MHIF is CT/MRI Core Laboratory

Baseline
- RVEDV = 237 ml
- Regurgitant Vol = 86 ml
- RV Diameter = 50.1 mm

30-days after TriClip
- RVEDV = 166 ml
- Regurgitant Vol = 2 ml
- RV Diameter = 43.8 mm

Images courtesy of Dr. João Cavalcante

PASCAL for TR
Compassionate Use Experience

28 patients (79 yrs, 54% women)
- Procedure time, 134 ± 68 min
- Independent grasping, 90%

No death, stroke, bleeding, MI, CV surgery at 30-days

Courtesy, Dr. Neil Fam
Device success in 96%
Device time, 72 ±28 min
LOS, 3 (0, 35) days
2.4% CV mortality at 30-days

Kodali S, et al., TCT 2021

EVOQUE Percutaneous TV Replacement
TRISCEND 6 Month Follow-up

Intrepid Case at MHI

Conformable, 42-48 mm
27 mm valve
35-42 Fr venous system

National PIs: Drs. Vinayak Bapat, Azeem Latib
VDyne Case at MHI (FIH)
Fits non-circular RV

28 Fr delivery sheath
30 mm valve
140-180 mm perimeter
Treats 70 mm diameter

National PIs: Drs. Michael Reardon, Paul Sorajja

How Will Transcatheter Therapy Change the Science of Tricuspid Regurgitation?
Percutaneous Opportunity #1: RCTs for TR

TRILUMINATE First, but not the last

Testing impact of TR reduction

Excellent safety permits randomization

Optimal GDMT ensured by ECPM committee
  RHC required

Broad inclusion criteria
  Intermediate risk, PAH <70, EF>20%, pacemaker leads

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Percutaneous Opportunity #2
Establishing New Clinical Pathways

New TR Quantitation

Better Description

Hahn RT. Circ Cardiovasc Imaging. 2016 Dec;9(12)
TR patients often at high surgical risk

In-hospital mortality for US surgery for TR (2000-13) = 8 to 13%


Zack CJ, et al JACC 2017

Percutaneous Opportunity #3
New Treatments for TR

EFS data: Any 1 Grade Reduction = better QOL

Need for Expanded TR Grading

Extreme Pathology is Out There

Images courtesy of Dr. Joao Cavalcante

Percutaneous Opportunity #5
New Diagnostic Methods
TRILUMINATE Imaging Substudy

Images courtesy of Dr. Joao Cavalcante
Percutaneous Opportunity #6
Pioneering the Benchmark Endpoints

**Powered for superiority**

- Randomized arm: Death, TVS, HF hosp, KCCQ
- Non-randomized arm: Death, KCCQ

**Key Points**
Percutaneous Therapy for TR

- Addressing a high-risk, neglected condition
- New clinical pathways being established
- More insight into impact on survival and QOL
- New benchmarks for future studies
MHI and MHIF Leadership in TR

Multiple National PIs in Multiple Studies
Top enrollments worldwide
First CT/MRI Core Lab for Pivotal TR Trial
Multiple FIH experiences
Tricuspid Valve Management: Anatomic and Procedural Considerations for Interventional Electrophysiology

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Researcher – Minneapolis Heart Institute Foundation®

Anatomic and Procedural Considerations for Interventional Electrophysiology

Review salient anatomy
Review mechanisms of lead related Tricuspid Valve regurgitation
Review indications for lead extraction relating to TR
Review technical and procedural elements of lead extraction
Review alternative pacing and defibrillation approaches to mitigate lead related TR risk
Interventional EP Anatomy:
Considerations for Endocardial and Epicardial EP Procedures

- When planning an EP procedure consider the following:
  - What is the Target Chamber of the intervention?
    - Right Atrium
    - Right Ventricle
    - Left Atrium
    - Left Ventricle
    - Coronary Sinus
    - Aortic Root
    - Pulmonary Artery
    - There may be other targets for intervention depending upon the intent of the intervention
  - On balance, is the best approach to the target from within the target chamber or otherwise?
  - Can I reach the target or influence it without being inside the target chamber?
Interventional EP Anatomy: Considerations for Endocardial and Epicardial EP Procedures

**RIGHT ATRIUM**
- **Critical Structures**
  - SA Node
  - Crista Terminalis
  - CTI
  - CS Ostium
  - TV annulus
  - Triangle of Koch
  - AV Node
  - Fast pathway
  - Slow Pathway
  - Fossa Ovalis
  - RAA Base
  - RAA Apex
  - Eustachian Ridge
  - Fenestrated CS membrane
  - Atrial Septal Aneurysm
- **Foreign Bodies**
  - RA pacing lead
  - RV/CS pacing leads traversing
  - TV ring/Valve
  - ASD/PFO closure device
  - ASD patch repair
  - LAPTOP Pressure sensor
- **ExtraCardiac Structures**
  - Right Phrenic Nerve
  - RCA under CTI

**RIGHT VENTRICLE**
- **Critical Structures**
  - Tricuspid Valve
  - His Bundle
  - Right Bundle Branch
  - Infundibulum
  - RV Outflow Tract
  - Membranous Septum
  - Muscular Septum
  - Papillary Muscle/Chordae
  - Moderator band
  - Apex
- **Foreign Bodies**
  - RV pacing leads
  - RV ICD leads
  - Micra Leadless pacemaker
  - TV Ring or valve
  - Percutaneously implanted TV clip
Mechanisms of TR attributable to RV leads

- Entrapment of the septal leaflet by the lead body
- Tethering of a TV leaflet by fibrosis to the lead body
- Perforation of a leaflet by the lead body
- Restriction of TV leaflet mobility if subvalvular apparatus ensnared by lead

Surgical misadventures with RV leads

- Removal and reimplantation intraoperatively is fraught with risk
- Jailing a functional RV pace/sense lead during TV replacement
  - Can cause RV lead dysfunction
  - Insulation break
  - Conductor cable fracture
- Precludes transvenous extraction
When to consider transvenous RV lead extraction for severe TR

- If severe TR is confirmed and:
  - TV intervention is feasible
  - Severe RV enlargement and dysfunction are absent
  - Severe annular dilatation is absent
  - Severe immittable PA HTN is absent
  - Severely elevated PVR is absent
- AND an alternative pacing or defibrillation strategy is feasible

![Diagram showing decision tree for transcatheter lead extraction for severe TR](image)


When to consider transvenous RV lead extraction for severe TR

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  - Severe immittable PA HTN is absent
  - Severely elevated PVR is absent
- AND an alternative pacing or defibrillation strategy is feasible
- With non-lead related functional TR and a lead traversing the TV annulus, extraction is indicated to facilitated percutaneous TV intervention
CIED Lead Extraction

- Complex procedure under GA
- Performed in the EP lab with full operative preparation and draping
- Cardiac surgical and perfusion backup
- Operative TEE
- Femoral venous and arterial access
  - Pacing
  - SVC occlusion balloon
  - Arterial pressure monitoring
  - Volume resuscitation/cannulation
- Full removal success 96%
- Mortality 1% (higher for endocarditis)
- 10% risk of TV damage and worsening TR

Extraction Technology: Mechanical rotating blade sheath

- Flexible and controllable – cutting within the tip
- Excellent for traversing the clavicle and subclavian vein
- Physically demanding tool to utilize
  - May require hundreds of clicks
Extraction Technology: Excimer Laser sheath

- 14-16 French 80Hz Excimer Laser 308nm sheath
- Somewhat pliable
- Usually requires a stiffer outer sheath 14-16 French
- Ineffective against calcified adhesions
- Higher risk at the SVC than mechanical solutions
- Greater success rate with lead removal

Extracted Leads
The Dropsy Cowpoke

- 69 year old male
- Congenital PV stenosis with three prior surgeries (age 2, 17, 49)
- ASD closure
- Mild LV dysfunction LVEF 45%
- Permanent AF with CRT-D/AVN RFA
- Kicked in the chest by a cow
- Severe MR repaired with MitraClip
- Severe TR with ICD lead impinging on TV
  - LE edema
  - Ascites

RAO Middle Cardiac Vein Injection

LAO
RAO LAO Anterior Cardiac Vein Injection

RAO LAO Anterior Cardiac Vein pacing lead implant for CRT
Device strategies to avoid causing TR

- LEADR Trial
- 4.7 French Single Coil ICD lead
- Smaller diameter, floppy lead design
- Should cause less TR by flipping to the commissure
- Very robust and easily extractable
- Less likely to cause vascular occlusion
Device strategies to avoid causing TR

- Medtronic 3830 pace/sense lead
- 4.0 French
- Floppy and compliant yet robust
- Suitable for deep septal pacing / conduction system pacing
- Unlikely to cause TR due to design and implant technique
- Very robust lead design

Device strategies to avoid causing TR

- MICRA leadless pacemaker
- Self contained single chamber pacing system
- Implanted in the distal RV septum/Moderator Band
- No lead or hardware impinging upon the TV leaflets
- Possible impingement of subvalvular apparatus
To Review

- Salient Anatomic considerations for EP intervention
- Mechanisms of TR and rationale for lead extraction
- Procedural considerations for extraction
- Cool videos and Gross Specimens
- Case example
- Alternative approaches to pacing and defibrillation to mitigate TR risk
  - LEADR Trial (4.7Fr ICD lead) is currently enrolling at MHI!
- Questions