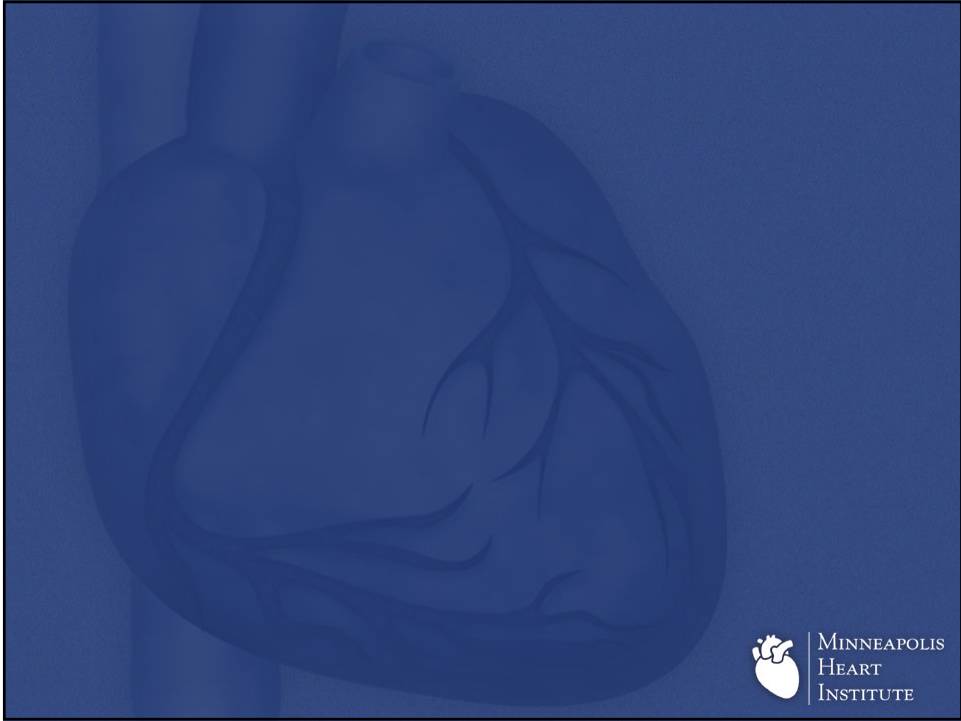


Scan the QR code above or go to Mplsheart.org/GR for a full list of presenters and topics





0

John and Paul

Old



New

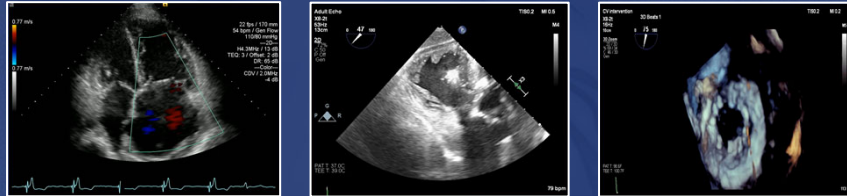




1

MHIF Grand Rounds 2022

Transcatheter Tricuspid Therapy



Paul Sorajja, MD
Roger L. and Lynn C. Headrick Family Chair
Valve Science Center
Minneapolis Heart Institute Foundation
Abbott Northwestern Hospital



2

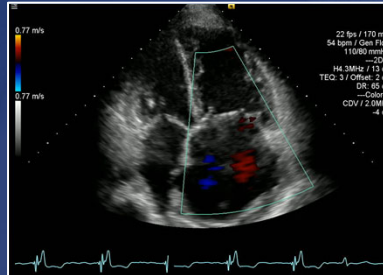
Disclosures

- **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



3

Tricuspid Regurgitation Reasons for Neglect



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



4

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

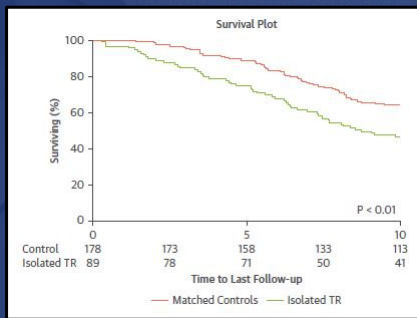
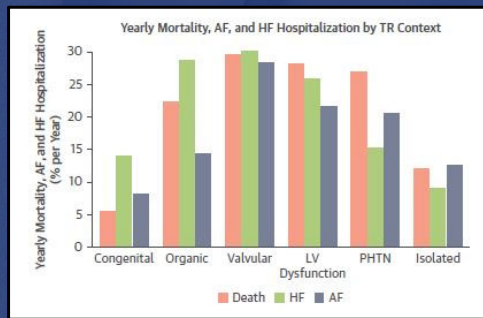


5

Survival with Tricuspid Regurgitation Community Population (n=1,095)

10-year survival, 14%

Isolated TR survival



Topilsky Y, et al. JACC Img 2018



6

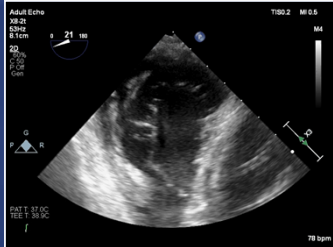
How Will Transcatheter Therapy Change Tricuspid Regurgitation?



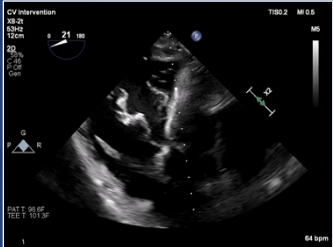
7

Primary and Secondary TR

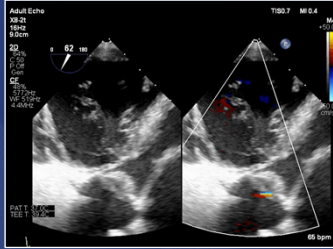
Goal is to Restore or Recreate Coaptation



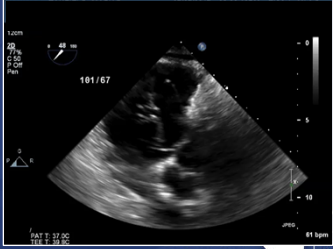
Adult Echo
28.21
28cm
8.1cm
21 mm
TSD2 MI 0.5
M4
78 bpm



CV Intervention
28.21
28cm
12cm
21 mm
TSD2 MI 0.5
M4
64 bpm



Adult Echo
28.21
28cm
10cm
62 mm
TSD7 MI 0.4
M4
65 bpm




1.0cm
20
28cm
48 mm
101/67
TSD7 MI 0.4
M4
61 bpm

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8

TriClip G4 IDE System


Specifically Designed for TR



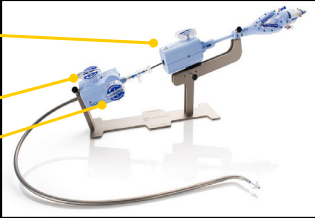
**Flex to TV,
same as SGC**

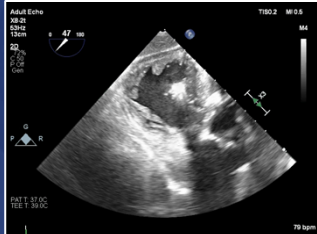


**Placement increases
S/L movement ~4x**

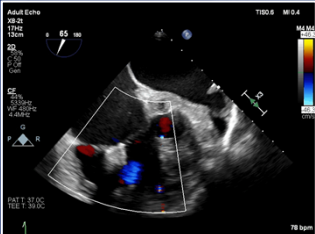


**Height
management**





Adult Echo
28.21
28cm
47 mm
TSD2 MI 0.5
M4
78 bpm




Adult Echo
28.21
28cm
65 mm
TSD5 MI 0.4
M4
78 bpm

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9

TriClip G4 IDE System

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

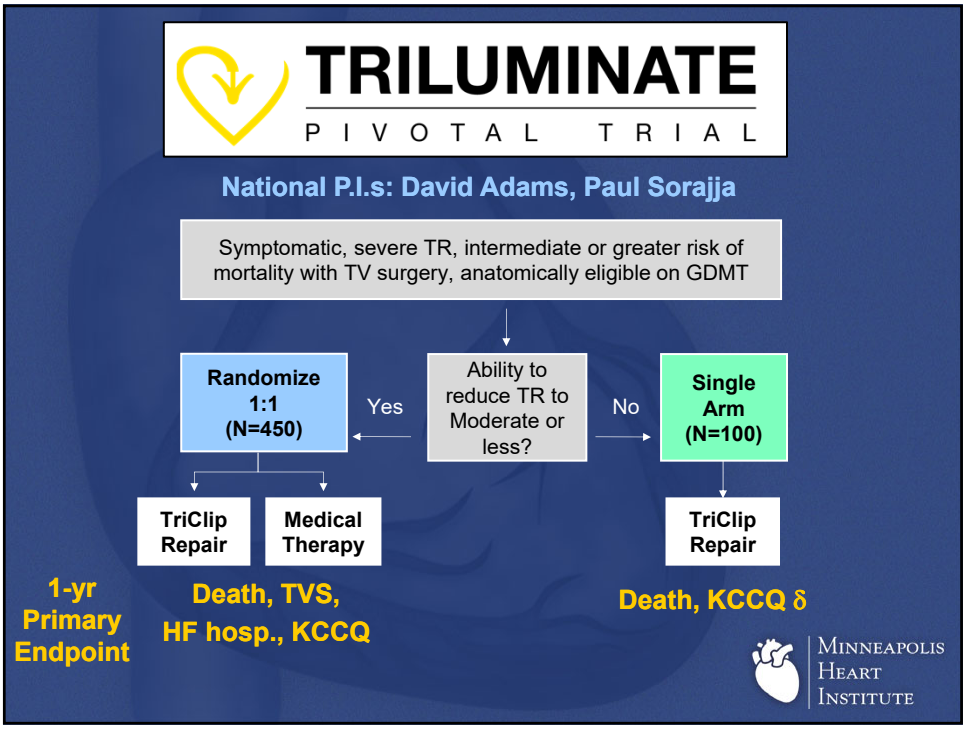


10

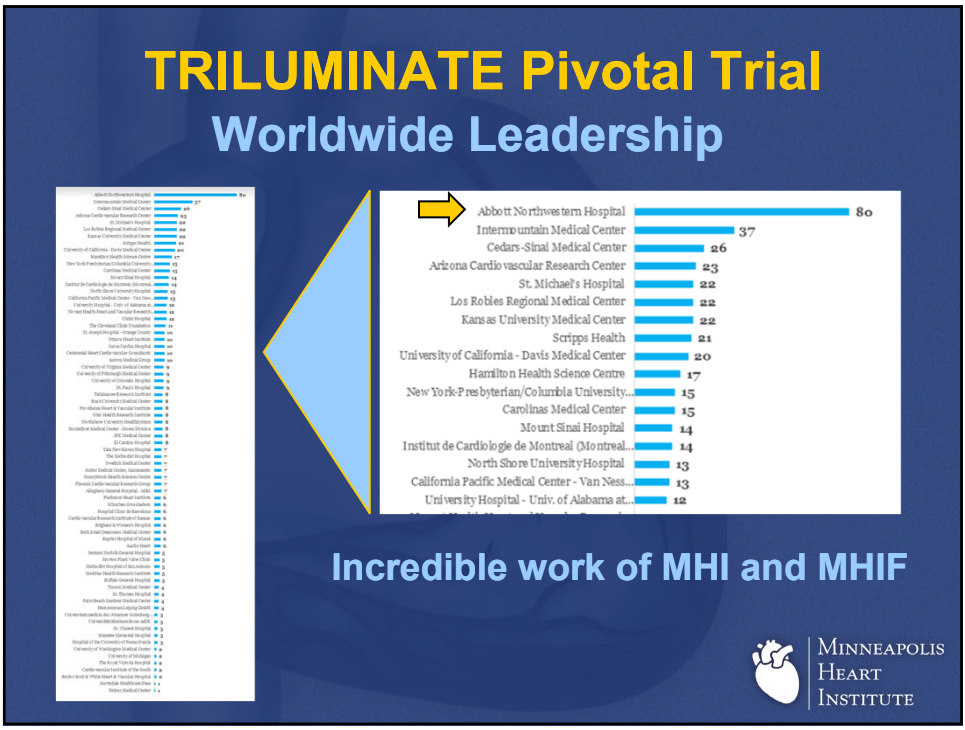
First-in-human TRILUMINATE Cases August 28, 2019



11



12

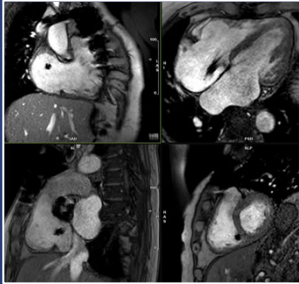


13

TRILUMINATE Pivotal Trial

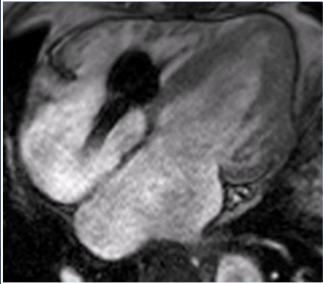
MHIF is CT/MRI Core Laboratory

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


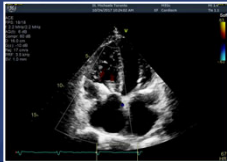
Images courtesy of Dr. João Cavalcante



14

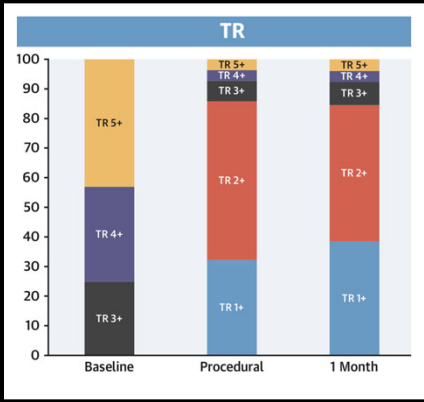
PASCAL for TR

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



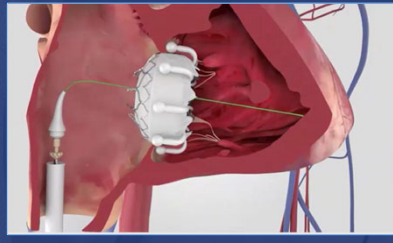
Time Point	TR 1+	TR 2+	TR 3+	TR 4+	TR 5+
Baseline	0%	0%	~25%	~35%	~30%
Procedural	~35%	~50%	~10%	~3%	~2%
1 Month	~40%	~45%	~10%	~3%	~2%

Courtesy, Dr. Neil Fam

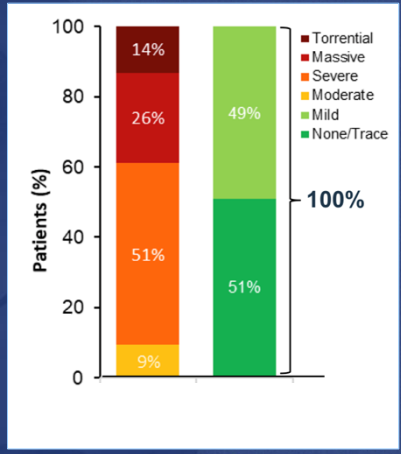


15

EVOQUE Percutaneous TV Replacement TRISCEND 6 Month Follow-up



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

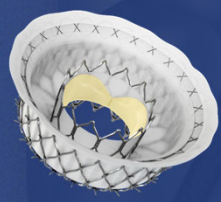


Kodali S, et al., TCT 2021

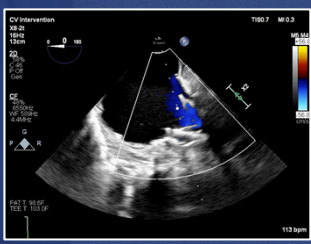
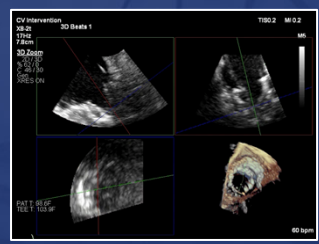
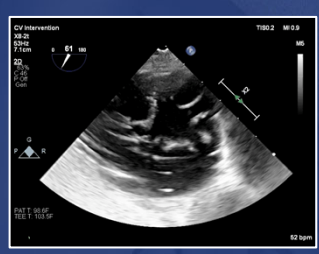


16

Intrepid Case at MHI



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

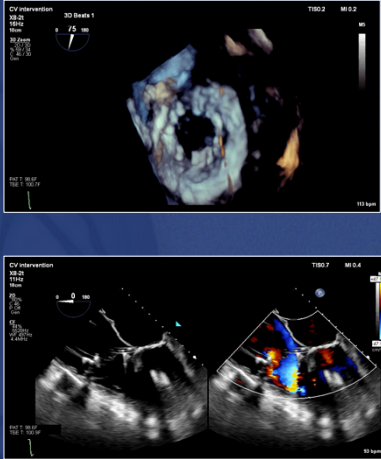




National PIs: Drs. Vinayak Bapat, Azeem Latib




17

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



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How Will Transcatheter Therapy Change the Science of Tricuspid Regurgitation?



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19

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



20

Percutaneous Opportunity #2 Establishing New Clinical Pathways



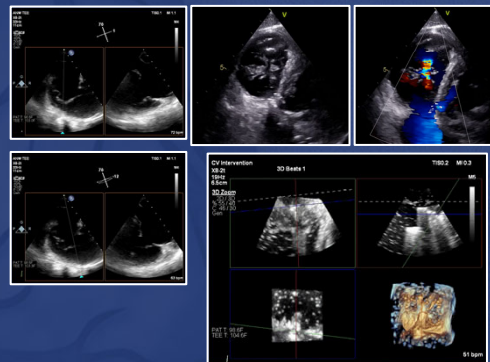
New TR Quantitation

Quantitation Method	Measurements Required	Example	Calculation
PISA	<ol style="list-style-type: none"> PISA radius (r) PISA aliasing velocity (v) (approximately 28 cm/s) TR peak velocity (v_{TR}) TR velocity time integral (TV_{TR}) 		$Q = 2\pi r^2 v$ $ROA = Q/v_{TR}$ $Reg Vol = ROA \times TR_{VTI}$
Quantitative Doppler	<ol style="list-style-type: none"> TV velocity-time integral (TV_{VTI}) PW Doppler sample volume at the annulus 		$Diastolic Stroke Volume = TV_{VTI} \times Area \times TV_{CS}$ $RegVol = Diastolic Stroke Volume - Forward Stroke Volume$ $ROA = RegVol / TR_{VTI}$
3D color Doppler	<ol style="list-style-type: none"> 3D Color Doppler planimetry of annus contracta area (VC_{ann}) TR velocity time integral (TV_{TR}) 		$ROA = VC_{ann} \times TV_{TR}$ $RegVol = VC_{ann} \times TR_{VTI}$

Abbreviations: PISA = proximal isovelocity surface area, TR = tricuspid regurgitation, Q = flow, ROA = regurgitant orifice area, TV = tricuspid valve, PW = pulsed wave, 3D = three-dimensional, RegVol = regurgitant volume, VC = vena contracta

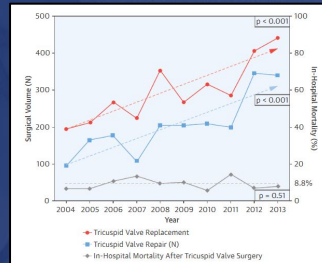
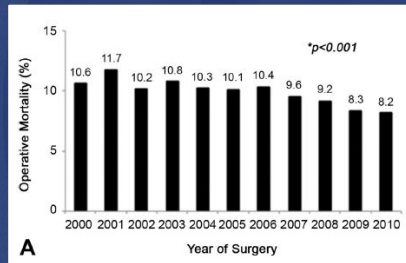
Hahn RT. *Circ Cardiovasc Imaging*. 2016 Dec;9(12)

Better Description



21

Percutaneous Opportunity #3 New Treatments for TR



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

TR patients often at high surgical risk

Zack CJ, et al JACC 2017
Kilic A, et al. Ann Thorac Surg 2013



22

Percutaneous Opportunity #4 Defining What is Meaningful for TR Severity



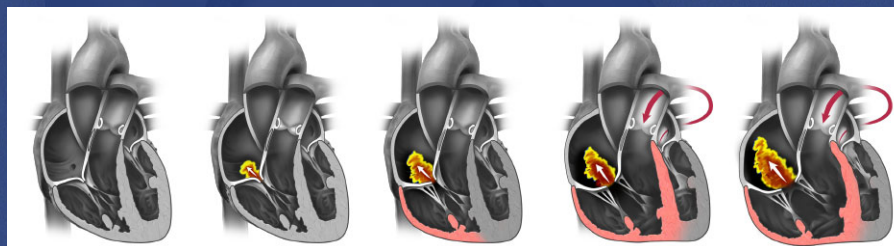
Mild
(Stage 1)

Moderate
(Stage 2)

Severe
(Stage 3)

Massive
(Stage 4)

Torrential
(Stage 5)



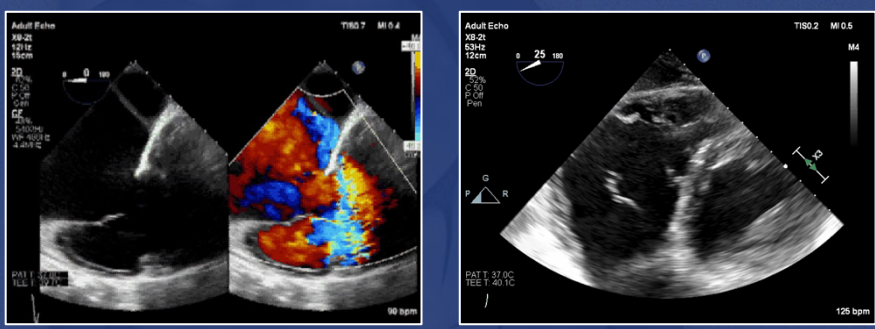
EFS data: Any 1 Grade Reduction = better QOL

Hahn RT and Zamorano JL, Europ Heart J Cardiovasc Imag 2017;18:1342-3



23

Need for Expanded TR Grading

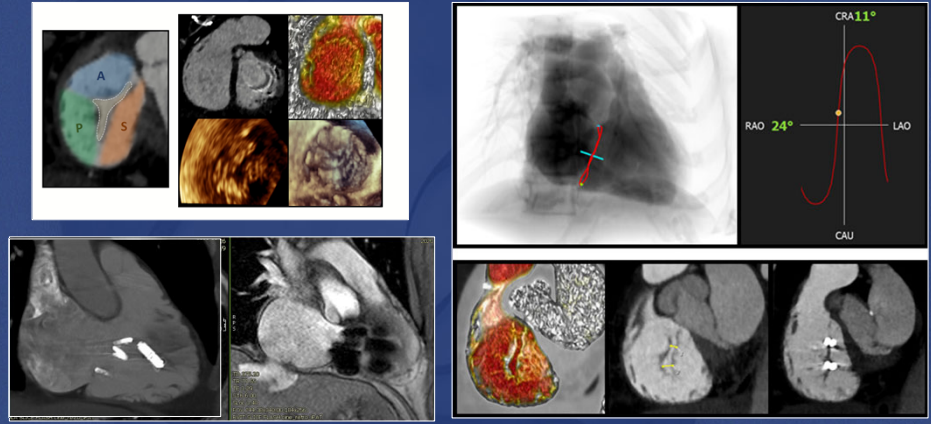


Extreme Pathology is Out There



24

Percutaneous Opportunity #5 New Diagnostic Methods TRILUMINATE Imaging Substudy



Images courtesy of Dr. Joao Cavalcante



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Percutaneous Opportunity #6 **Pioneering the Benchmark Endpoints**



Powered for *superiority*

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



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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**



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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

John S. Zakaib, MD

Cardiac Electrophysiologist - Minneapolis Heart Institute®

Researcher – Minneapolis Heart Institute Foundation®



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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

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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?

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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

Opened right atrium: right lateral view

5

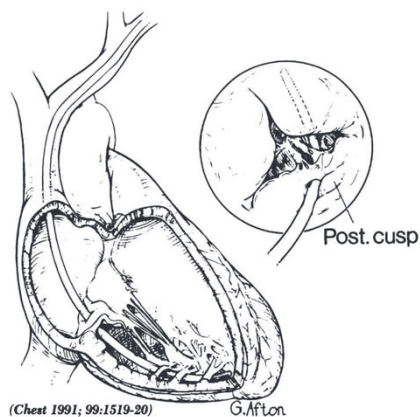
Interventional EP Anatomy: Considerations for Endocardial and Epicardial EP Procedures

- **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

6

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



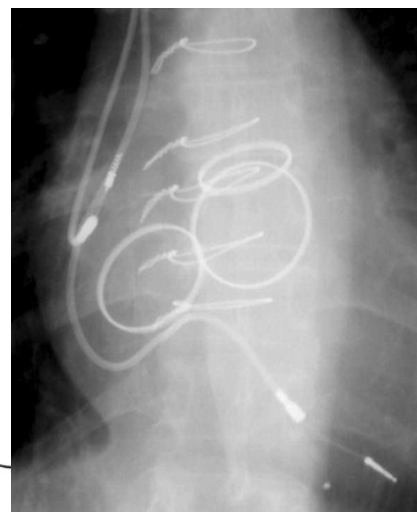
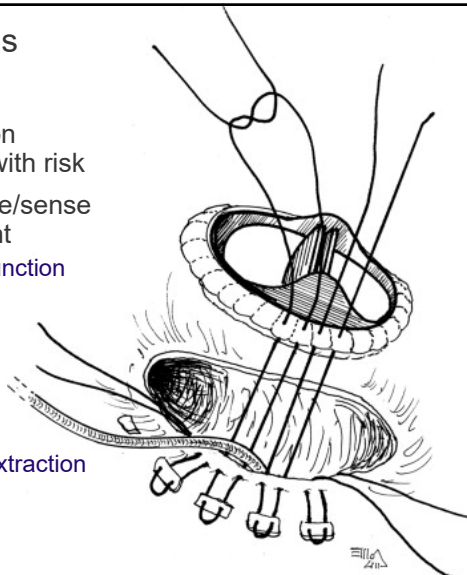
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Surgical misadventures with RV leads

- 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



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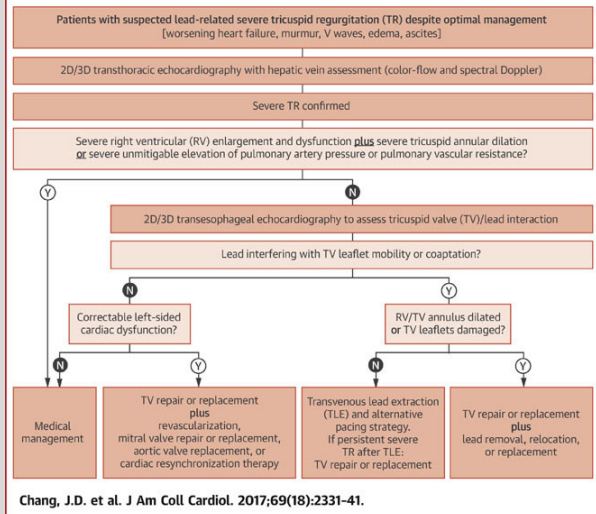
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8

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 inmitigable PA HTN is absent
 - Severely elevated PVR is absent
- AND an alternative pacing or defibrillation strategy is feasible

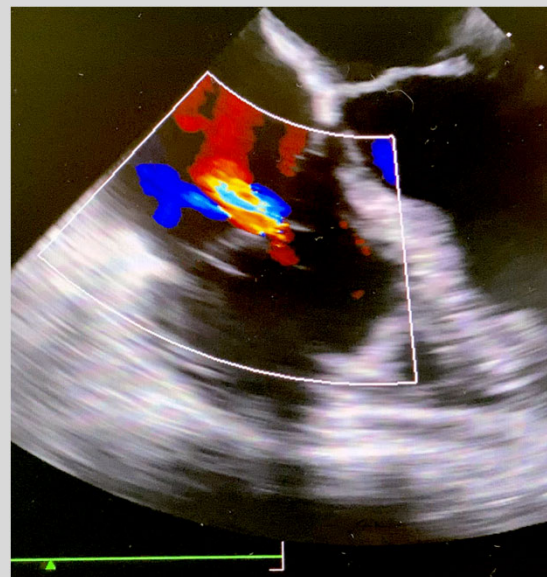
CENTRAL ILLUSTRATION: Decision Tree for Cardiac Implantable Electronic Device Lead Removal for the Indication of Tricuspid Regurgitation in the Absence of Device or Endovascular Infection



9

When to consider transvenous RV lead extraction for severe TR

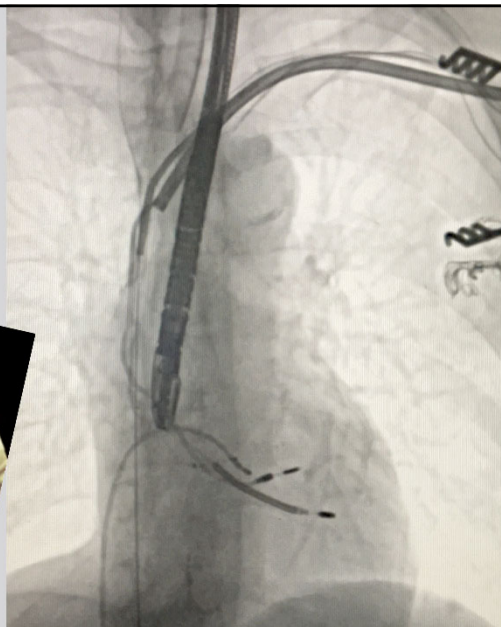
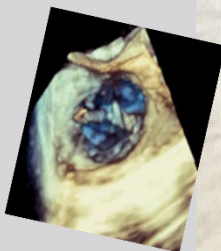
- If severe TR is confirmed and:
 - TV intervention is feasible
 - Severe RV enlargement and dysfunction are absent
 - Severe annular dilatation is absent
 - Severe inmitigable PA HTN is absent
 - Severely elevated PVR is absent
- AND an alternative pacing or defibrillation strategy is feasible
- With non-lead related functional TR and a lead traversing the TV annulus, extraction is indicated to facilitated percutaneous TV intervention



10

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



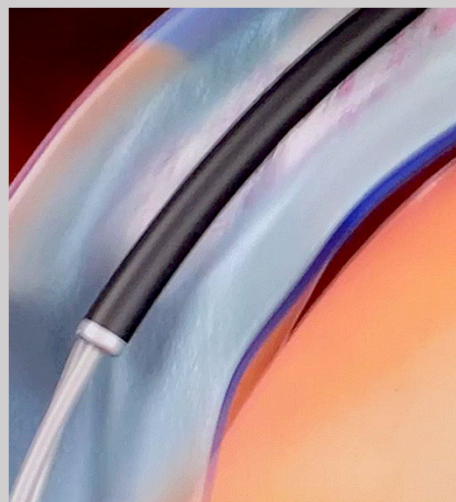
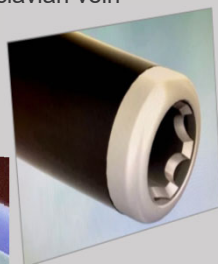
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Extraction Technology: Mechanical rotating blade sheath

- 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



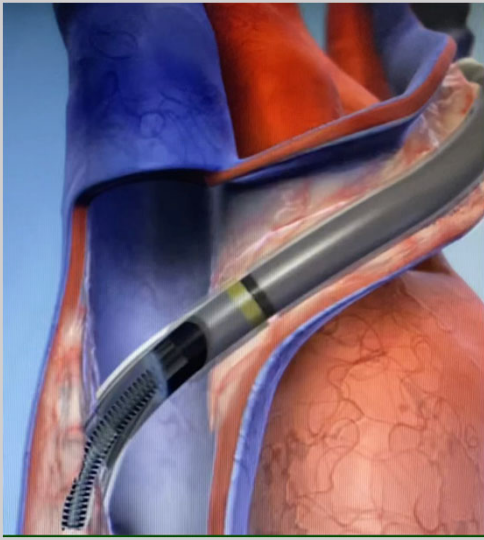
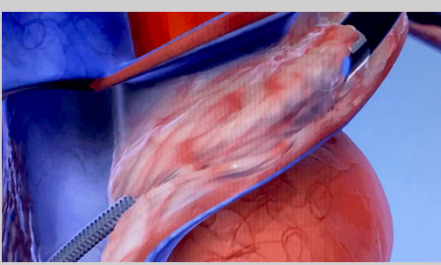
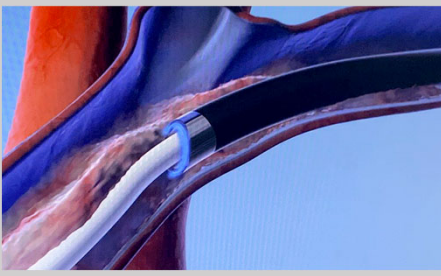
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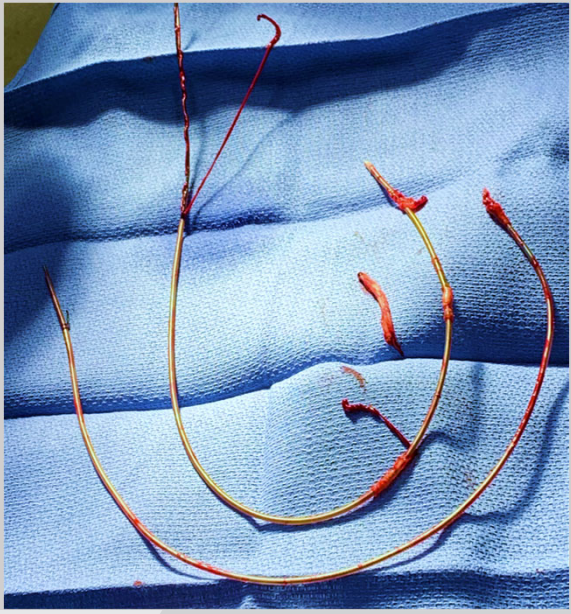
Extraction Technology: Excimer Laser sheath

- 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



13

Extracted Leads



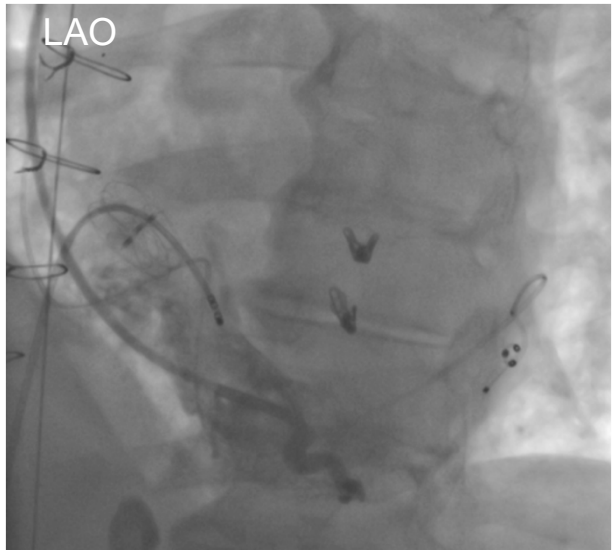
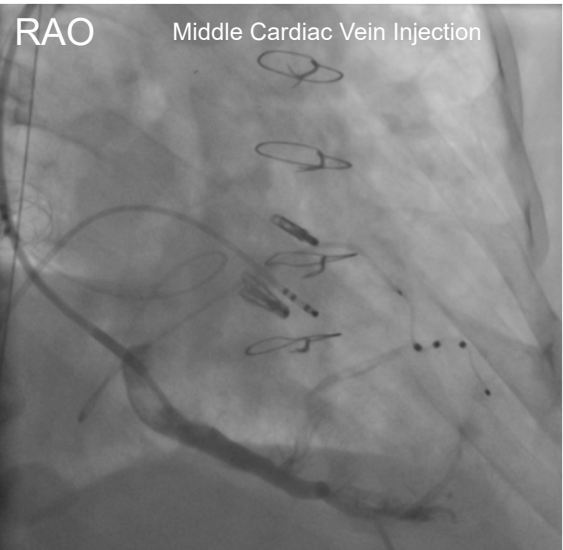
14

The Dropsy Cowpoke

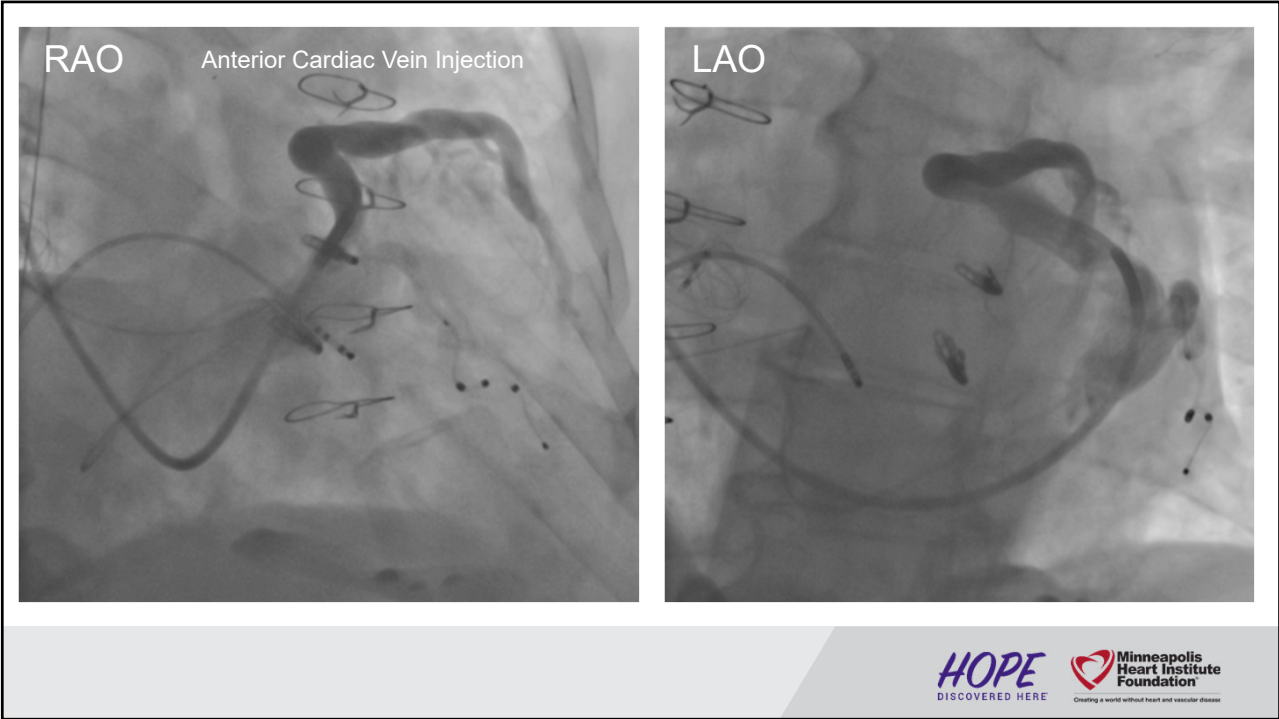
- 69 year old male
- Congenital PV stenosis with three prior surgeries (age 2, 17, 49)
- ASD closure
- Mild LV dysfunction LVEF 45%
- Permanent AF with CRT-D/AVN RFA
- Kicked in the chest by a cow
- Severe MR repaired with MitraClip
- Severe TR with ICD lead impinging on TV
 - LE edema
 - Ascites



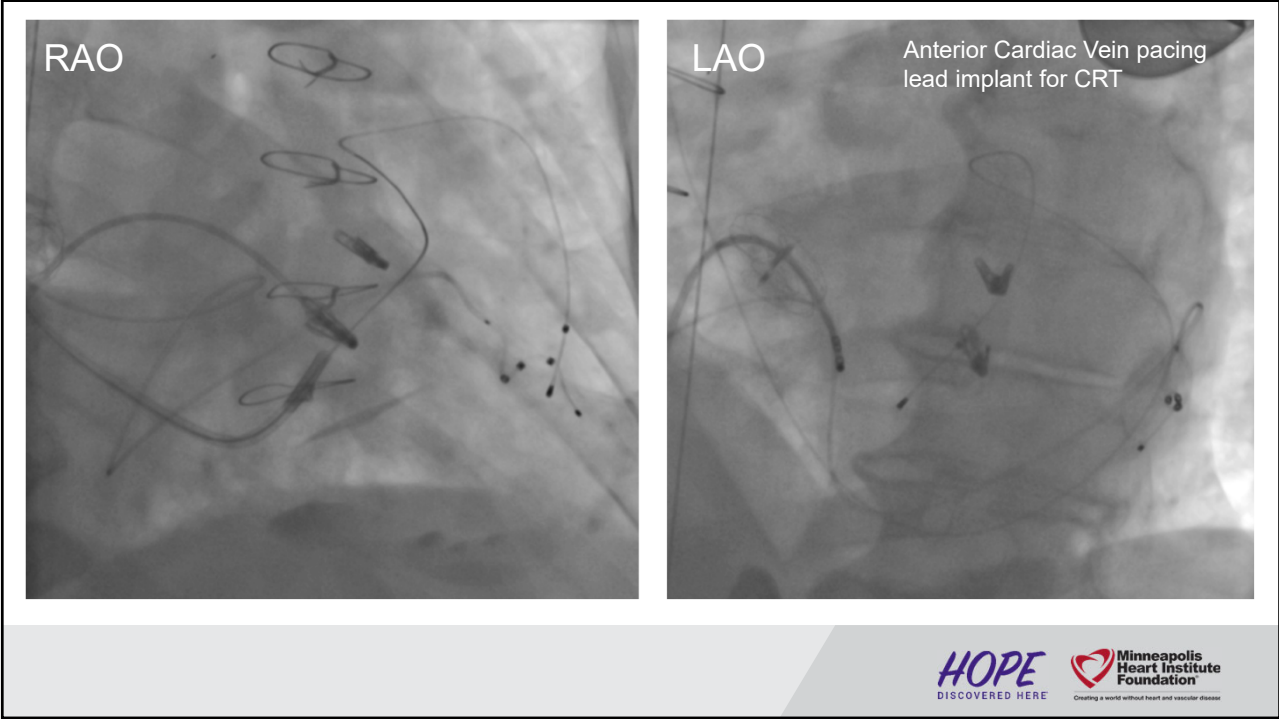
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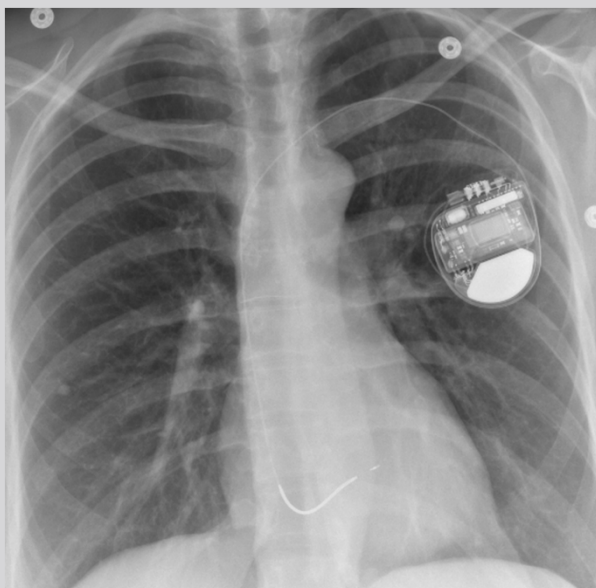
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Device strategies to avoid causing TR

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



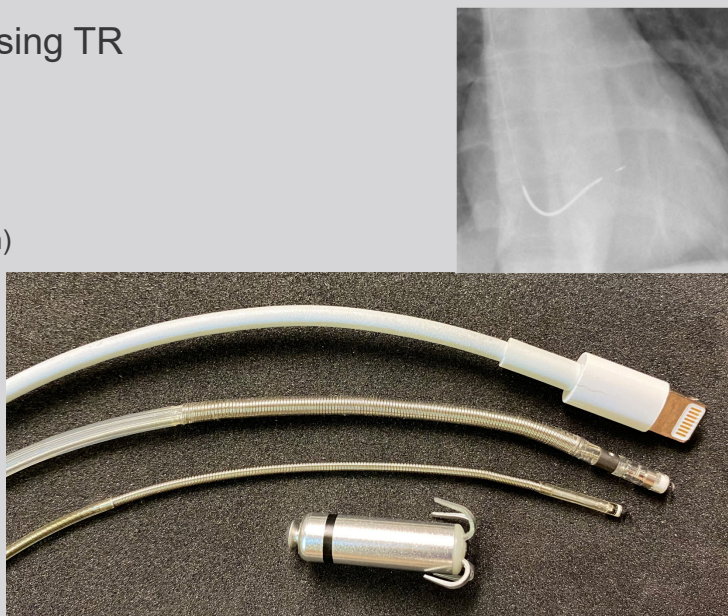
HOPE
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Device strategies to avoid causing TR

- LEADR Trial
- 4.7French Single Coil ICD lead (1.5mm)
- 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



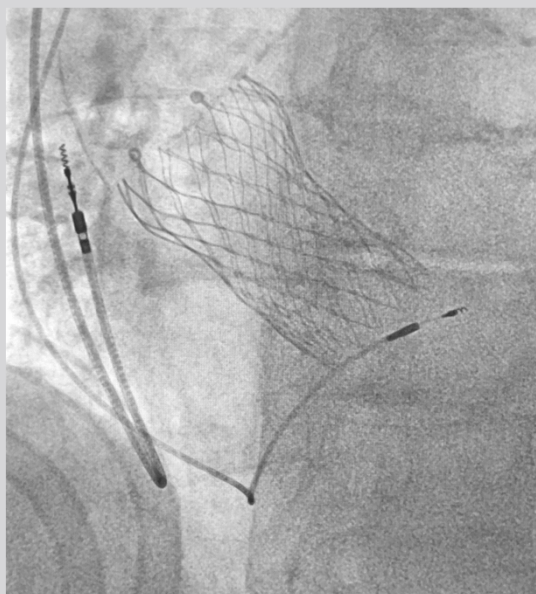
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Device strategies to avoid causing TR

- 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



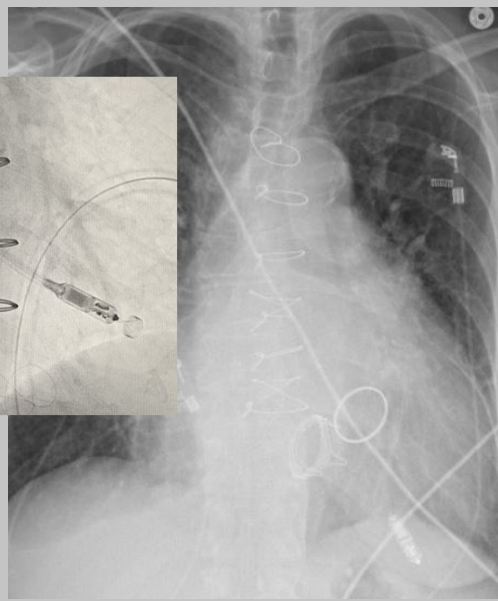
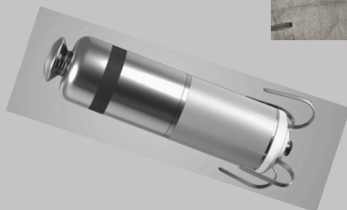
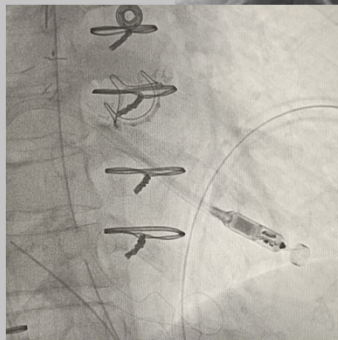
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Device strategies to avoid causing TR

- 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



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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

