MHIF Research Highlights: JANUARY 2020

SHARING EXPERTISE:

Dr. Miedema was featured in *Men's Health Magazine…* in an article, "The Great Millennial Blood Pressure Problem," addressing why high blood pressure is rising for millennials.

MHIF on KSTP Channel 5 News!

Dr. Scott Sharkey and patient, Kristen Bowlds were interviewed by the local KSTP, Channel 5 news for a story about women's heart research and Kristen's experience with SCAD.

FEATURED MHIF STUDIES

Open for Enrollment and Referrals!

HITSOVA for heparin induced thrombocytopenia

CONTACTS: Carina Benson, 612-863-4393 and Jane Fox, 612-863-6289

VESALIUS for high cardiovascular risk without prior myocardial infarction or stroke

CONTACT: Ezi Ebere, 612-863-4393

REDUCE LAP-HF RCT II for heart failure

CONTACT: Jane Fox, 612-863-6289

Shout out of gratitude for Dr. Wang's support of research…

Dr. Wang is appreciated by research staff for always being so open to research and speaking with his patients about the studies! After he gives the introduction, patients are often interested in participating and we are grateful!

MARK YOUR CALENDARS

Heart Valve Awareness Event for Patients!

Thursday, February 20

Minnesota Valley Country Club

REGISTER:
Mplsheart.org/valveday

HOPE DISCOVERED HERE

Minneapolis Heart Institute Foundation
Creating a world without heart and vascular disease

UPDATE ON TRICUSPID REGURGITATION – Evaluation and Treatment

ANENE UKAIGWE, MB;BS
Structural Heart Disease Fellow
Minneapolis Heart Institute/ Abbot Northwestern Hospital
Minneapolis , MN

DISCLOSURES

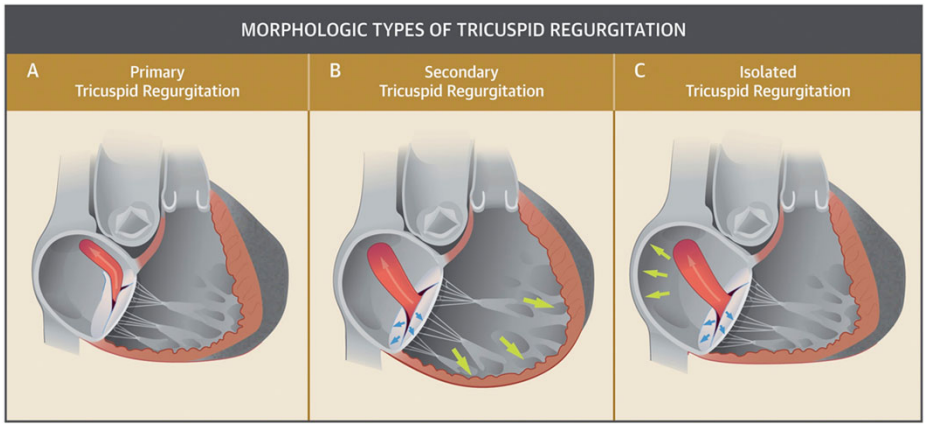
- None
- Off label use and Investigational devices

OBJECTIVES

- Understand burden of Tricuspid Regurgitation and clinical implications
  - Clinical problem, implications, prognosis
- Outline how to evaluate a patient with Tricuspid Regurgitation
  - Annulus, severity, coaptation, RV chambers, PA pressures, planning
- Outline transcatheter treatment options and outcomes.

Classification and Etiology

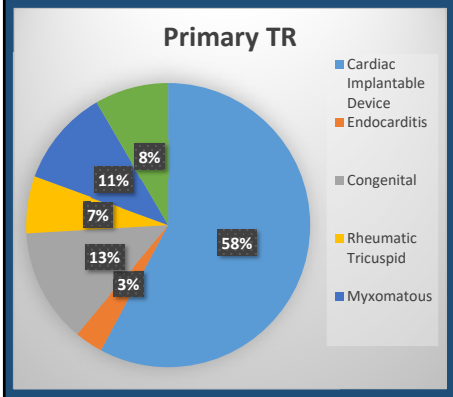
CENTRAL ILLUSTRATION: Schematic Drawing of the Different Morphologic Types of Tricuspid Regurgitation

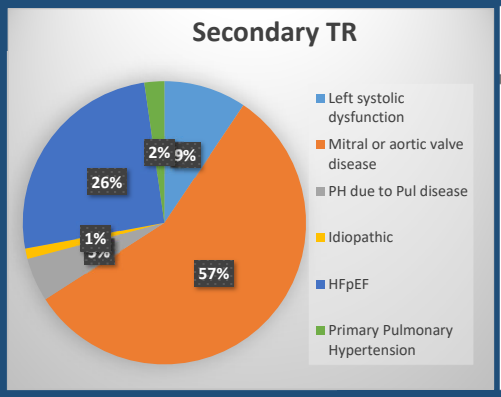


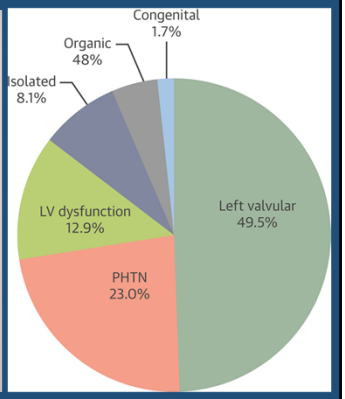
Prihadi, E.A. et al. J Am Coll Cardiol Img. 2019;12(3):491-9.

Prihadi EA at al JACC Cardiovasc Imaging. 2019 Mar;12(3):491-499

TR is common and Multifactorial





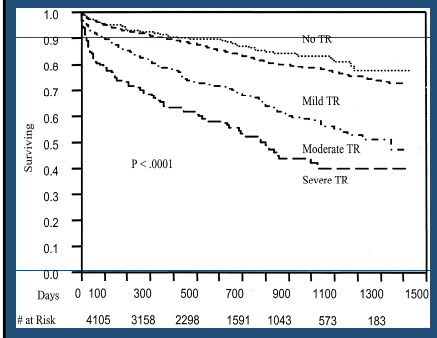


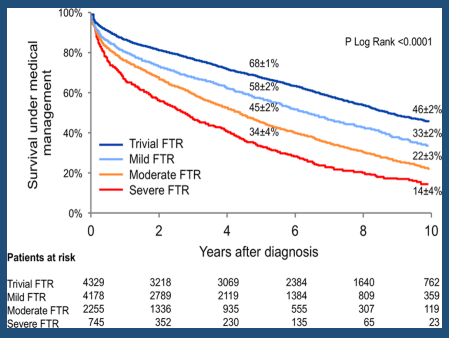
35,000 patient echo based study in Madrid
~5% Torrential or massive TR.
22% TR

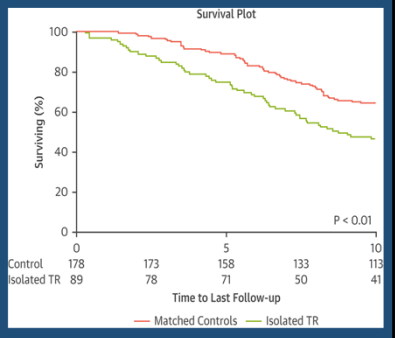
417 patients with ≥moderate TR
Olmstead County

Zamarano JL et al (in press) courtesy PCR online.com
Topilsky Y et al JACC Cardiovasc Imaging. 2019 Mar;12(3):433-442.

TR is common and impacts Survival







5223 Patients in VA 4 y follow up.
90% had TR

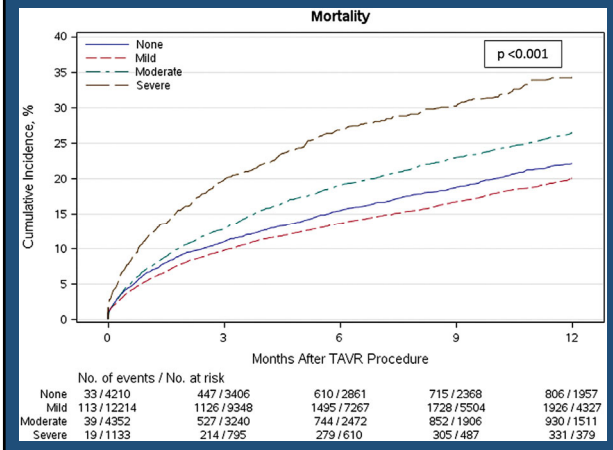
13,026 Patients with HFrEF
88% had FTR
FTR is associated with more dyspnea, impaired renal function and low CO (P<0.003 for all)

417 Patients 10 years mod TR or greater.
8% had isolated TR
Associated with –old age, female gender, atrial fibrillation

Nath J et al J Am Coll Cardiol. 2004 Feb 4;43(3):405-9.
Benfari et al Circulation. 2019 Jul 16;140(3):196-206
Topilsky Y et al JACC Cardiovasc Imaging. 2019 Mar;12(3):433-442

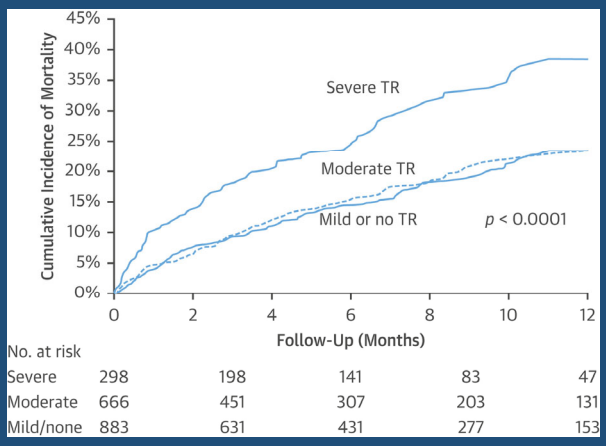
TR impacts on survival even after transcatheter valve interventions on left heart valves

TR after TAVR



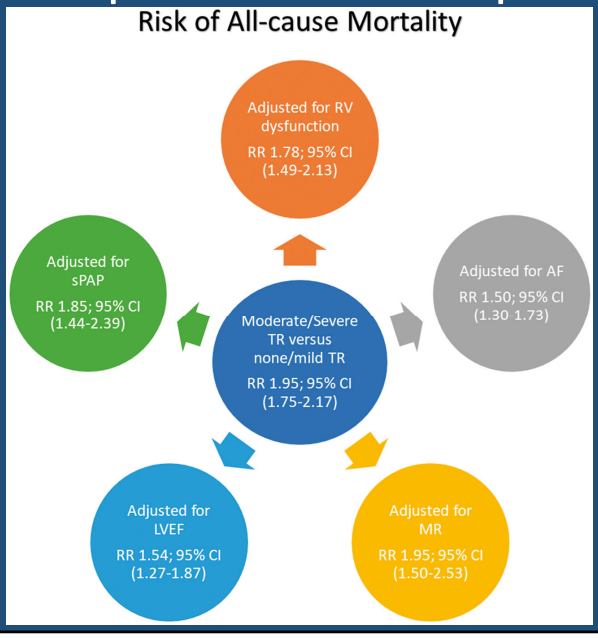
TR in 80% of TAVR pts, severe in 5%

TR after MitraClip



McCarthy et al. Ann Thorac Surg. 2018 Apr;105(4):1121-1128
Sorajja P et al J Am Coll Cardiol. 2017 Nov 7;70(19):2315-2327

Impact on survival persists after adjustments



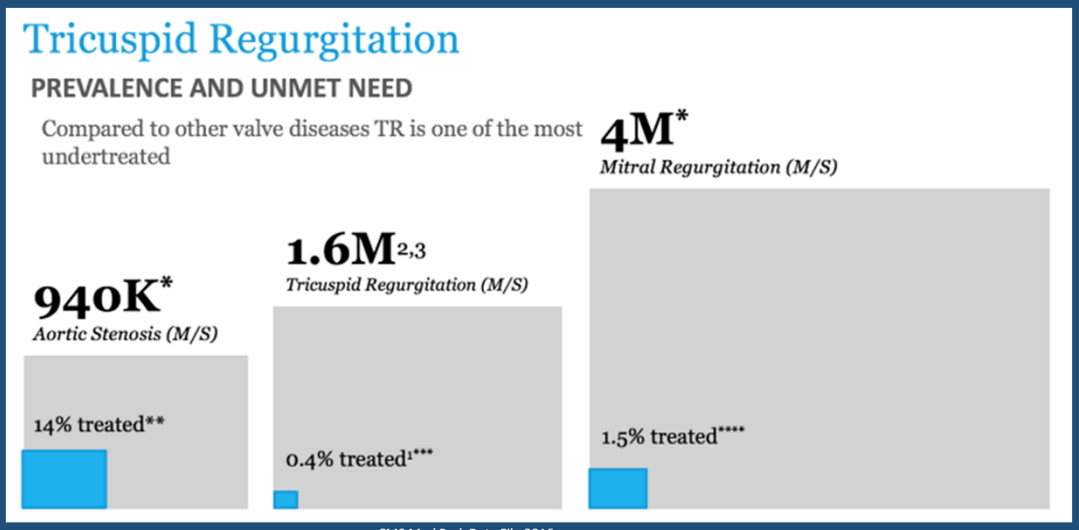
Pooled analysis of all studies reporting outcomes for TR patients, n= 32, 601
Moderate to Severe on 3 scale grading

- 1.95 fold increase in All cause mortality
- 2.56 increase in cardiac mortality
- 1.73 fold increase in HF hospitalization

- All cause mortality
- 1.25 fold increase with Mild
- 1.61 fold increase with moderate
- 3.44 fold increase with severe

Wang N et al Eur Heart J. 2019 Feb 1;40(5):476-484

TR – We can do better

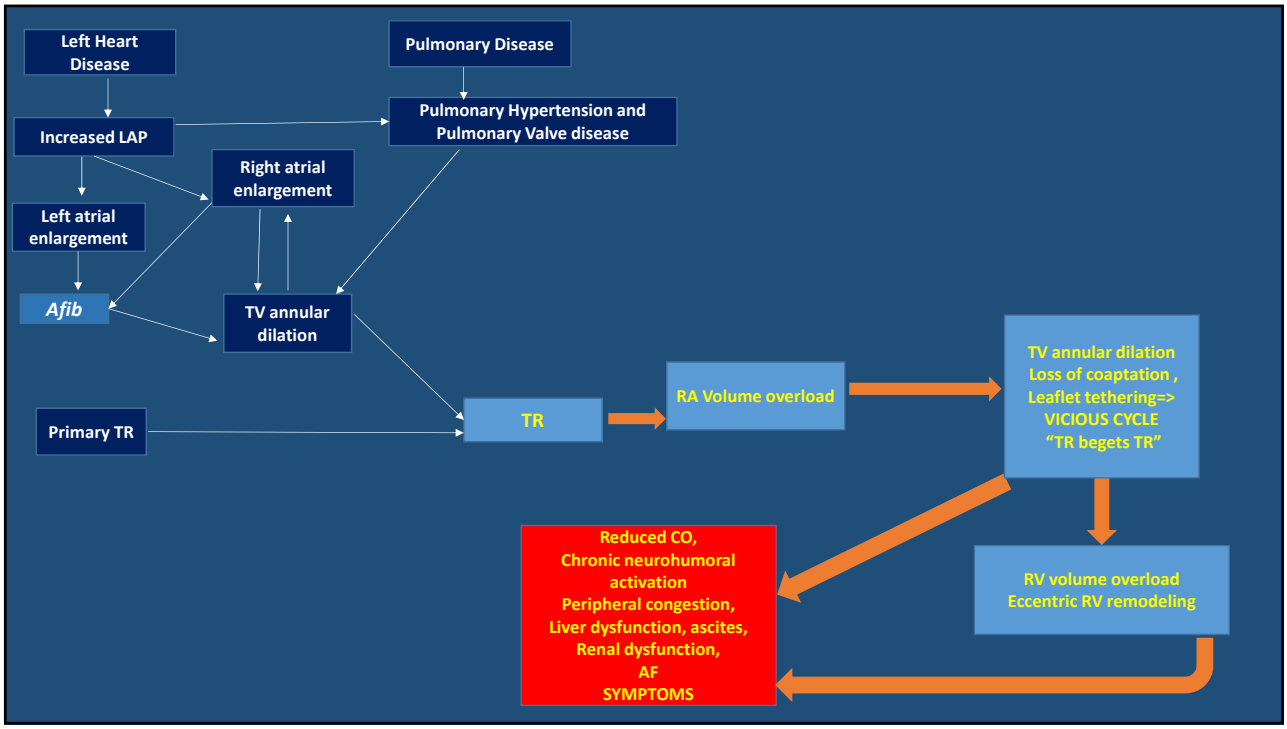


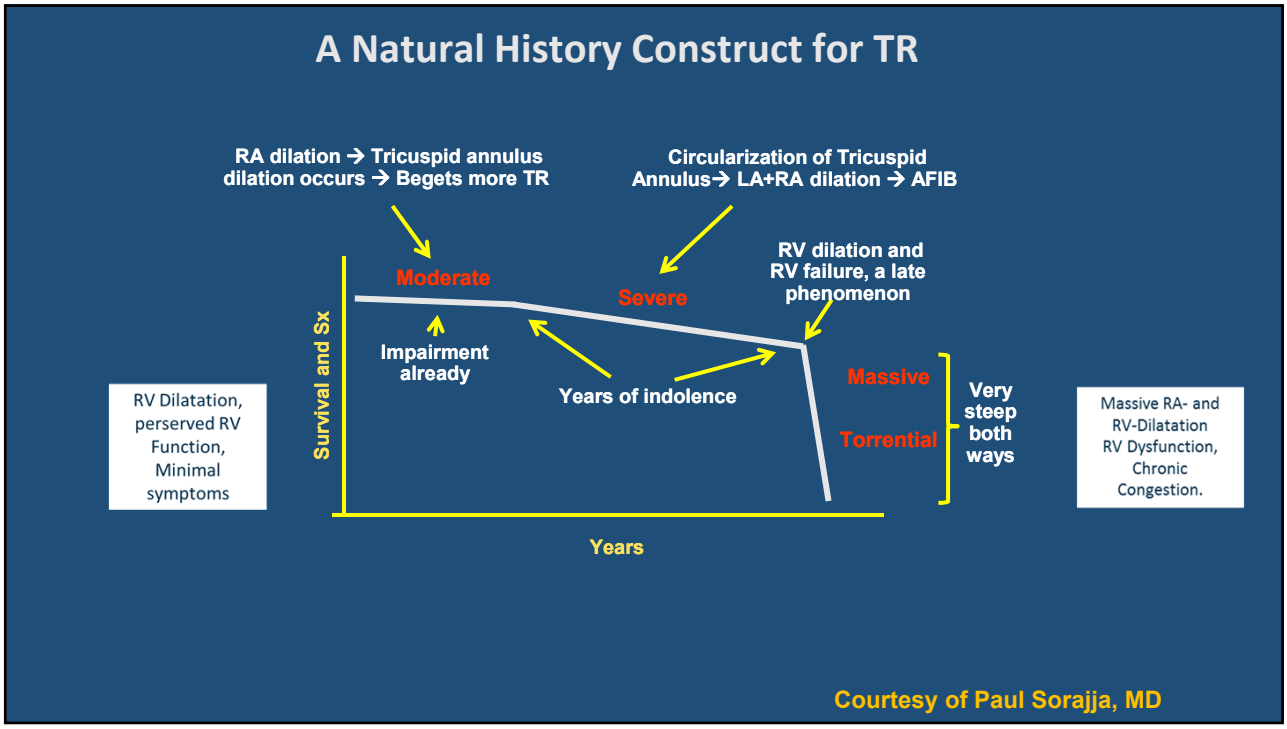
CMS Med Park Data File 2016
Topilsky et al Burden of Tricuspid Regurgitation in Patients Diagnosed in the Community Setting. JACC Cardiovasc Imaging. 2019 Mar;12(3):433-442
Topilsky Y Tricuspid valve regurgitation: epidemiology and pathophysiology. Minerva Cardioangiol. 2018 Dec;66(6):673-679.

- Calculation based on references from 1 and 2, ** Calculations by Abbott based on above references.
- Courtesy PCRonline

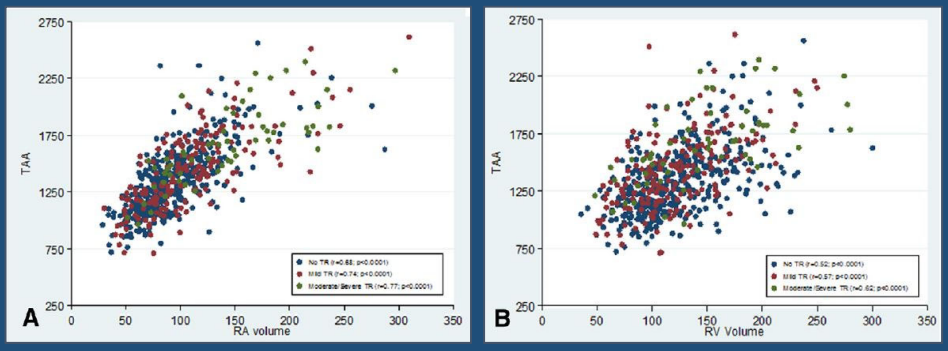
Possible reasons for under-treatment of TR

- Under-estimation of TR severity pre-operatively or under general anesthesia
- Over-estimation of surgical risk of concomitant TV surgery
- Misconception that TR resolves after treatment of mitral valve disease.


Left Heart Disease
Pulmonary Disease
Increased LAP
Pulmonary Hypertension and Pulmonary Valve disease
Right atrial enlargement
Left atrial enlargement
Afib
TV annular dilation
Primary TR
TR
RA Volume overload
TV annular dilation
Loss of coaptation ,
Leaflet tethering=>
VICIOUS CYCLE
"TR begets TR"
Reduced CO,
Chronic neurohumoral activation
Peripheral congestion,
Liver dysfunction, ascites,
Renal dysfunction,
AF
SYMPTOMS
RV volume overload
Eccentric RV remodeling


A Natural History Construct for TR
RA dilation → Tricuspid annulus dilation occurs → Begets more TR
Circularization of Tricuspid Annulus→ LA+RA dilation → AFIB
RV dilation and RV failure, a late phenomenon
Moderate
Severe
Impairment already
Years of indolence
Massive
Torrential
Very steep both ways
Survival and Sx
Years
RV Dilatation, perserved RV Function, Minimal symptoms
Massive RA- and RV-Dilatation RV Dysfunction, Chronic Congestion.
Courtesy of Paul Sorajja, MD

Right-Sided Chamber Remodeling
RA, RV, and Tricuspid Annulus



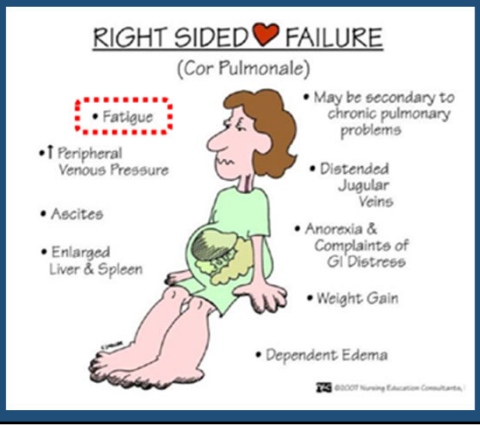
Tricuspid Annulus and RA volume Change First

Nemoto N et al. JTCVS 2015

Clinical Presentation

- Usually have prolonged asymptomatic interval.
- May be *very subtle*
- Hepatic congestion, hepatic fibrosis.
- Worsening renal dysfunction
- Low cardiac output
- Atrial tachycardias, Atrial fibrillation.

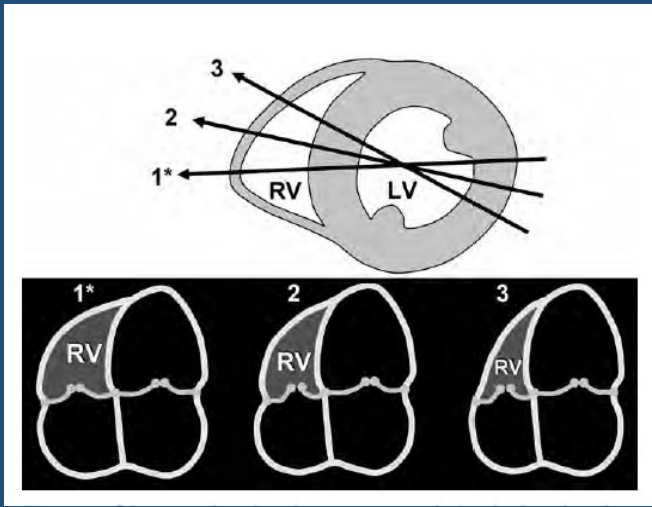
TR seen on Echo



GOALS OF IMAGING

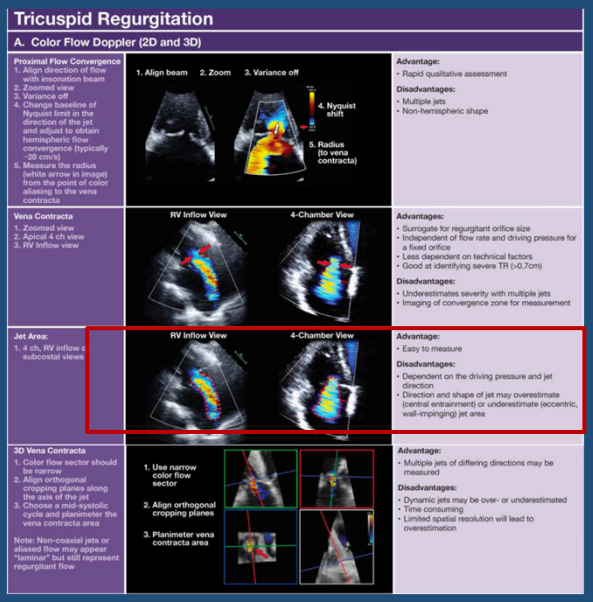
- Diagnosis
- Severity
- Etiology
- Concomitant lesions
- RA and RV assessment
- Pulmonary hypertension
- Plan intervention – Morphology of TV apparatus, Geometry of Landing zone, Anatomic relationships, vascular access assessment, angle of deployment.

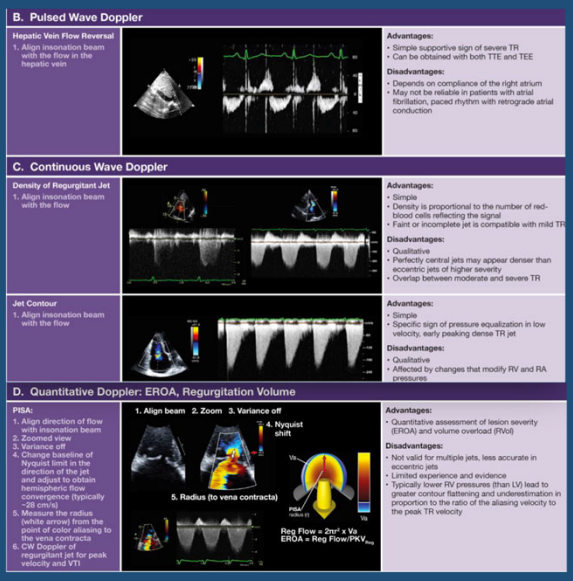
TR and RV assessment on TTE can be challenging



Rudski et al. J Am Soc Echocardiogr. 2010 Jul;23(7):685-713; quiz 786-8.

ASE Guidelines →Multiple parameters
In daily practice →





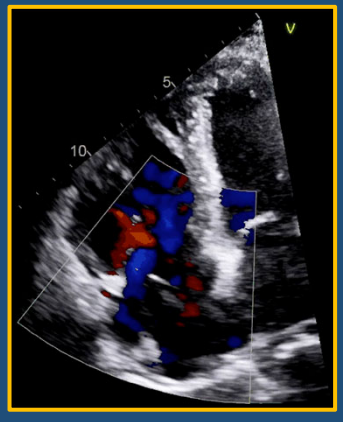
Slide Courtesy Joao Cavalcante MD

Zoghbi WA et al. J Am Soc Echocardiogr 2017; 30: 303-371.

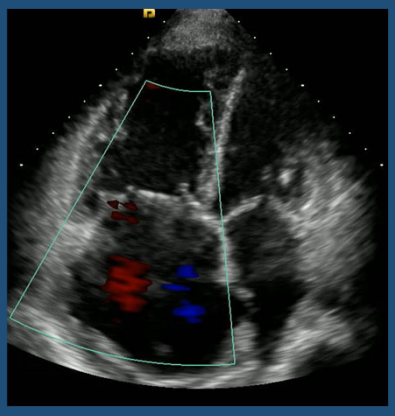
Example….

Mild

Moderate

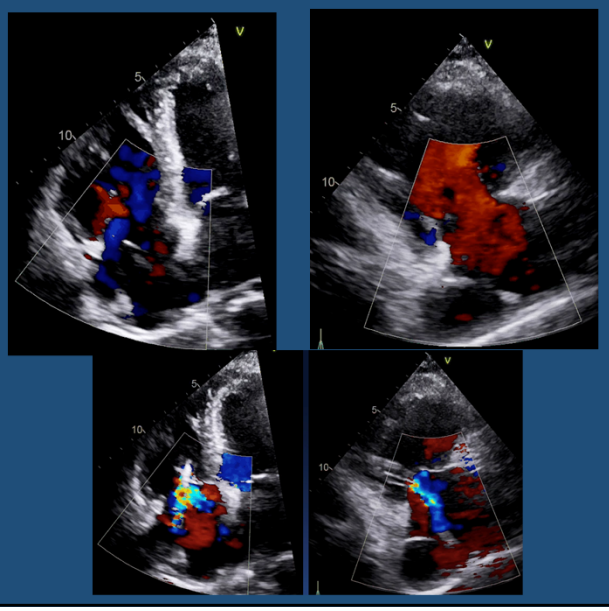


Massive/Torrential

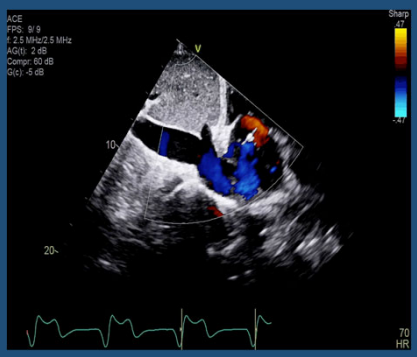


Slide Courtesy Joao Cavalcante MD

In Reality…..Additional Views with Color Doppler -

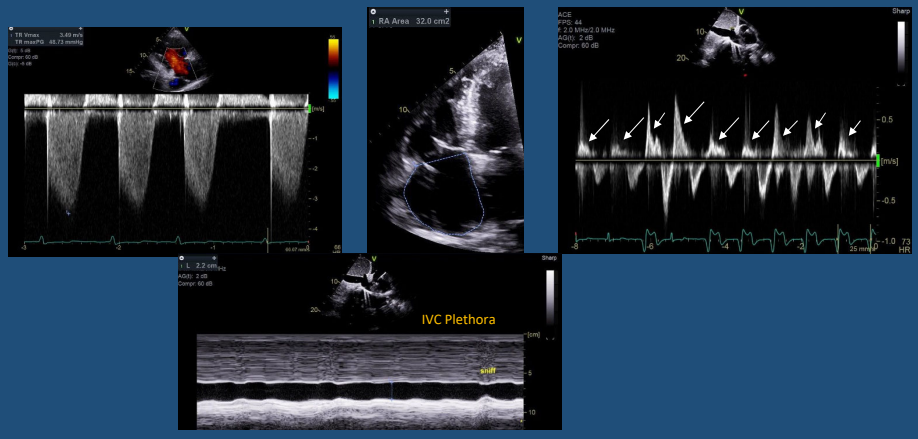


Unable to define flow convergence zone for PISA calculation



Slide Courtesy Joao Cavalcante MD

Doppler of TR jet



Slide Courtesy Joao Cavalcante MD

Grading the Severity of Chronic TR by Echocardiography

TR Severity	Mild	Moderate	Severe
Structural			
TV morphology	**Normal or mildly abnormal leaflets**	Moderately abnormal leaflets	**Severe valve lesions** (e.g., flail leaflet, severe retraction, large perforation)
RV and RA size	Usually normal	Normal or mild dilation	Usually dilated[1]
Inferior vena cava diameter	Normal <2cm	Normal or mildly dialated 2.1-2.5cm	Dilated >2.5cm
Qualitative Doppler	Bolded signs are considered specific for their AR grade.		
Color flow jet area[2]	**Small, narrow, central**	Moderate central	**Large central jet** or eccentric wall-impinging jet of variable size
Flow convergence zone	**Not visible, transient or small**	Intermediate in size and duration	**Large throughout systole**
CWD jet	**Faint/partial**/parabolic	Dense, parabolic or triangular	Dense, often triangular
Semiquantitative	Bolded signs are considered specific for their AR grade.		
Color flow jet area (cm^2)[2]	Not defined	Not defined	>10
VCW (cm)†	<0.3	0.3-0.69	≥0.6
PISA radius (cm)[3]	≤0.5	0.6-0.9	>0.9
Hepatic vein flow[4]	Systolic dominance	Systolic blunting	**Systolic flow reversal**
Tricuspid inflow[4]	**A-wave dominant**	Variable	E-wave >1.0m/sec
Quantitative			
EROA (cm^2)	<0.20	0.20-0.39[5]	≥0.40
RVol (mL/beat)	<30	30-44[5]	≥45

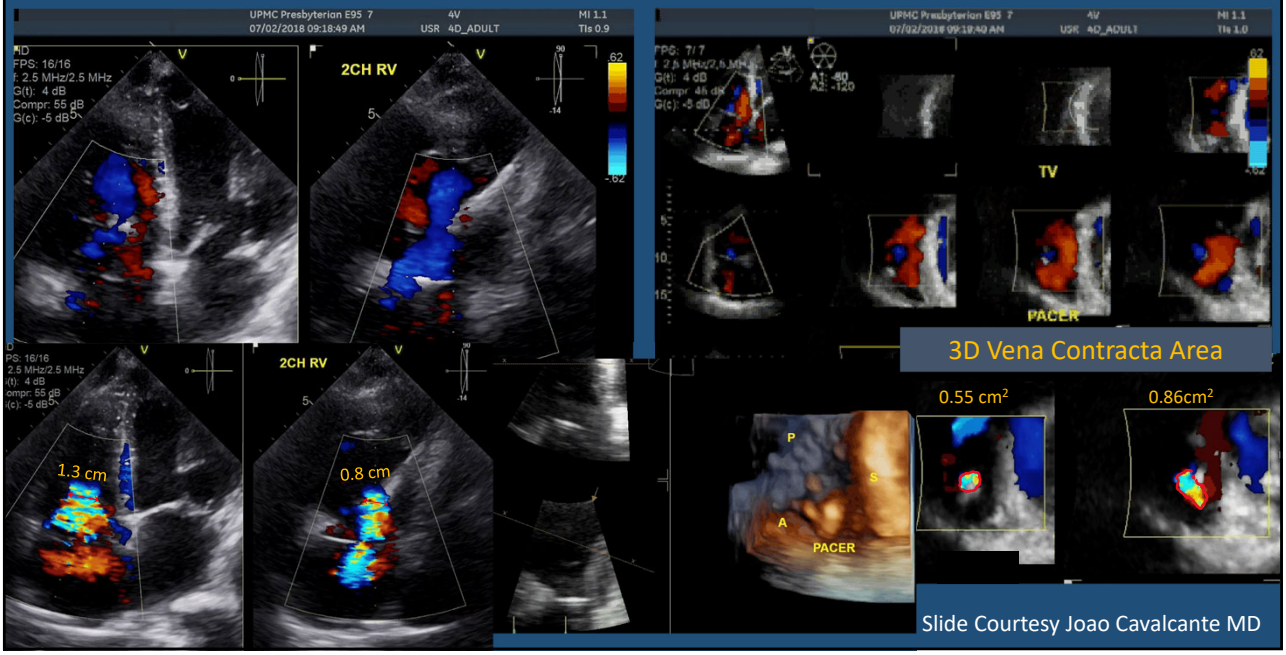
[1]RV and RA size can be within the "normal" range in patients with acute severe TR.
[2]With Nyquist limit >50-70 cm/sec.
[3]With baseline Nyquist limit shift of 28 cm/sec.
[4]Signs are nonspecific and are influenced by many other factors (RV diastolic function, atrial fibrillation, RA pressure).
[5]There are little data to support further separation of these values.

?Mild-Moderate-Severe TR

Slide Courtesy Joao Cavalcante MD

Zoghbi WA et al. J Am Soc Echocardiogr 2017; 30: 303-371.

Same patient, same day, different probes… (3D TTE)



Slide Courtesy Joao Cavalcante MD

Proposed Grading Scheme

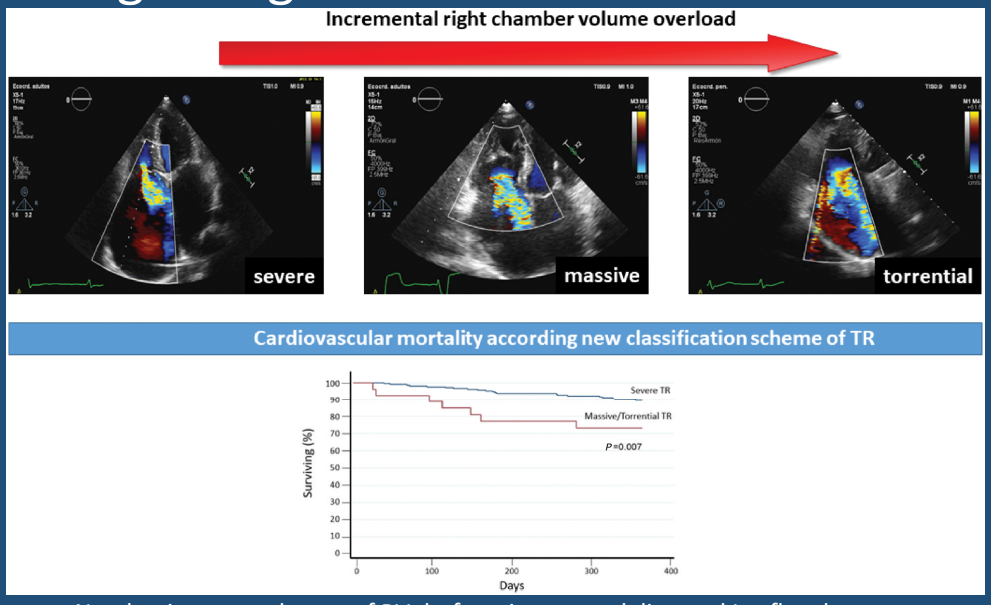
Table I **Proposed expansion of the 'Severe' grade**

Variable	Mild	Moderate	Severe	Massive	Torrential
VC (biplane)	<3 mm	3-6.9 mm	7–13 mm	14–20 mm	≥21 mm
EROA (PISA)	<20 mm^2	20–39 mm^2	40–59 mm^2	60–79 mm^2	≥80 mm^2
3D VCA or quantitative EROA[a]			75–94 mm^2	95–114 mm^2	≥115 mm^2

VC, vena contracta; EROA, effective regurgitant orifice area; 3D VCA, three-dimensional vena contracta area.
[a]3D VCA and quantitative Doppler EROA cut-offs may be larger than PISA EROA.

Hahn R et al. Eur Heart J Cardiovasc Imaging. 2017 Dec 1;18(12):1342-1343.

Proposed grading scheme



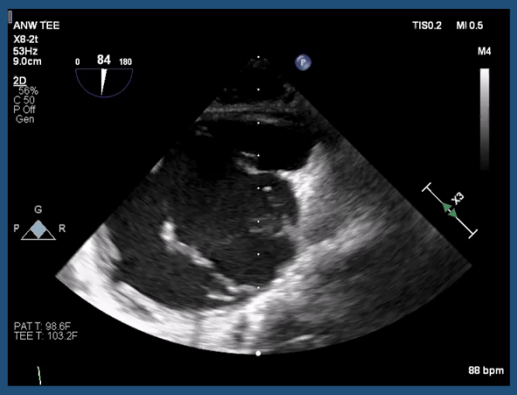
- Need to integrate degree of RV dysfunction, remodeling and Leaflet changes

Santoro C et al Eur Heart J Cardiovasc Imaging. 2019 Sep 1;20(9):1035-1042

Echocardiographic/clinical evaluation of TR disease by **main pathogenic/prognostic mechanisms**	
TR quantitative parameters 	Vena contracta width (biplane average) PISA EROA and RegVol Quantitative Doppler EROA and RegVol 3D vena contracta area and RegVol
Annular dilation 	≥40 mm or ≥21 mm/m^2 from apical 4ch view *Note: Annular dilation may be a surrogate for severe TR in absence of adequate quantitative measures.*
Leaflet coaptation 	Tenting length and area (2D echo, 4Ch view) Tenting volume (3D echo) *Note: coaptation parameters may be a surrogate for severe TR in absence of adequate quantitative measures.*
Right ventricle remodeling, dilation, dysfunction	Multiparametric assessment of global right ventricle function: TAPSE, S'TDI, 2D-longitudinal strain, FAC%, 3D-RVEF%
RV-PA coupling	Measure of RV contractile function indexed to afterload
Clinical features	High CVP, renal dysfunction, liver dysfunction, ascites, edema

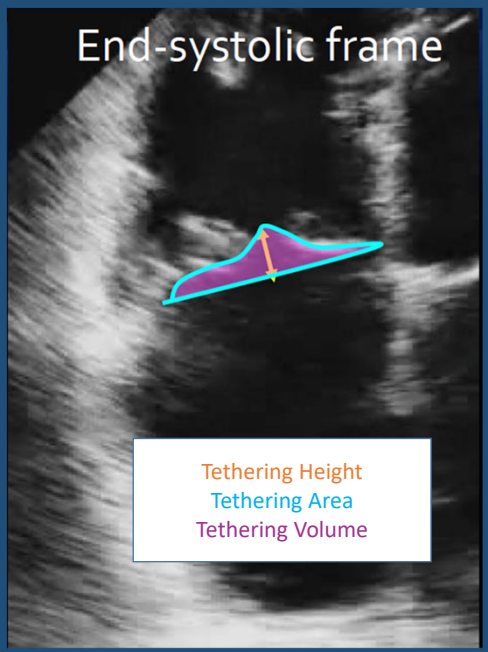
Taramasso M et al JACC Cardiovasc Imaging. 2019 Apr;12(4):605-621.
Dreyfus GD et al J Am Coll Cardiol. 2015 Jun 2;65(21):2331-6

Planning Intervention



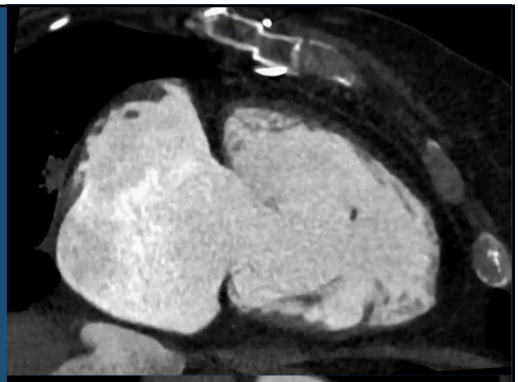
Severe leaflet tethering - advanced
May not benefit for TV repair and need replacement.
Combination transcatheter therapies

Coaptation gap – for edge to edge repair

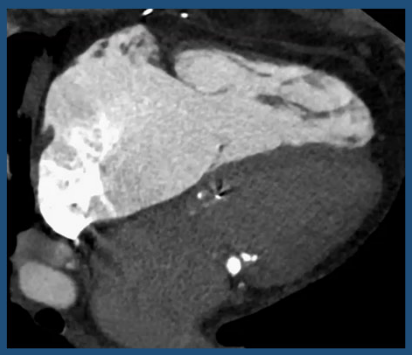


Functional CTA for Quantification of right-sided function and Remodeling

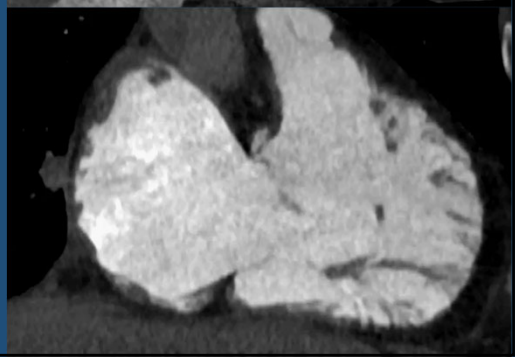
RV 2ch View



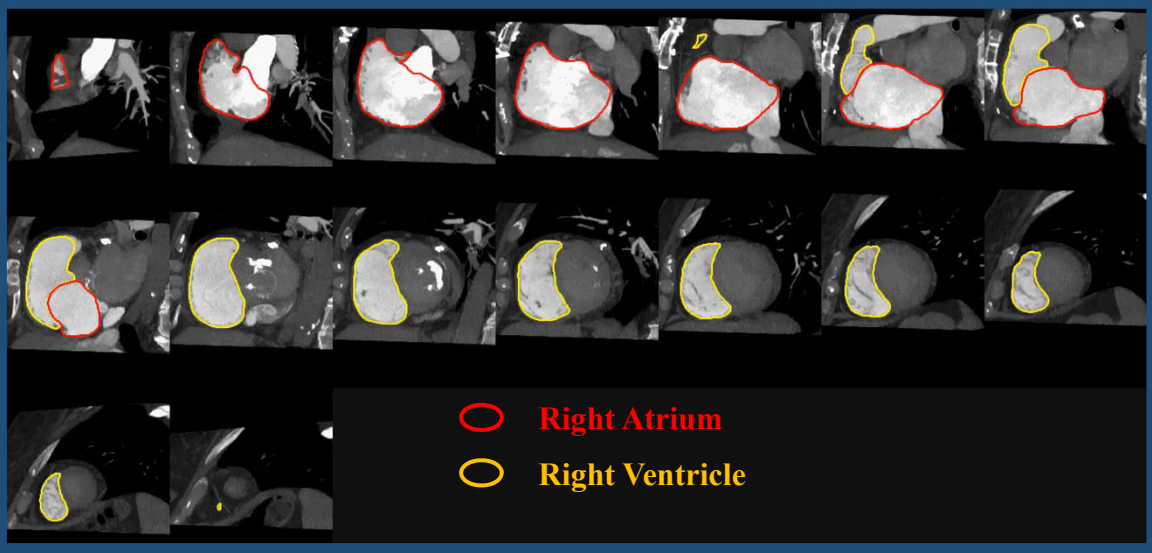
RV 4ch View



RV 3ch View

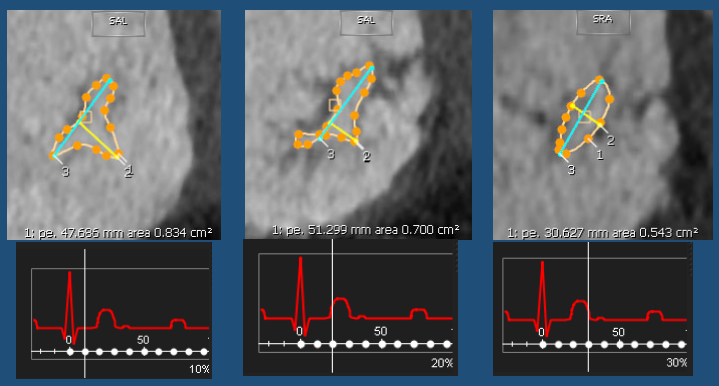


RV "centric" SAX Reconstruction allow for quantification of RA, RV volumes and EF



Anatomical ROA – Average Systolic Frames

Systolic Frame 10% **Systolic Frame 20%** **Systolic Frame 30%**



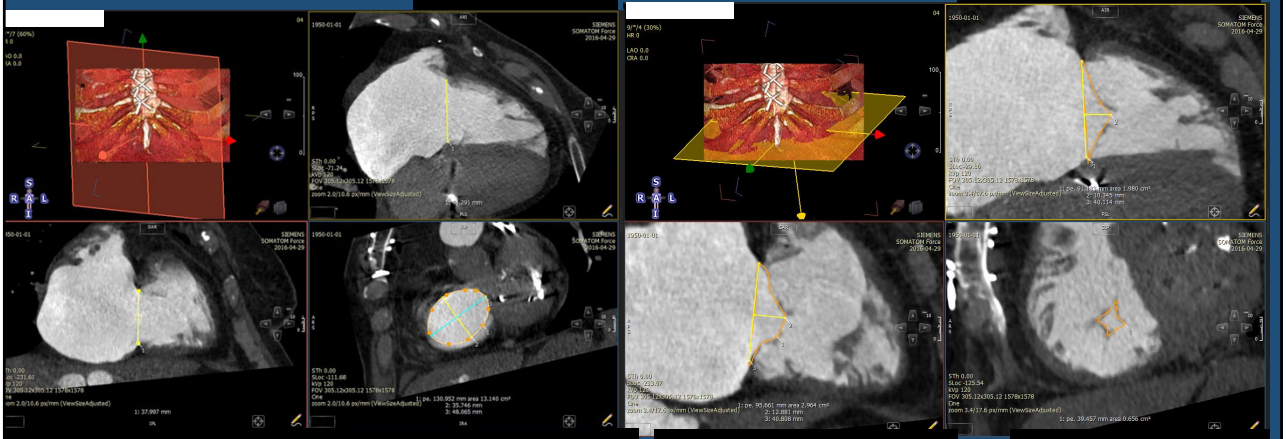
Average Anatomical ROA=0.629 cm²

Slide Courtesy Joao Cavalcante MD

Hahn RT et al. JACC Cardiovasc Imaging. 2019 Mar;12(3):469-490.

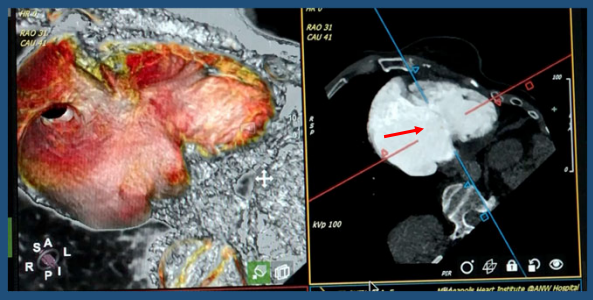
Tricuspid Annulus, tethering height and Anatomic ROA

4ch Diameter **4ch Area and Height**

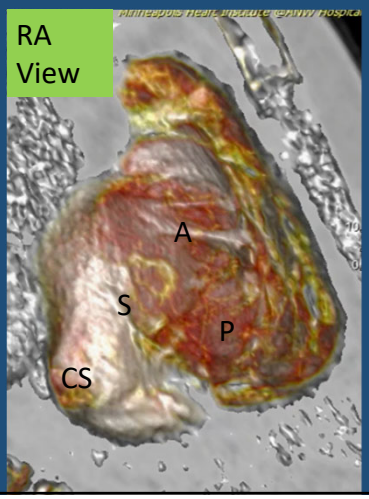


2ch Diameter Area & Major/Minor Diameter **2ch Area and Height** **Anatomical ROA**

Slide Courtesy Joao Cavalcante MD



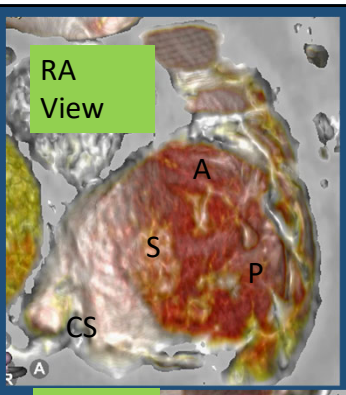
RA View

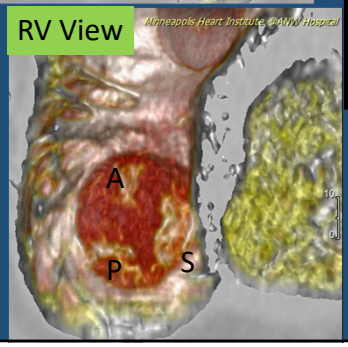


Endoluminal 3D Views

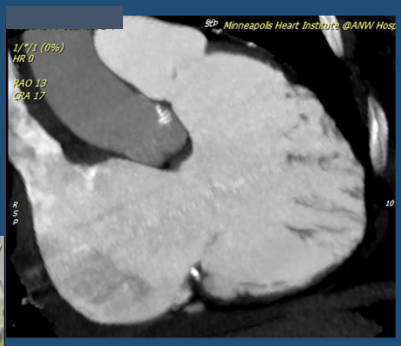
- Leaflet Motion
- Visualization of the valve gap
  - Evaluation of TR severity
  - Individualization of therapy
- Best angles for leaflet grasping and coplanar alignment for commissures

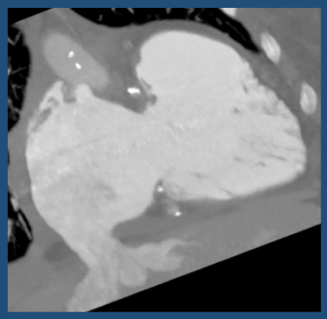
Slide Courtesy Joao Cavalcante MD





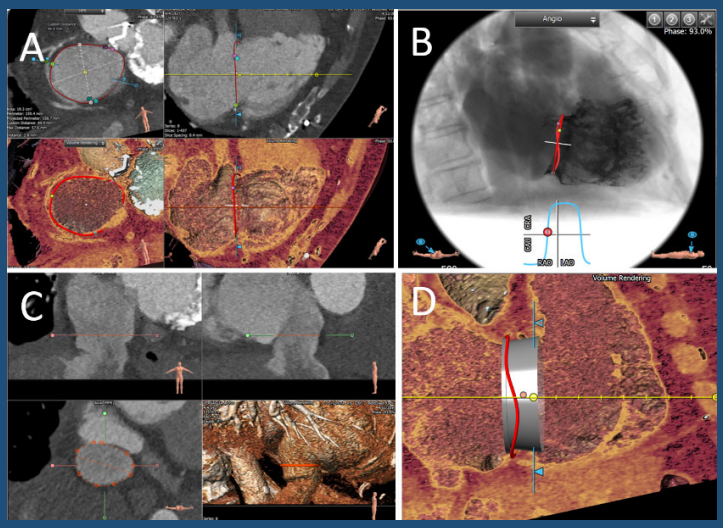
Patient with prior large inferior MI with RV infarct. Tethering of the posterior leaflet





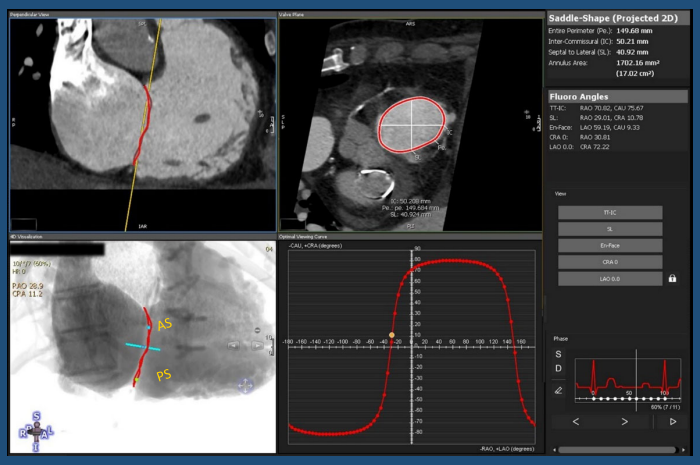
Endoluminal 3D Views
- Leaflet Motion
-Visualization of the valve gap
-Evaluation of TR severity
-Individualization of therapy
- Best angles for leaflet grasping and coplanar alignment for commissures

CTA for Procedural Planning

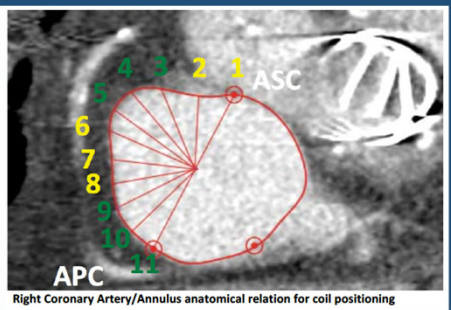


Hahn et al. JACC Cardiovasc Imaging. 2019 Mar;12(3):469-490.

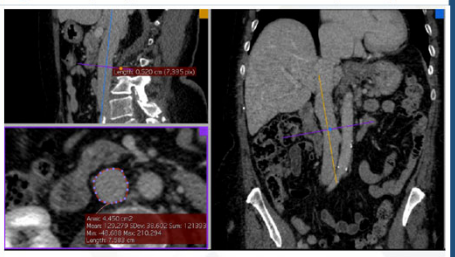
CTA for Fluoroscopy Angle Planning



CTA for Procedural Planning

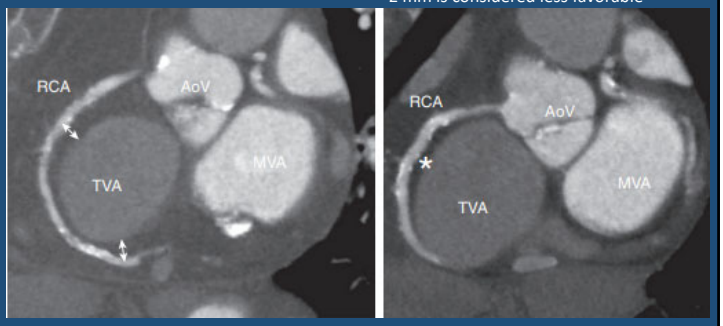


Right Coronary Artery/Annulus anatomical relation for coil positioning



IVC analysis from the RA junction below the renal veins

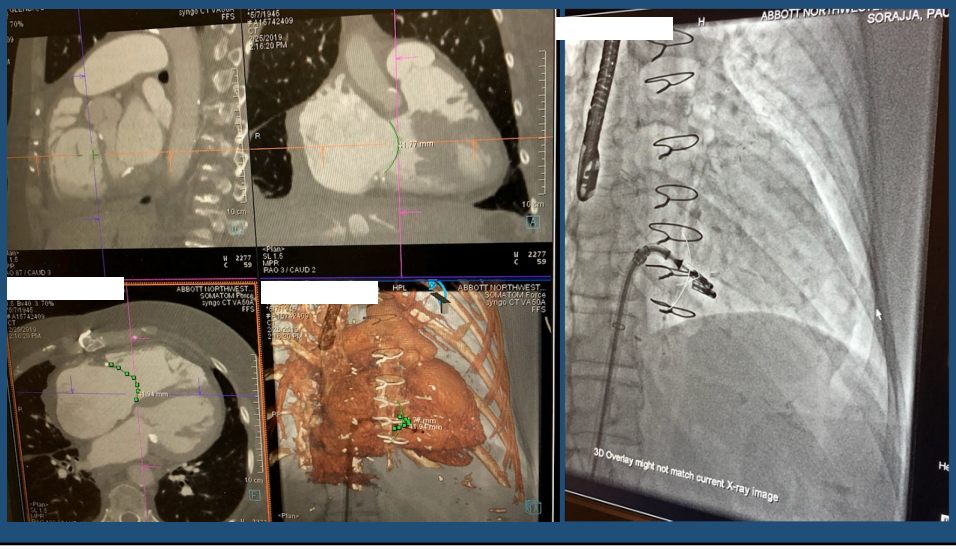
A distance between RCA and TV annulus of ≤ 2 mm is considered less favorable

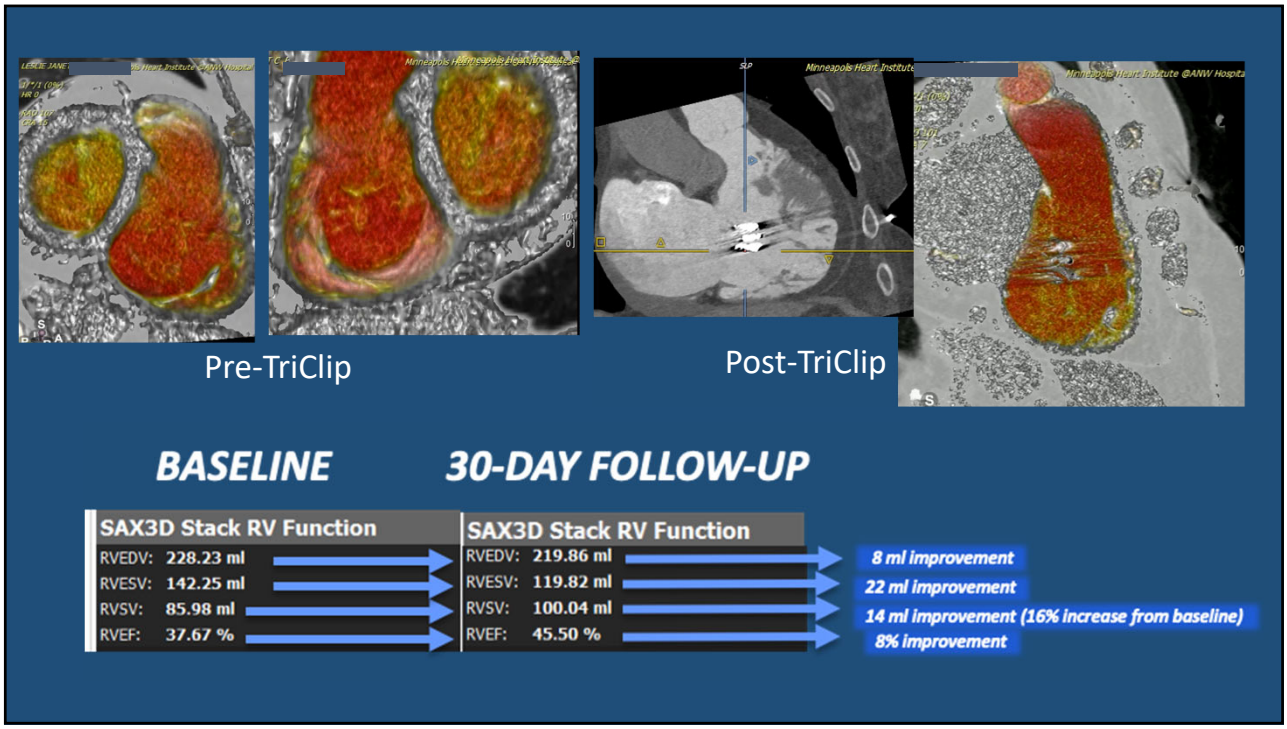


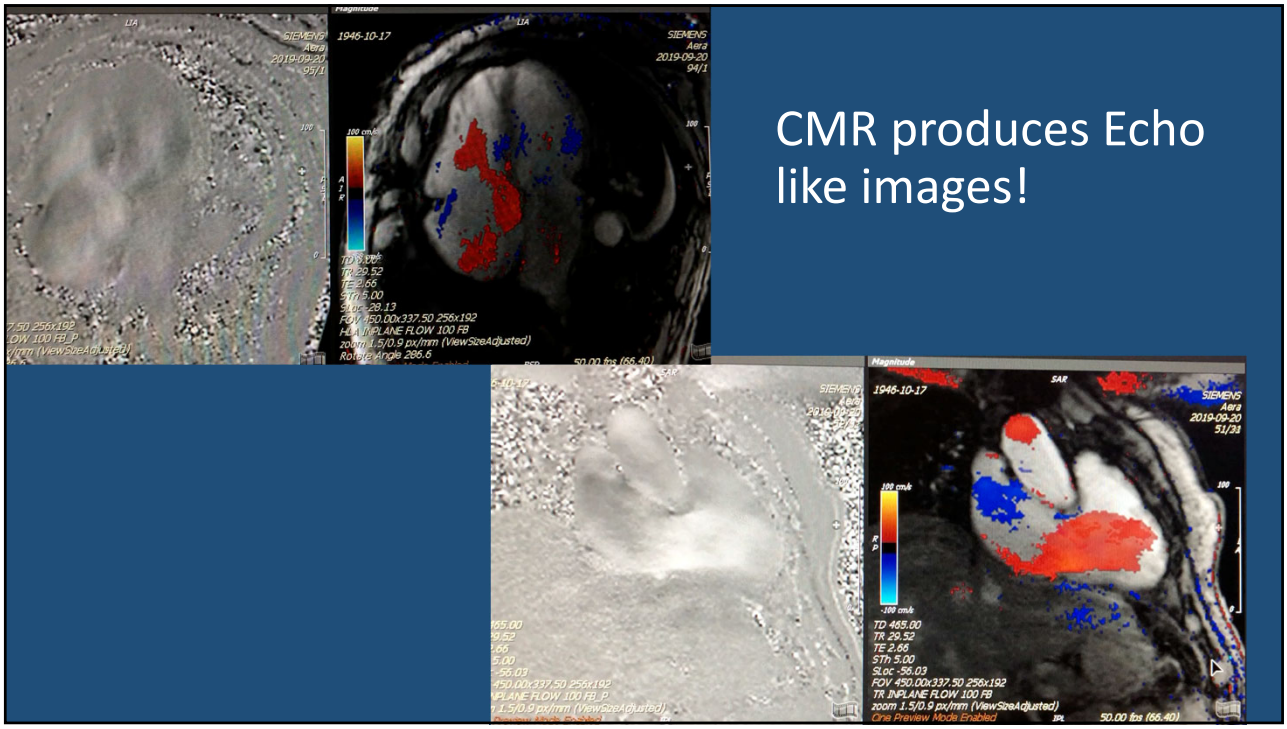
Curved spline for RCA segmentation and tricuspid annulus, important for tricuspid annular devices (Tricinch, Millipede, Cardioband, etc).

Prihadi et al. JACC Cardiovasc Imaging. 2018 May;11(5):736-754.

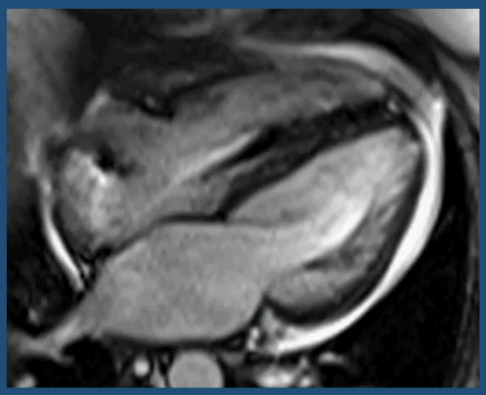
Importing CT for tricuspid leaflet segmentation and angles for fluoro overlay

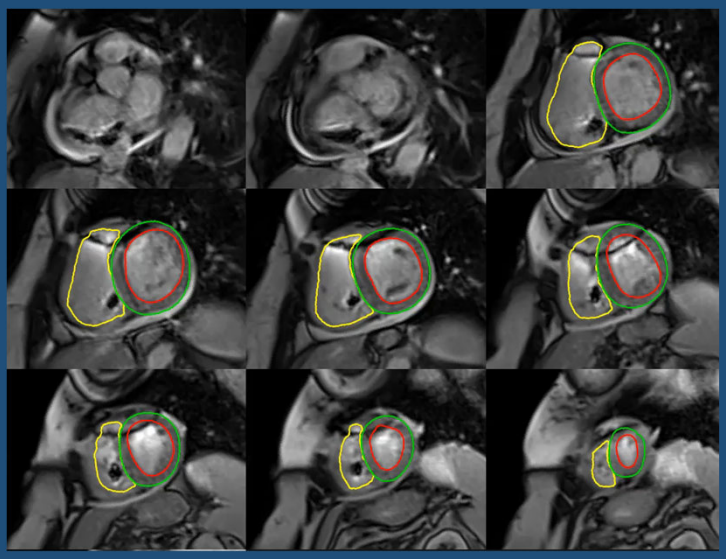



Pre-TriClip
Post-TriClip
BASELINE
30-DAY FOLLOW-UP
SAX3D Stack RV Function
RVEDV: 228.23 ml
RVESV: 142.25 ml
RVSV: 85.98 ml
RVEF: 37.67 %
SAX3D Stack RV Function
RVEDV: 219.86 ml
RVESV: 119.82 ml
RVSV: 100.04 ml
RVEF: 45.50 %
8 ml improvement
22 ml improvement
14 ml improvement (16% increase from baseline)
8% improvement

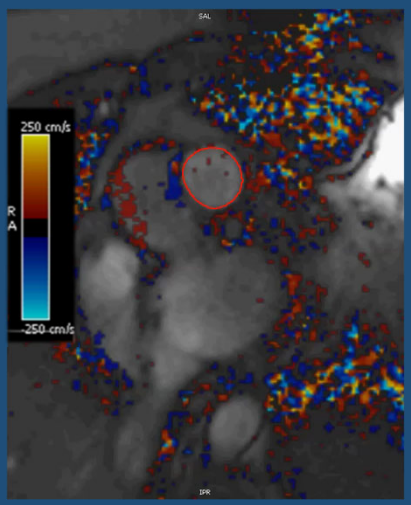

CMR produces Echo like images!

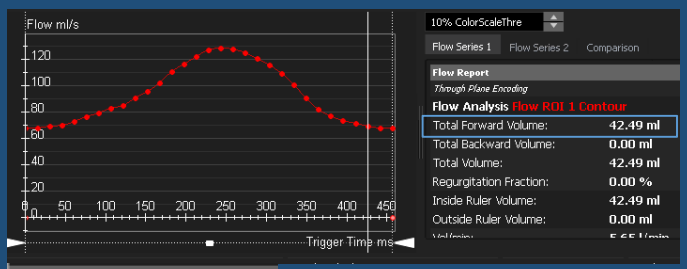
CMR Scanning of patients with Pacemaker and Defibrillator is feasible and safe





TR Quantification is Feasible Despite PM/ICD





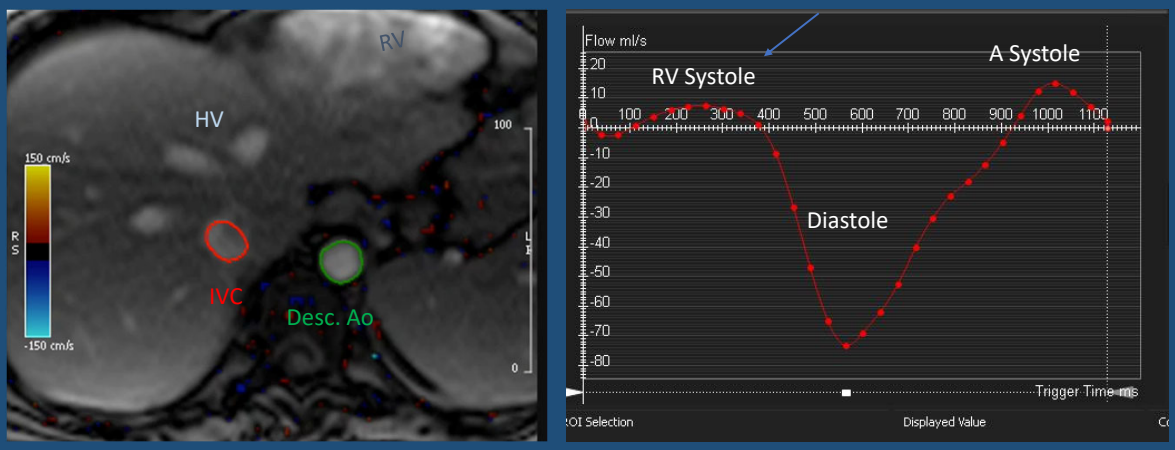
SAX3D Stack RV Function

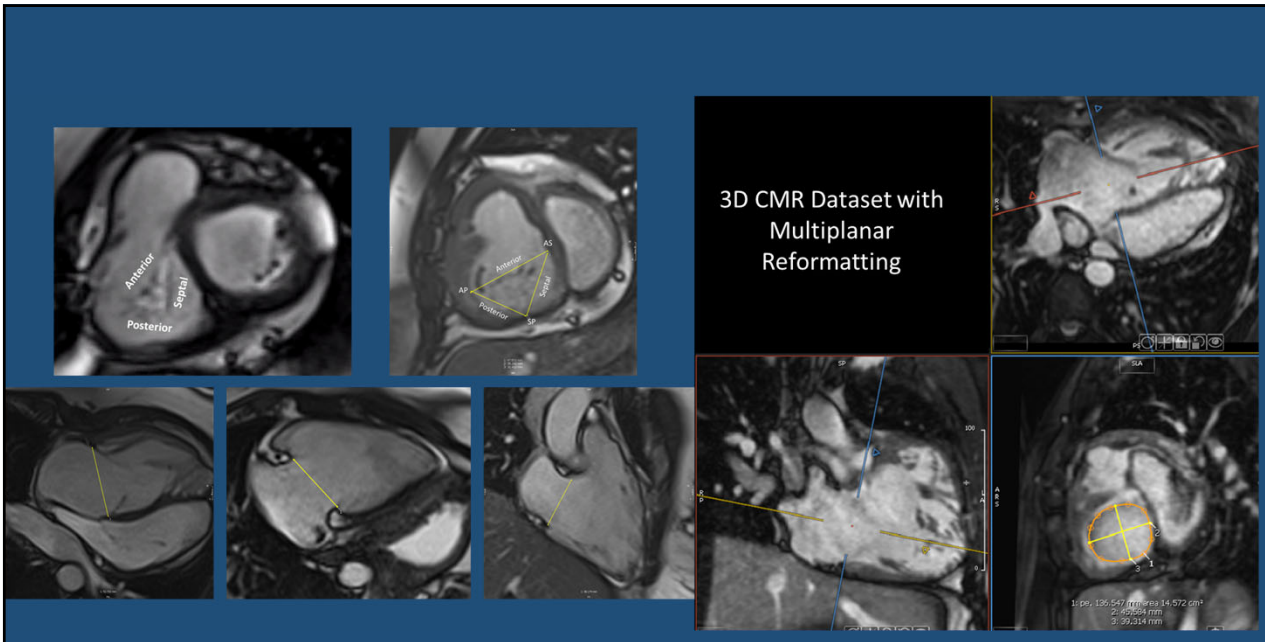
Manual Definition of Diastole and Systole

RVEDV:	167.39 ml
RVESV:	65.04 ml
RVSV:	102.35 ml
RVEF:	61.14 %
RVCO:	9.21 l/min
RVCI:	4.66 l/min/m²
HR:	90.0/min

TR Volume=102-42= 60 ml/beat
TR Fraction=60/102 = 59%

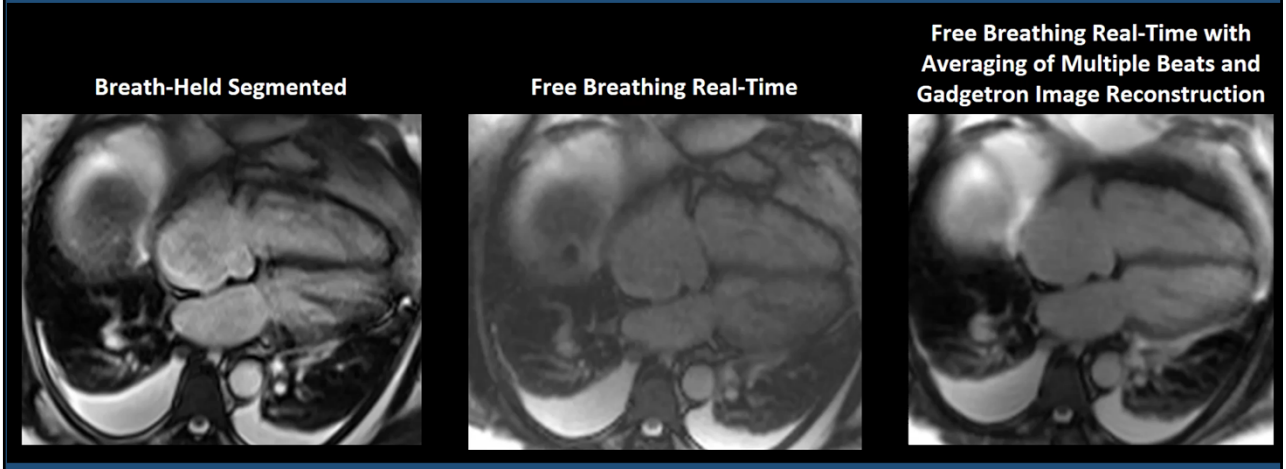
IVC systolic flow reversal on CMR





Naoum et al. Circ Cardiovasc Imaging. 2017;10(3). pii: e005331

CMR Technology Continues to Evolve for patients with Afib and unable to perform breath-hold



Same patient, same scanner, different pulse sequence…
Superior and diagnostic image quality

Both RVEF and RVEDVi are prognostically important prior to TV surgical intervention

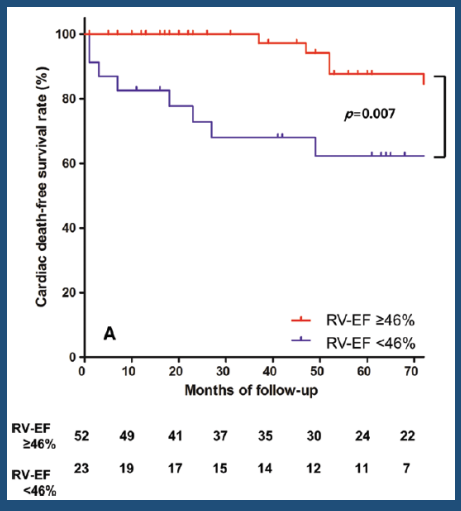
Table 4

Adjusted Analysis by Using Cox Proportional Hazards Models of Cardiac Death and Major Postoperative Cardiac Events in Relation to Cardiac MR Imaging–determined RV EF and RV ESVI

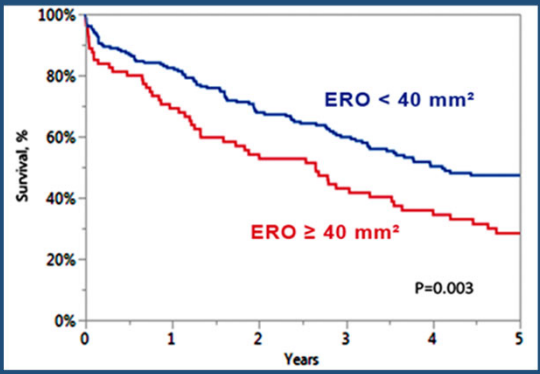
	Cardiac Death			Major Postoperative Cardiac Events		
Parameter	Hazard Ratio	95% CI	*P* Value	Hazard Ratio	95% CI	*P* Value
RV EF, per 5% higher						
Univariate	0.790	0.626, 0.998	.048	0.825	0.686, 0.991	.040
Age and sex adjusted	0.756	0.588, 0.972	.029	0.806	0.669, 0.970	.023
Age, sex, and NYHA class adjusted	0.713	0.530, 0.959	.025	0.819	0.672, 0.997	.046
Age, sex, NYHA class, and hemoglobin level adjusted	0.673	0.478, 0.946	.023	0.795	0.649, 0.974	.027
Age, sex, NYHA class, hemoglobin level, and GFR adjusted	0.714	0.528, 0.966	.029	0.795	0.649, 0.974	.027
RV ESVI, per 10 mL/m^2 higher						
Univariate	1.151	1.040, 1.274	.006	1.083	0.998, 1.175	.055
Age and sex adjusted	1.166	1.057, 1.286	.002	1.100	1.015, 1.192	.021
Age, sex, and NYHA class adjusted	1.280	1.114, 1.472	.001	1.139	1.036, 1.252	.007
Age, sex, NYHA class, and hemoglobin level adjusted	1.214	1.052, 1.401	.008	1.111	1.007, 1.226	.036
Age, sex, NYHA class, hemoglobin level, and GFR adjusted	1.183	1.025, 1.365	.021	1.102	0.997, 1.218	.057

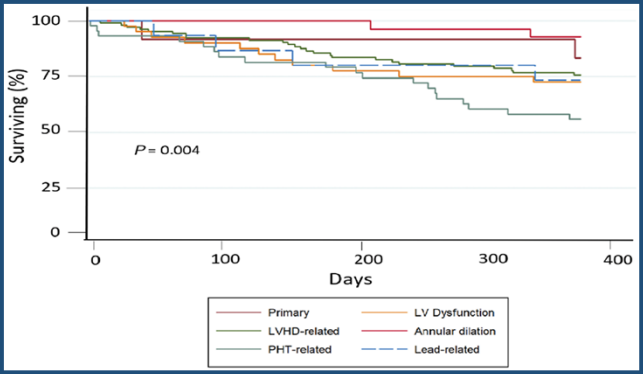
Note.—Hemoglobin level was incorporated without platelet count to avoid collinearity.

Park JB et al. Radiology. 2016 Sep;280(3):723-34



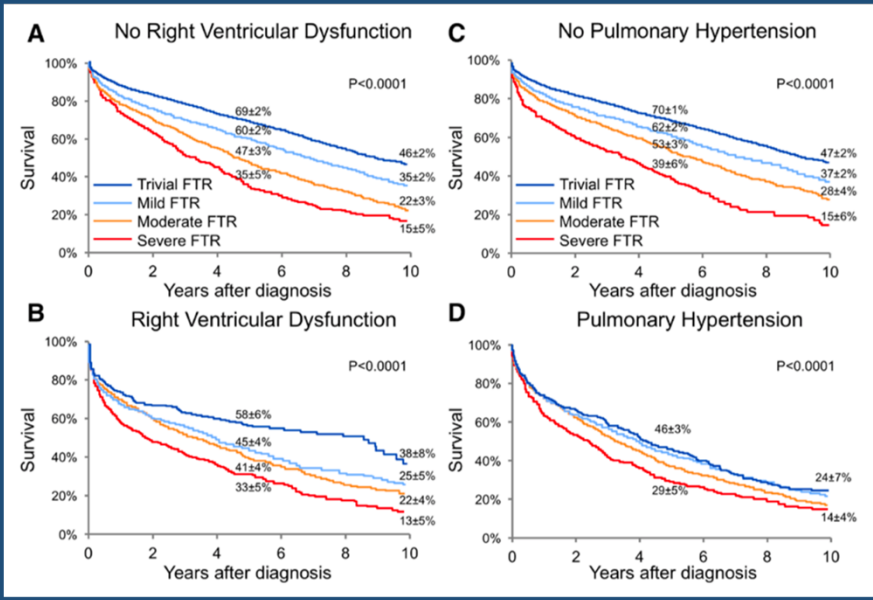
Why Quantify and assess etiology





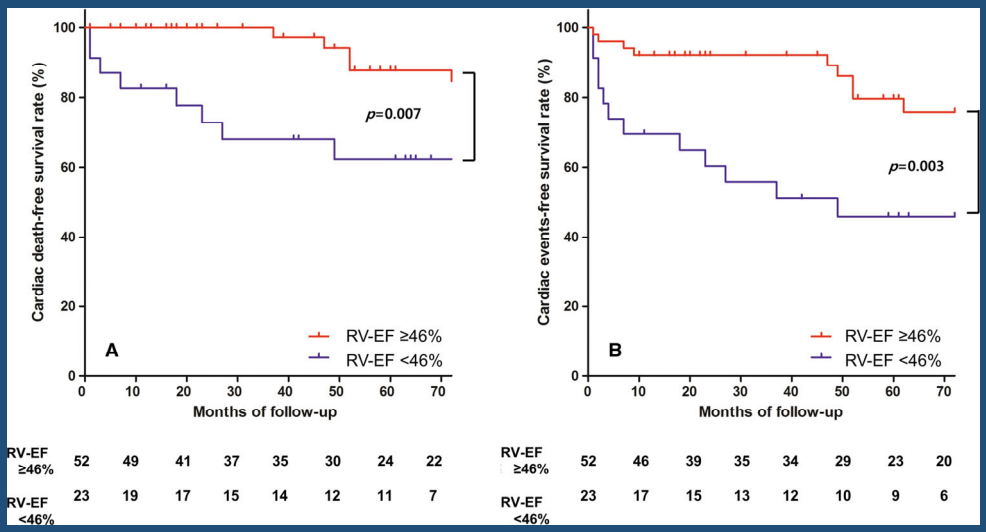
Topilsky et al Eur Heart J. 2018 Jul 27
Santoro C et al Eur Heart J – CV Imaging, Vol 20, Issue 9, Sept 2019, pp 1035–1042,

Why assess RV size and Pulmonary Pressures

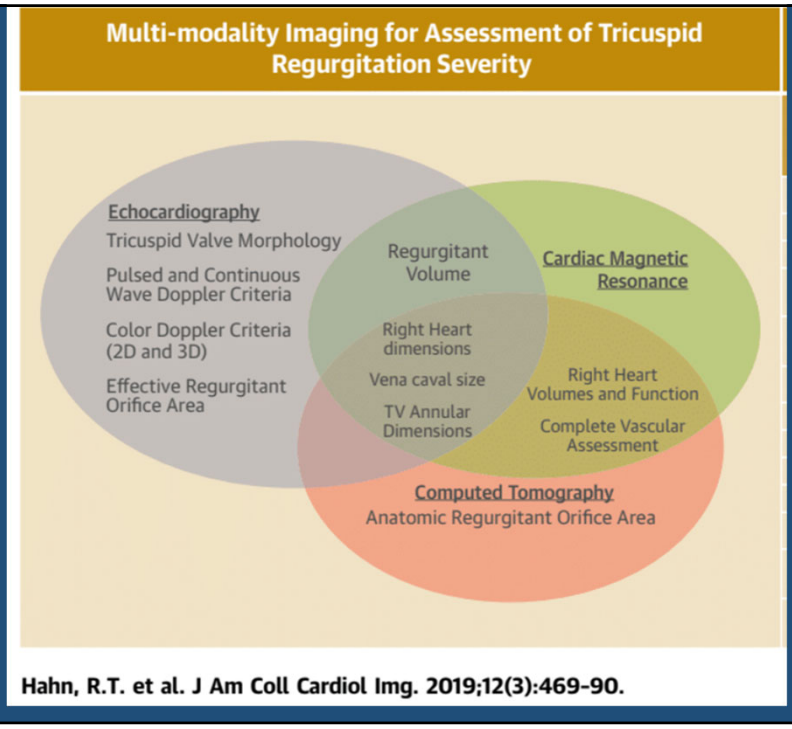


Benfari et al, Circulation. 2019;140:196–206

Why assess RV size and function



Park JB et al. Radiology. 2016 Sep;280(3):723-34



TREATMENT

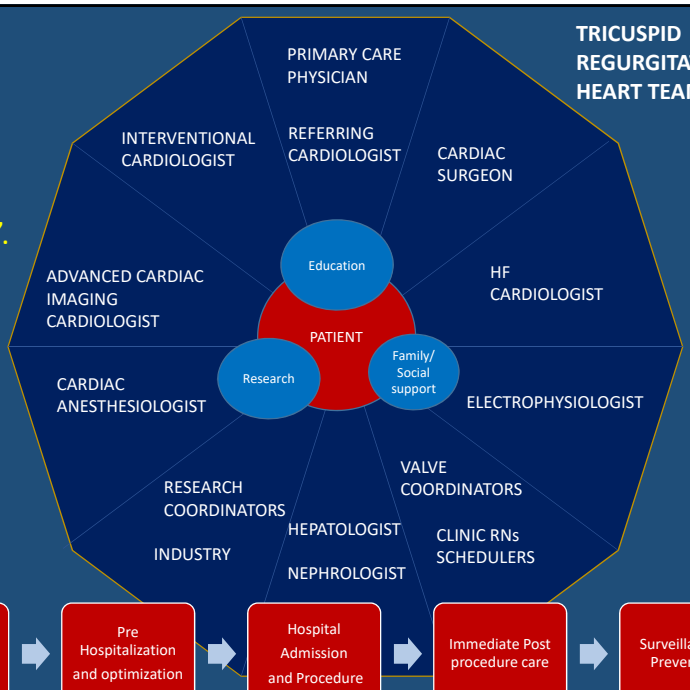
- "……Treating Tricuspid regurgitation and right heart failure is an art rather than evidence based medicine".

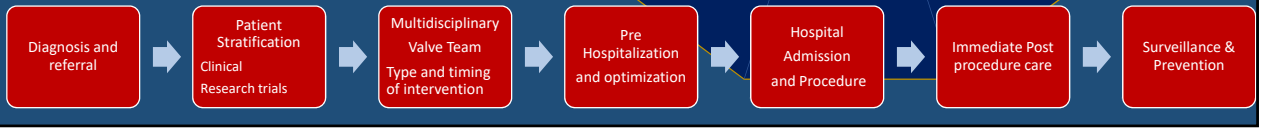
  Prof Zamarano PCRLV 2019

  Madrid, Spain

Paraphrased –

"TR is a part of a spectrum of complex cardiac, pulmonary, arrhythmia and right heart failure syndromes. Treating TR is as much a team sport as it is an art and a science".





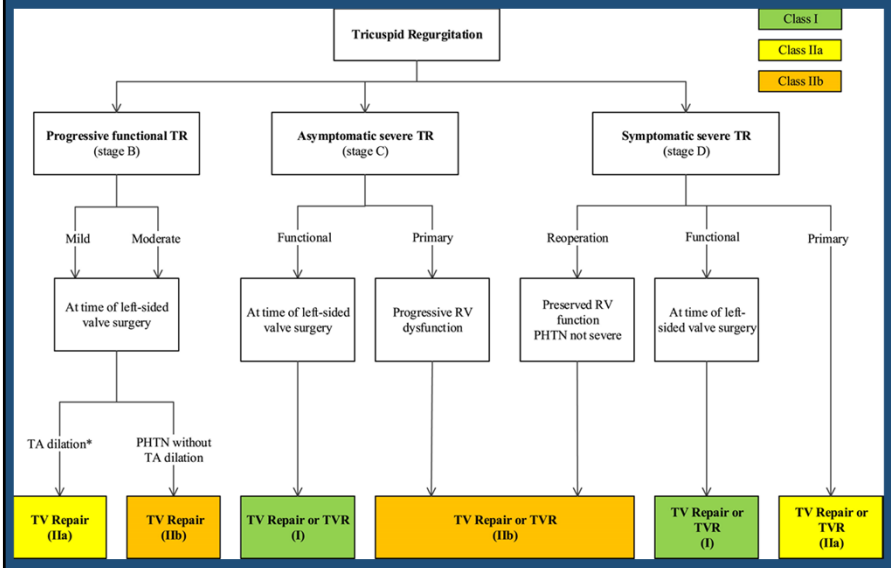
Goals of Medical Therapy

- Preload management.
- Optimize Left sided heart disease
- Manage right heart failure
- Afterload reduction
- Prevent / Treat end organ damage

WHAT DO THE GUIDELINES SAY ABOUT MEDICAL THERAPY?

Guideline	Recommendation	COR	LOE
2013 ACC/AHA HF	Right heart failure is an indicator of poor outcomes in acute decompensated HF		
2014 ACC/AHA Valve	• Diuretics can be useful for patients with severe TR and signs of right-sided HF (stage D). • Medical therapies to reduce elevated PAP and/or PVR might be considered in patients with severe functional TR (stages C,D)	II a IIb	C
2017 ESC Valve	• Diuretics are useful in the management of RHF but are of limited long term efficacy		
2016 ESC HF	• Severe TR causes/deteriorates RHF, thus diuretics are used to reduce peripheral oedema. • As hepatic congestion is often present in these patients MRA may improve decongestion • Management of HF which underlies secondary TR should be optimized • Indications for surgical correction of secondary TR complicating HF are not clearly established		

ACC/AHA Valve 2014

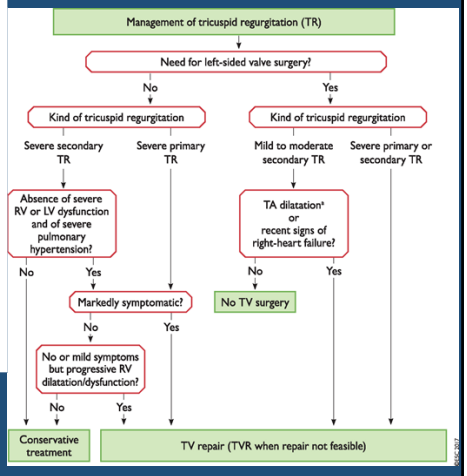


No Class I indications for surgery in isolated TR
Heterogenous group
No trials

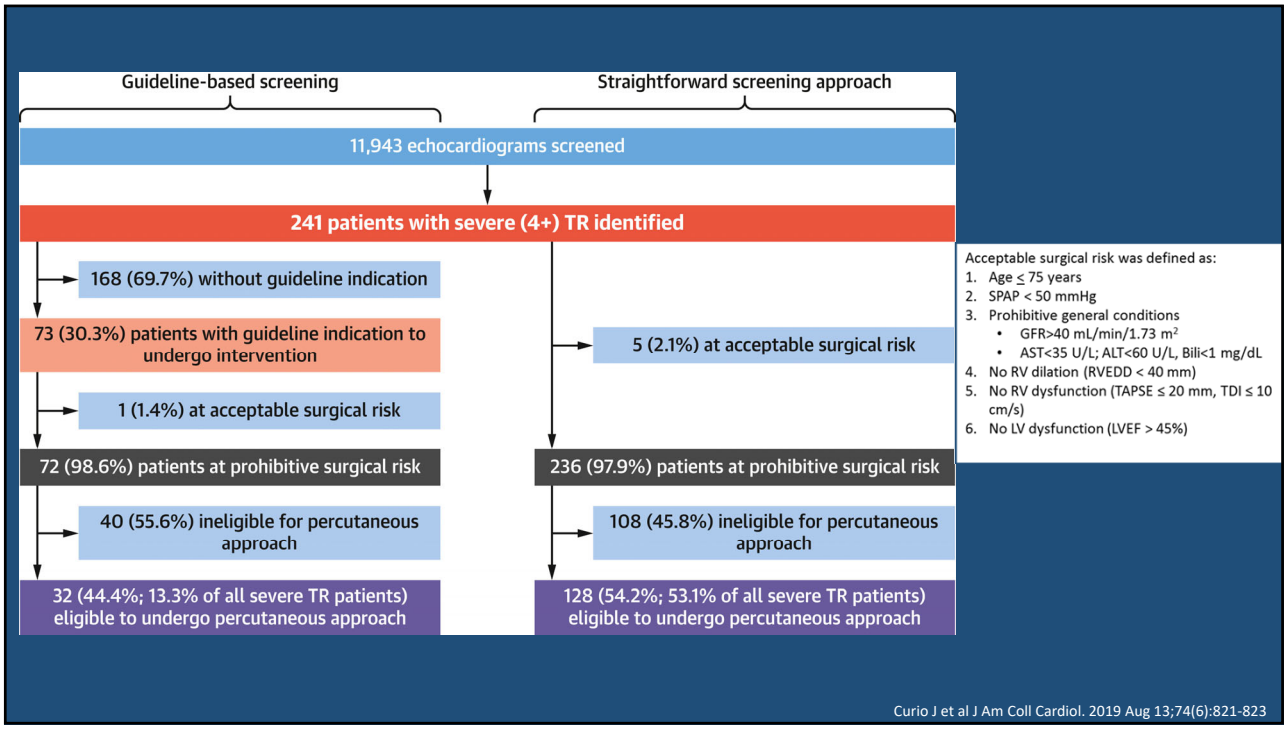
ESC Valve 2017

Recommendations on primary tricuspid regurgitation		
Surgery is indicated in patients with severe primary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery is indicated in symptomatic patients with severe isolated primary tricuspid regurgitation without severe RV dysfunction.	I	C
Surgery should be considered in patients with moderate primary tricuspid regurgitation undergoing left-sided valve surgery.	IIa	C
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.	IIa	C

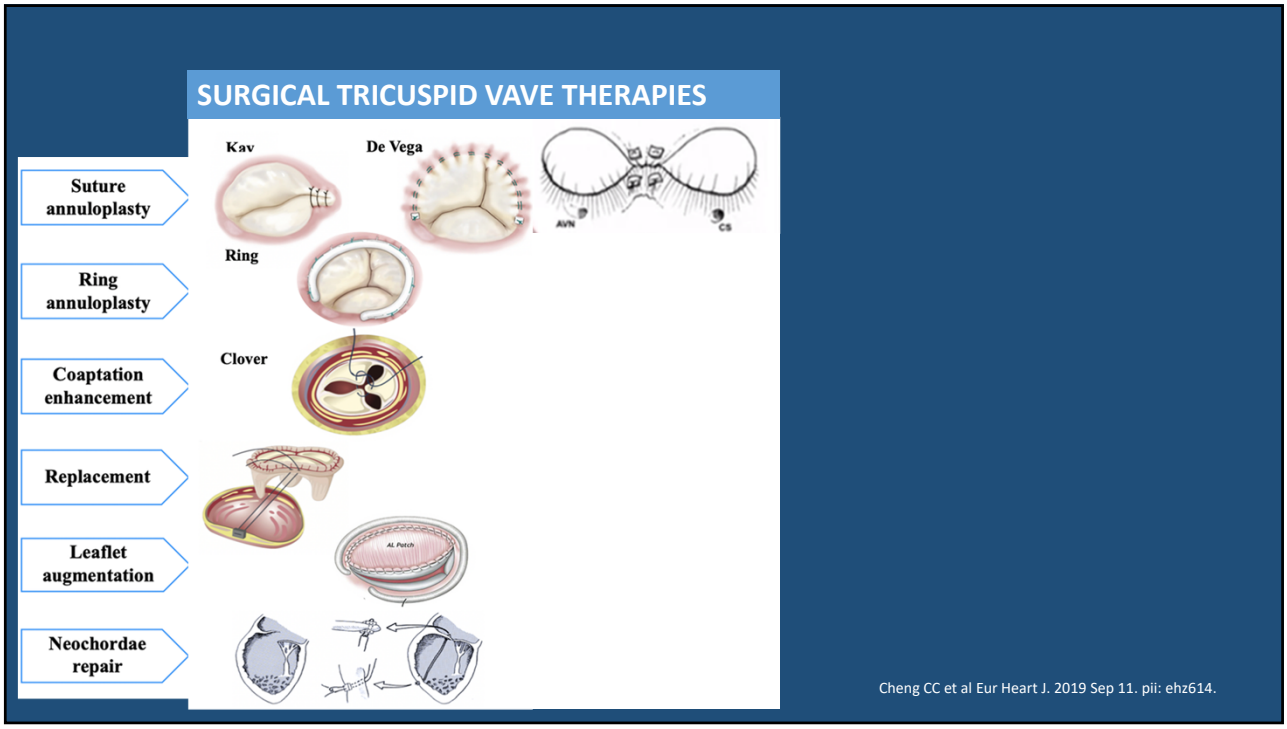
Recommendations on secondary tricuspid regurgitation		
Surgery is indicated in patients with severe secondary tricuspid regurgitation undergoing left-sided valve surgery.	I	C
Surgery should be considered in patients with mild or moderate secondary tricuspid regurgitation with a dilated annulus (≥40 mm or >21 mm/m² by 2D echocardiography) undergoing left-sided valve surgery.	IIa	C
Surgery may be considered in patients undergoing left-sided valve surgery with mild or moderate secondary tricuspid regurgitation even in the absence of annular dilatation when previous recent right-heart failure has been documented.	IIb	C
After previous left-sided surgery and in absence of recurrent left-sided valve dysfunction, surgery should be considered in patients with severe tricuspid regurgitation who are symptomatic or have progressive RV dilatation/dysfunction, in the absence of severe RV or LV dysfunction and severe pulmonary vascular disease/hypertension.	IIa	C



"Although asymptomatic severe isolated TR respond well to diuretic therapy, delaying surgery is likely to result in irreversible RV damage, organ failure and poor results of late surgical intervention"

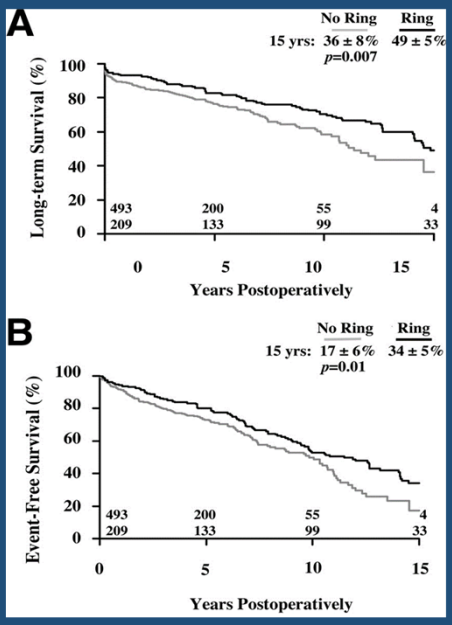


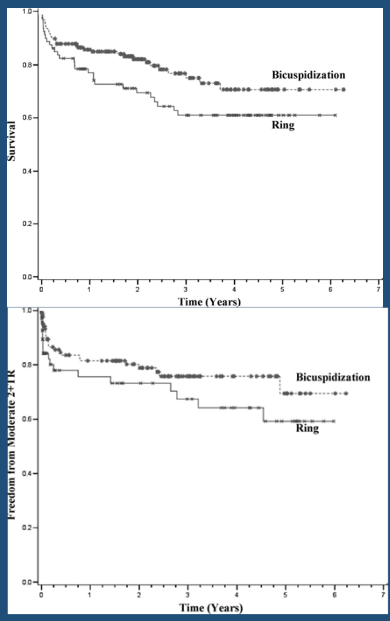
Curio J et al J Am Coll Cardiol. 2019 Aug 13;74(6):821-823



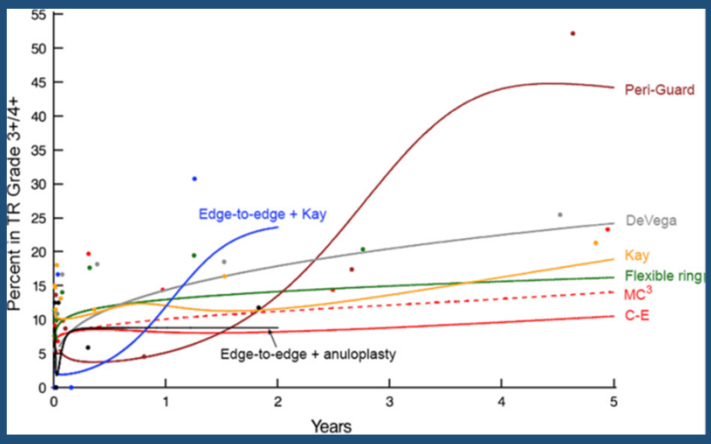
Cheng CC et al Eur Heart J. 2019 Sep 11. pii: ehz614.

COMPARING TV surgery strategies





Ghanta RK et al J Thorac Cardiovasc Surg. 2007 Jan;133(1):117-26. Epub 2006 Dec 4.
Tang GH et al Circulation. 2006 Jul 4;114(1 Suppl):I577-81.



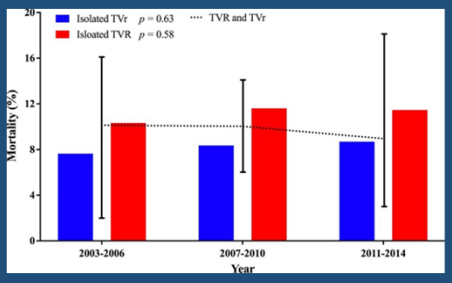
PREDICTORS OF RECURRENT TR AFTER ANNULOPLASTY

- ↑TR severity
- ↑TV annulus
- ↑Leaflet tethering >1cm, 1.6cm2
- Severe Pulmonary hypertension
- ↓LV function
- Pacemaker leads
- Mitral valve replacement

=> Consider Replacement or alternate repair techniques

Navia JL et al J Thorac Cardiovasc Surg. 2010 Jun;139(6):1473-1482.e5
McCarthy PM et al J Thorac Cardiovasc Surg. 2004 Mar;127(3):674-85.
Fukuda S et al Circulation. 2005 Mar 1;111(8):975-9.
Fukuda S et al Circulation. 2006 Jul 4;114(1 Suppl):I582-7.
Min SY et al Eur Heart J. 2010 Dec;31(23):2871-80.
Kabasawa M et al J Thorac Cardiovasc Surg. 2014 Jan;147(1):312-20
Fukuda S et al Circulation. 2005 Mar 1;111(8):975-9. Epub 2005 Feb 14.
Guerin A et al Arch Cardiovasc Dis 2019

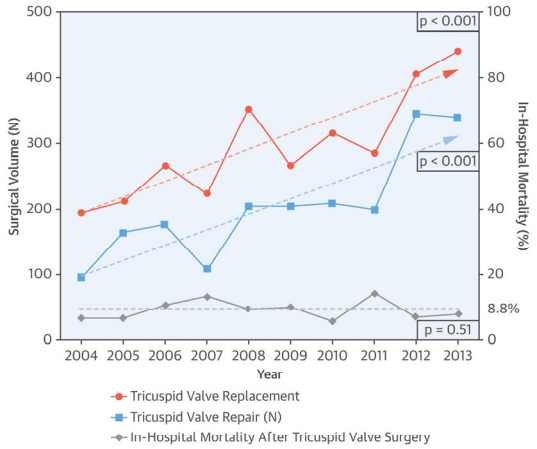
WHY TRANSCATHETER OPTIONS



Jan 1 2003 – Dec 31 2014
12 562 underwent TV surgery
TV surgery increased 48% from 2003 to 2014
Isolated TV Surgery 15%.
Concomitant with left heart surgery 85%.

Isolated TV replacement 10.9% in hospital mortality
5.5% New Dialysis, PPM 34%
Isolated TV repair mortality 8.1%,
PPM 11%, New dialysis 4.4%

CENTRAL ILLUSTRATION: Temporal Trends in Surgical Volume and Mortality for Isolated Tricuspid Valve Surgery



Zack, C.J. et al. J Am Coll Cardiol. 2017;70(24):2953-60.

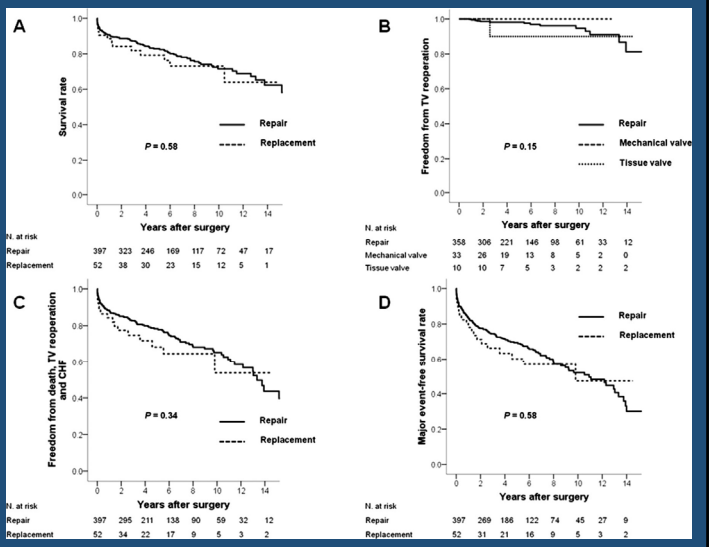
Isolated TV surgery 5005, Mortality 8.8%

Zack CJ et al J Am Coll Cardiol. 2017 Dec 19;70(24):2953-2960
Alqahtani F et al J Am Heart Assoc. 2017 Dec 22;6(12). pii: e007597

WHY SUCH OUTCOMES?

397 TV repairs and 52 TV replacement at
a Single center 1997-2020
Factors that had no impact on mortality

- Procedure Type
- Etiology of TR



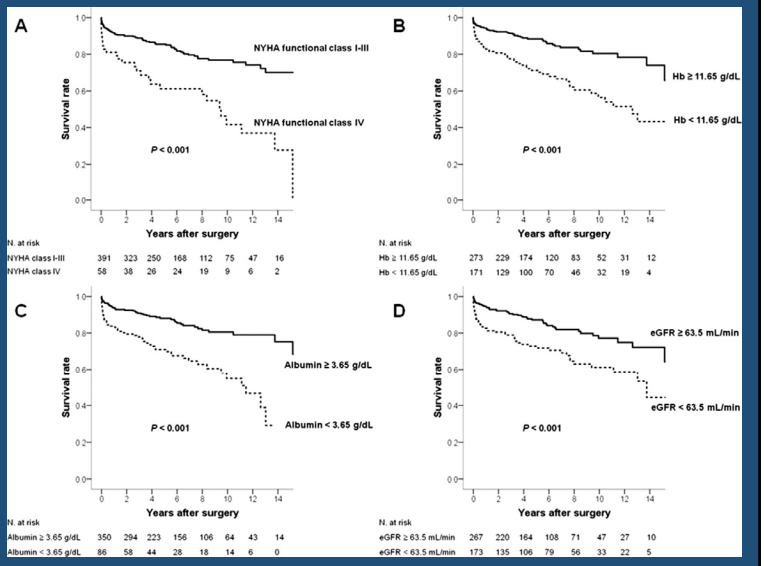
Kim JB et al Heart. 2013 Feb;99(3):181-7

WHY SUCH OUTCOMES?

397 TV repairs and 52 TV replacement at a Single center 1997-2012

<u>Independent Predictors of Mortality</u>

- Male gender
- Age
- NYHA IV
- Liver Cirrhosis
- GFR
- Albumin
- Pre-operative hemoglobin

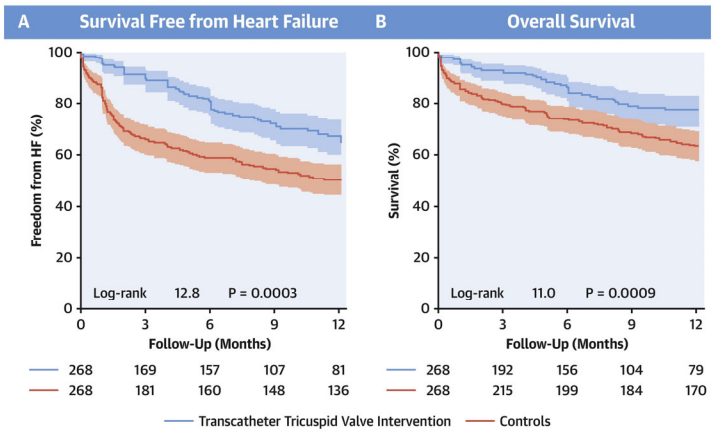


Kim JB et al Heart. 2013 Feb;99(3):181-7

WHY SUCH BAD OUTCOMES??

TRIVALVE REGISTRY

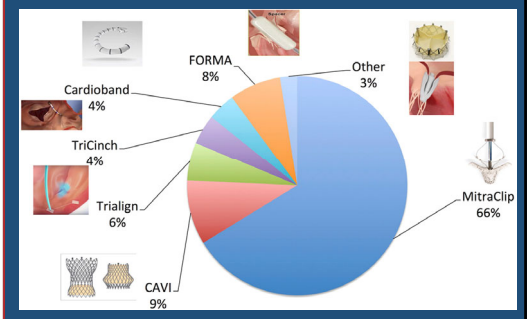
CENTRAL ILLUSTRATION: Transcatheter Treatment of Severe Tricuspid Regurgitation: Primary and Secondary Endpoints



Taramasso, M. et al. J Am Coll Cardiol. 2019;74(24):2998-3008.

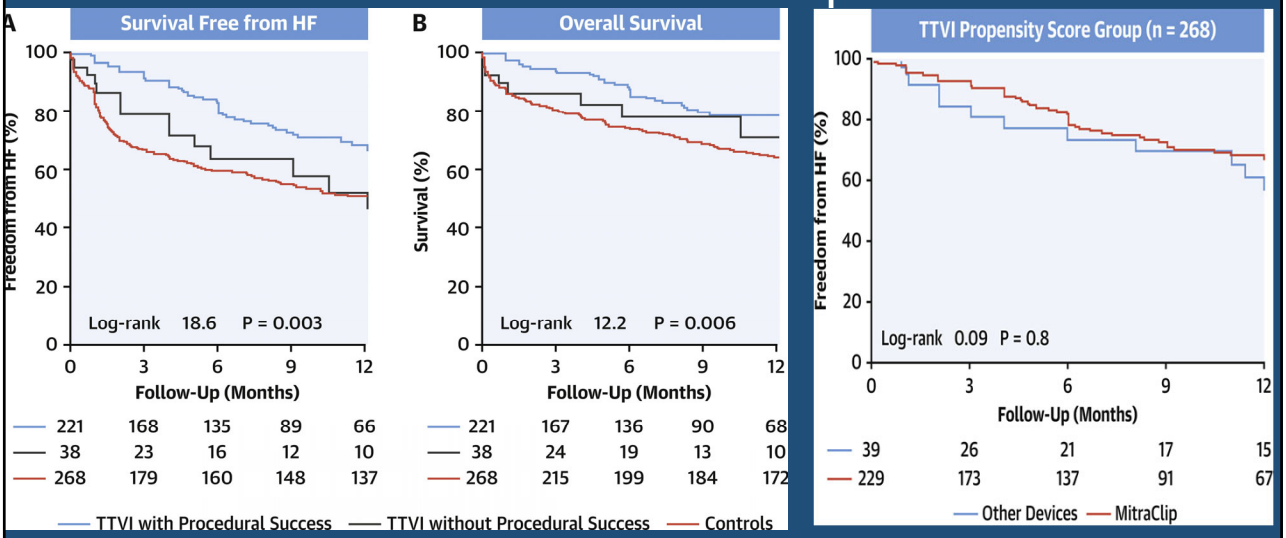
Propensity score matched Age, EuroScore, PASP – 268 matched pairs

Baseline characteristics similar - RV dysfunction, PASP MR, AF, Pacemaker



Taramasso M et al J Am Coll Cardiol. 2019 Dec 17;74(24):2998-3008.
Taramasso M et al JACC Cardiovasc Interv. 2019 Jan 28;12(2):155-165.

TRIVALVE Procedural success impact on outcomes



Procedural Failure 14%

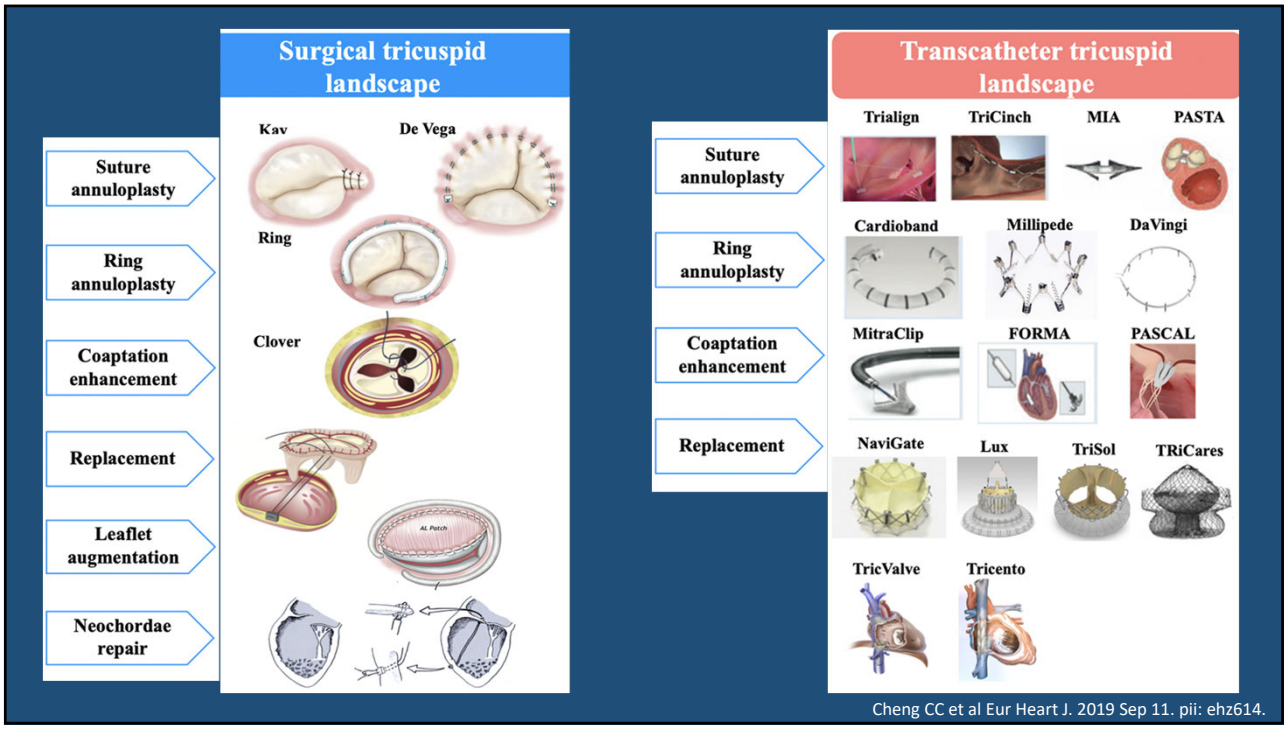
Higher with severe RV dysfunction

Taramasso M et al TRIVALVE registry J Am Coll Cardiol. 2019 Dec 17;74(24):2998-3008.

Patients being treated with transcatheter options currently have advanced TV disease and multiple co-morbidities

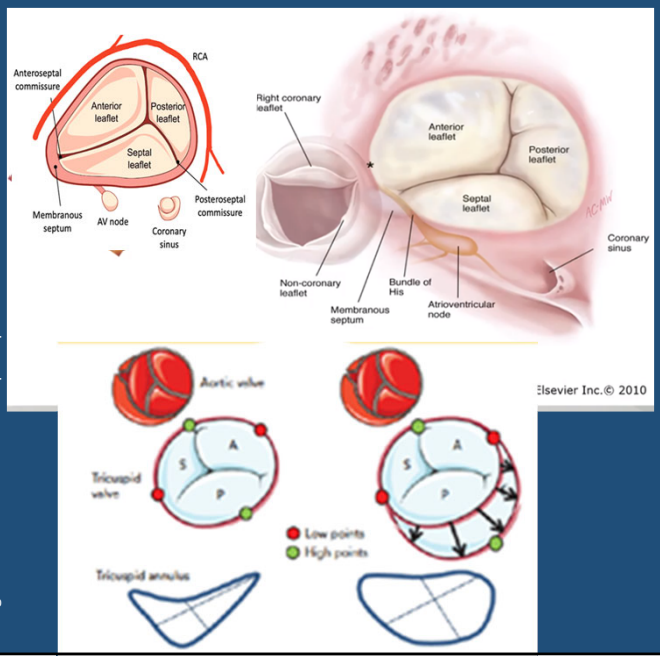
Baseline clinical profile of the overall study population	
Age (years)	76±8.6
Female gender (n, %)	176 (56)
EuroScore II (mean ± SD)	9±8
TR Etiology (n, %)	
Functional	280 (93)
Degenerative	8 (2)
Mixed	9 (3)
Pacemaker induced	7 (2)
Previous left side valve intervention (surgical/transcatheter)	75/24
Trans-valvular tricuspid lead (n, %)	71 (23)
Atrial fibrillation (n, %)	239 (78)
eGFR (ml/min)	43±19
NT pro-BNP (median; IQR – pg/ml)	2759 (1298;5627)
Ascites (n, %)	81 (28)
Peripheral oedema (n, %)	255 (85)
NYHA functional class III-IV (n, %)	290 (95)
Previous admission for RV failure (n, %)	208 (71)

Taramasso et al. J Am Coll Cardiol Intv 2018



Cheng CC et al Eur Heart J. 2019 Sep 11. pii: ehz614.

ANATOMY



- Anterior, oriented Vertically.
- Larger than mitral valve
- Fibrous annulus, size varies with loading conditions
- Variable papillary muscles
- Thin leaflets
- Variable leaflets
- Adjacent structures – RCA, CS, AVN

CS – btw IVC orifice and Septal leaflet

Cheng CC et al Eur Heart J. 2019 Sep 11. pii: ehz614.

ANATOMIC CONSIDERATIONS

Access

- RV complex shape and thin walled – Transapical/transventricular is not desirable
- Angulation between IVC and TV can be challenging for TF esp if prominent Eustachian valve
- TJ approach – ergonomically challenging in cath lab
- Large profile delivery systems needed due to large size of TV annulus

Imaging

- TEE is limited due to anterior location of the valve
- Esophagus is not axial or close to TV so mid esophageal views are not axial and difficult to orient
- Thin leaflets obscured by shadowing from left heart structures
- 3D – shows all 3 leaflets but poor acoustic windows

ANATOMIC CONSIDERATIONS

- Device design
  - Anchoring – No calcification, oversizing for dynamic TV annulus.
  - Leaflet repair – Thin, fragile leaflets, varying anatomy
- Surrounding structures
  - Annuloplasty – RCA
  - TTVR – AV node
  - All - RV trabeculations limit movements below the TV plane

COAPTATION ENHANCEMENT

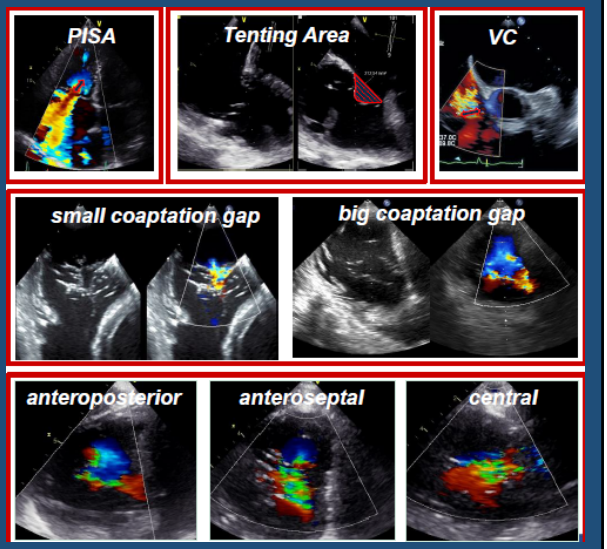
- Leaflet repair – MitraClip, PASCAL
- Spacer - FORMA

MITRACLIP/TRICLIP (Abbott Vascular)

- Trans-catheter edge-to-edge repair
  - Goal is to recreate normal coaptation
- MitraClip
  - Modified steering
- TriClip
  - Designed for the right atrium and access all areas of the leaflets
- Impossible without echocardiographic guidance. Tricuspid imaging is difficult
- TEE – can't see all leaflets at same time
  - Multi-level imaging needed
- Alternatives
  - Intravascular imaging in RA right above the leaflets – better anatomic and temporal resolution
  - 3D ICE

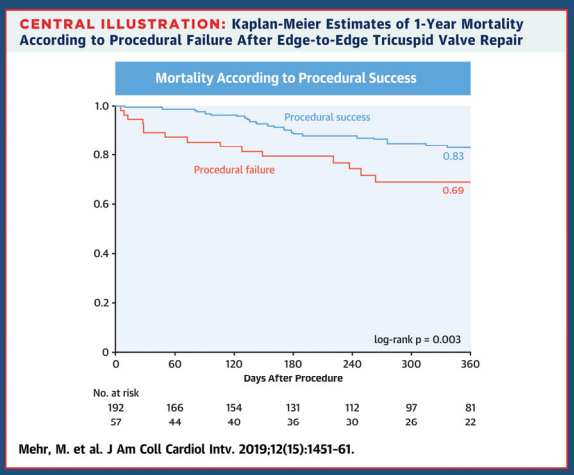
Predictors of Procedural failure - NT

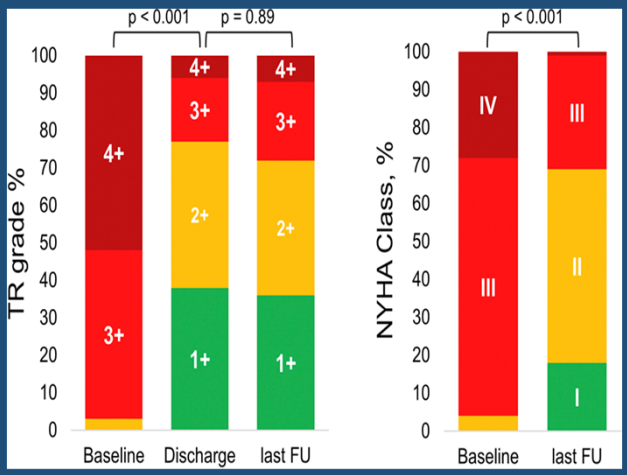
- Coaptation gap
  - Coaptation gap >10mm had a 30% predicted success.
- Tethering distance/Area
- Non-central and non-anteroseptal jets
- EROA >0.65cm2
- VC 11mm
- Large flail gap >10mm (from MitraClip)



Mehr M et al JACC Cardiovasc Interv. 2019 Aug 12;12(15):1451-1461
Besler C et al JACC Cardiovasc. Interv. 2018;11:1119 -1128
Lurz P et al TCT 2018

Transcatheter Edge to Edge repair in the TRIVALVE registry

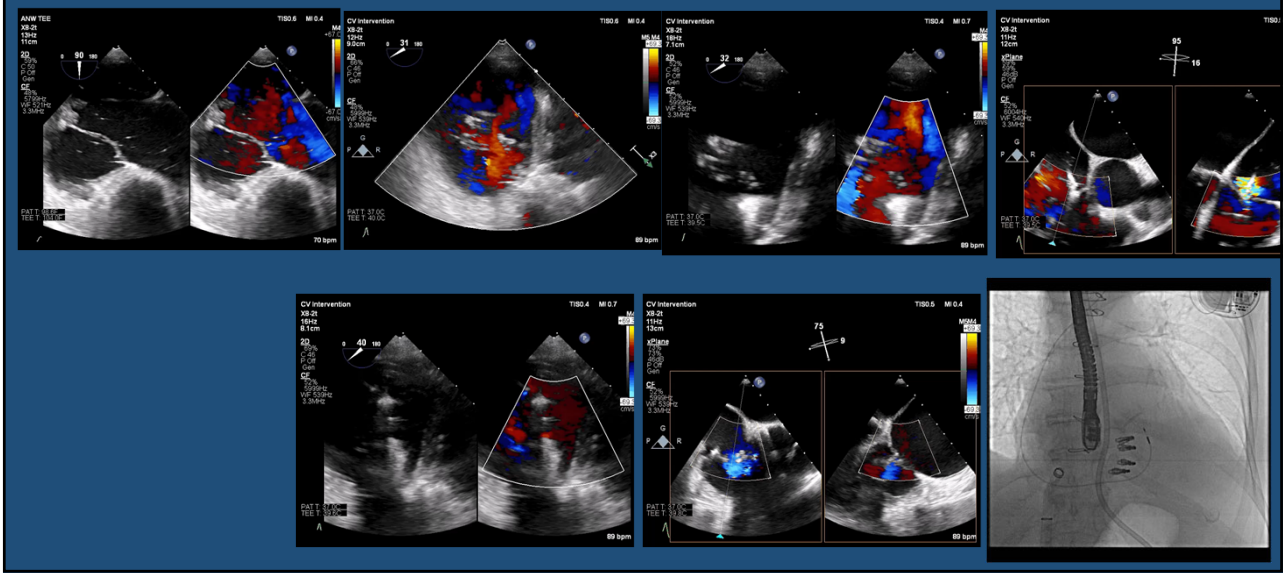




249 patients , centers in Europe and North America. June 2015 and June 2018
24% ascites, 84% peripheral edema, and 74% HF hospitalizations
Predisposing factors for TR HFrEF 26%, left-sided valve disease in 68%,
COPD 25%, AF 74%, and ICD of pacemaker lead in 30% of patients.
Secondary TR in 90%

Mehr M et al JACC Cardiovasc Interv. 2019 Aug 12;12(15):1451-1461

MitraClip



Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study

Georg Nickenig, Marcel Weber*, Philipp Lurz, Ralph Stephan von Bardeleben, Marta Sitges, Paul Sorajja, Jörg Hausleiter, Paolo Denti, Jean-Noël Trochu, Michael Näbauer, Abdellaziz Dahou, Rebecca T Hahn*

- Prospective Single arm, multi center trial enrolling 85 subjects across Europe and USA
- To evaluate performance of a purpose built clip delivery system to the tricuspid valve in patients with ≥ Moderate TR
- Primary Endpoint - Echo TR reduction ≥ 1 grade at 30d Composite MAE at 6 months

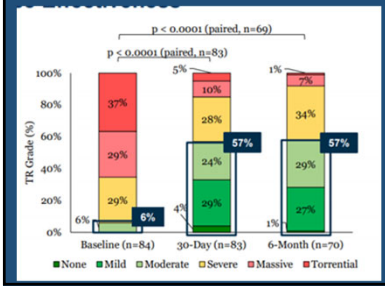
Procedural data

Parameter	TVRS
Implant Success Rate	100%
Acute Device Success	100%
Acute Procedural Success	91.6%
Device Time, min	75.2±49.4
Total Procedure Time, min	152.7±57.8
Fluoroscopy Duration, min	23.3±17.8

Primary Safety End Point

Event	(n)
Major Adverse Event (MAE) through 6 months	3
Cardiovascular Mortality	2
Myocardial Infarction	0
Stroke	0
New Onset Renal Failure	1
Non-elective CV surgery, TVRS Device-related AE	0

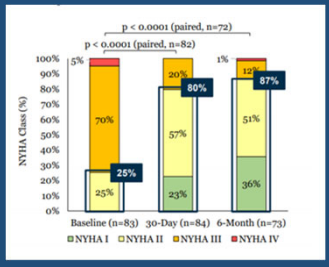
Device Effectiveness



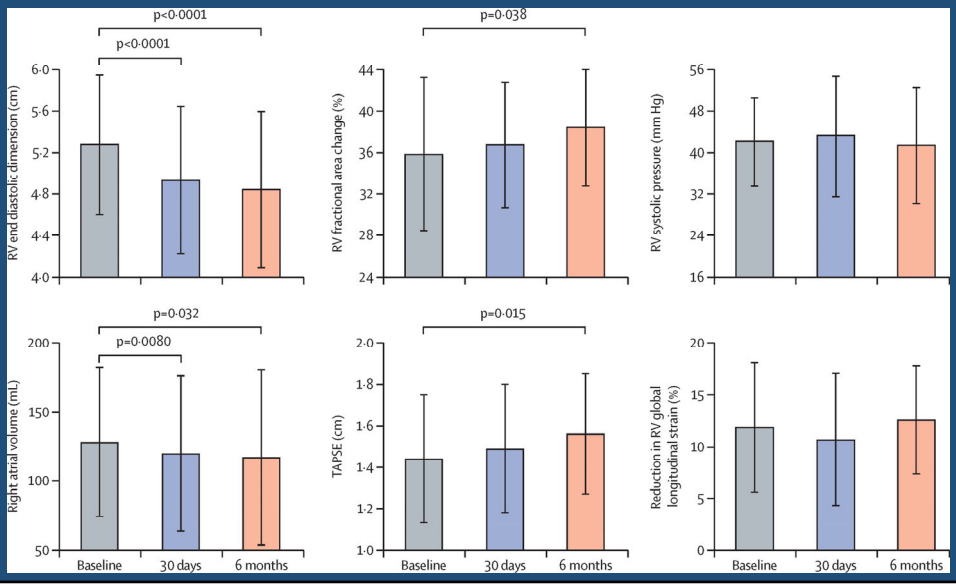
Additional Safety Endpoints

Event	(n)
Other Clinical Safety Endpoints	
All-cause Mortality	4
Major Bleeding[1]	9
Pulmonary Thromboembolism	0
New Onset Liver Failure	0
New Onset Atrial Fibrillation	1
Single Leaflet Device Attachment[2]	5
Embolization	0
Tricuspid Valve Mean Gradient ≥ 5mmHg	6

Symptom Improvement



Right cardiac chamber remodeling



MHIF Featured Study: TRILUMINATE PIVOTAL

CONDITION:
Severe Tricuspid Regurgitation (TR)

***NATIONAL* PI:** Paul Sorajja, MD

CONTACT: Kate Jappe, RN
Kate.jappe@allina.com; 612-863-7347

SPONSOR:
Abbott Vascular, Inc.

DESCRIPTION:

Prospective, randomized, multicenter trial of TriClip™ device in symptomatic patients with severe tricuspid regurgitation (TR) who have been determined to be at intermediate or greater estimated risk for mortality with tricuspid valve surgery.

ACTION:

Are the patients you see experiencing symptoms of severe TR?

If so, please contact Dr. Sorajja or Kate Jappe, RN (Study Coordinator)

PARTIAL CRITERIA LIST / QUALIFICATIONS:

Inclusion

- Symptomatic severe TR despite optimal medical therapies (drug and/or device)
- Adequately treated per applicable standards and stable for 30 days
- Intermediate or greater surgical risk of mortality with tricuspid valve surgery

Exclusion

- Systolic pulmonary artery pressure (sPAP) >70 mmHg
- Severe uncontrolled hypertension Systolic Blood Pressure (SBP) ≥180 mmHg and/or Diastolic Blood Pressure (DBP) ≥110mmHg
- Pacemaker or ICD leads that would prevent appropriate placement of TriClip
- Left Ventricular Ejection Fraction (LVEF) ≤ 20%

HOPE DISCOVERED HERE

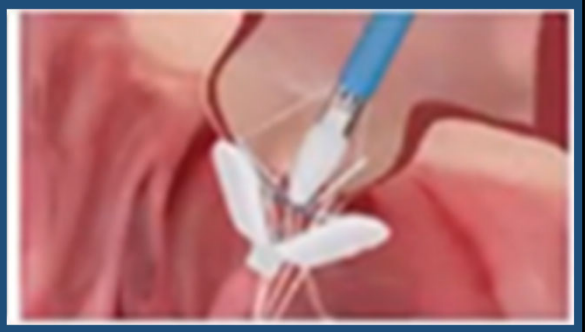
Minneapolis Heart Institute Foundation

PASCAL – (Edwards Lifesciences, Irvine CA)

PAddles**S**pacer**C**lasp**AL**fieri

22F Delivery System
Central Spacer to fill the ROA
Spacer + Broad contoured paddles reduce stress on leaflets.

Independent leaflet capture

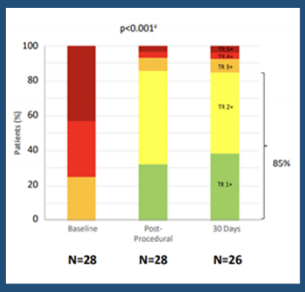


COMPASSIONATE USE - PASCAL

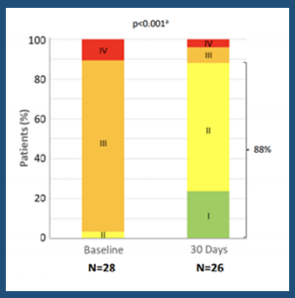
Procedural Data

	n=28 % (n) or Mean ± SD
Procedural Success	86% (24)
Mean # of Devices Implanted	1.4 ± 0.6
Independent Leaflet Grasping	90%
Procedure Time (Skin to Skin), mins	134 ± 68
Mortality	0%
Conversion to Surgery	0%

TR Reduction

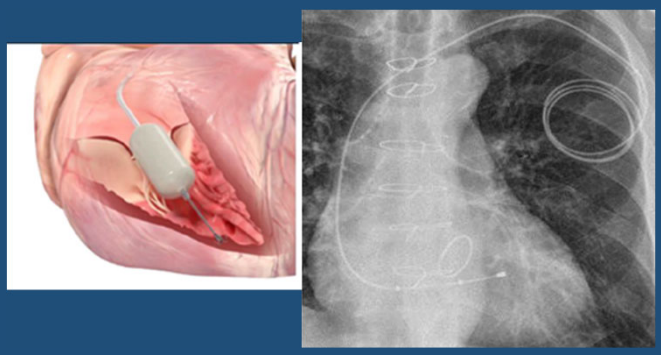


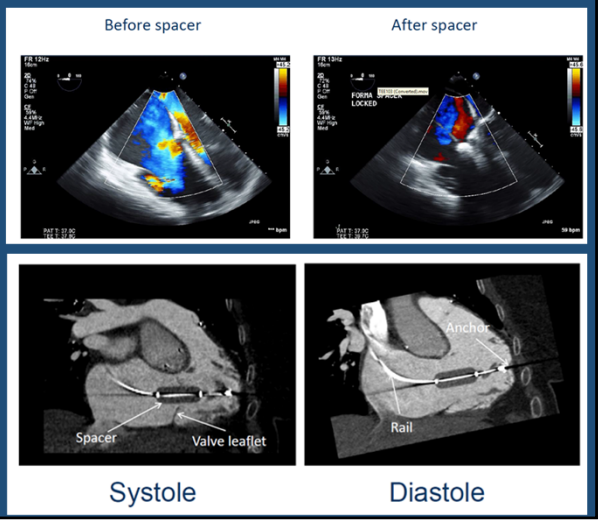
Functional Status

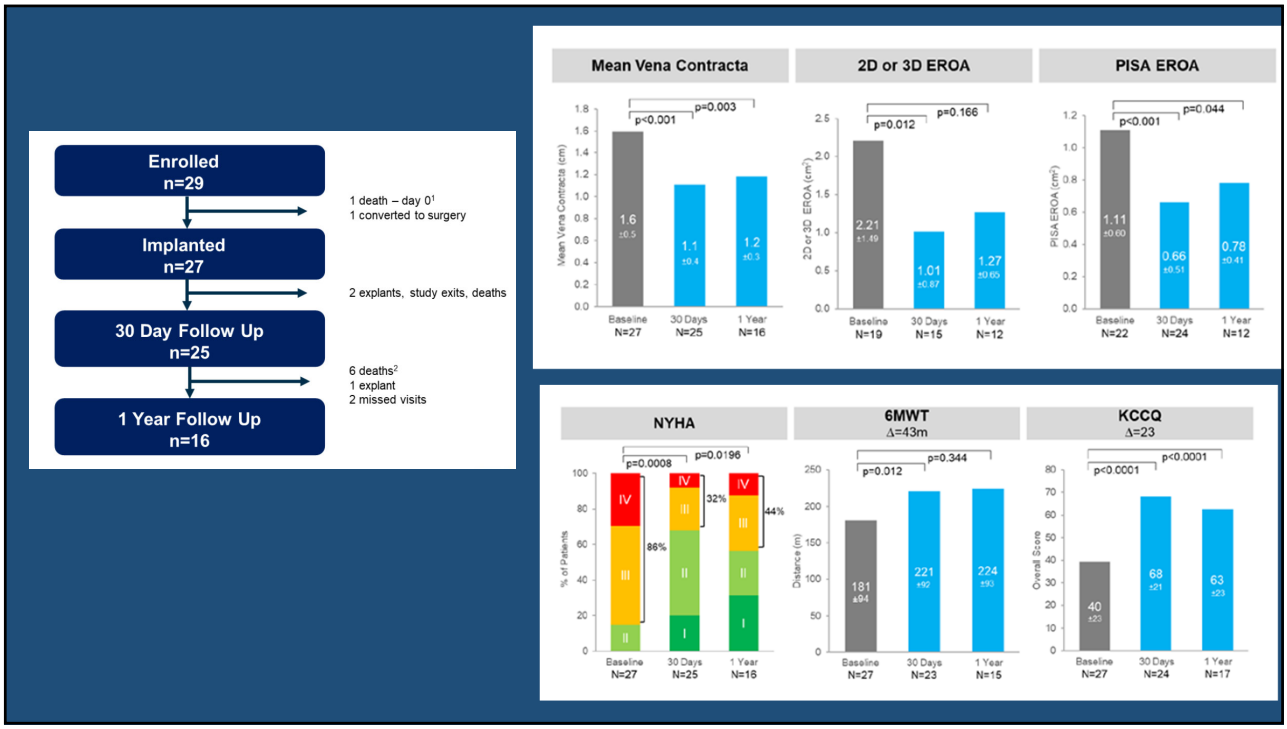


FORMA (Edwards Lifesciences, Irvine CA)

- Coaptation enhacement with Forma, a foam filled expandable device anchored in septal portion of RV
- Fills central TV annulus and provides new coaptation area.







ANNULOPLASTY

- 4Tech Tricinch – Bicuspidization by cinching
- Trialign - Bicuspidization
- Cardioband –Incomplete ring
- Millipede – Complete Semi-rigid ring

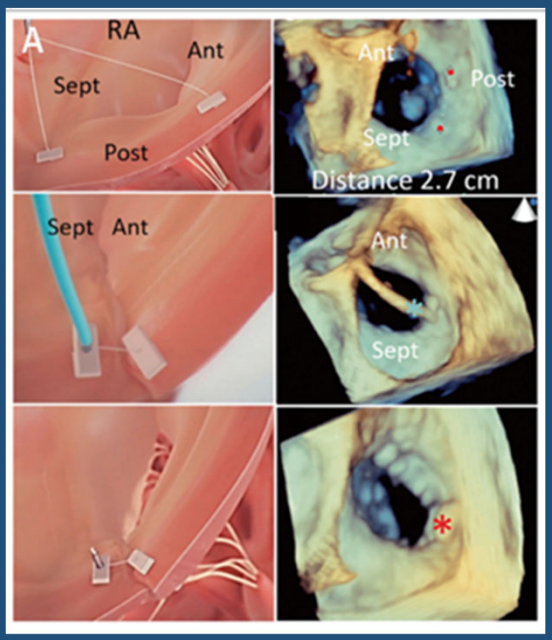
TRIALIGN – Mitralign Tewksbury MA

Early feasibility of a Percutaneous Tricuspid Valve Annuloplasty System for Symptomatic ChrOnic FUnctional Tricuspid regurgitation (SCOUT I) Study

(excluded pacemaker leads, ACHD, Transplanted hearts)

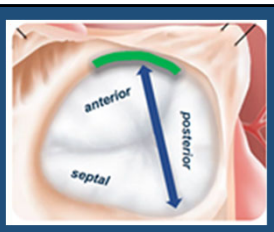
3 Pledget dehiscence
No death
Reduced severity of TR
Improved QoL

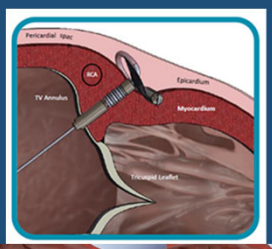
SCOUT II registered.

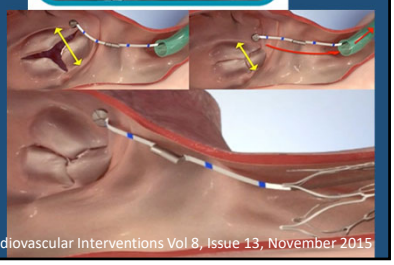


TriCinch (4TECH Cardio, Galway, Ireland)

- Single 25F Delivery System
- Epicardial placement of coil for secure anchoring
- Single anchor
- Recapturable self expanding stent attached to a Dacron band deployed in the subhepatic region of the IVC to maintain tension.
- Multiple stent sizes cover a range of IVC diameters

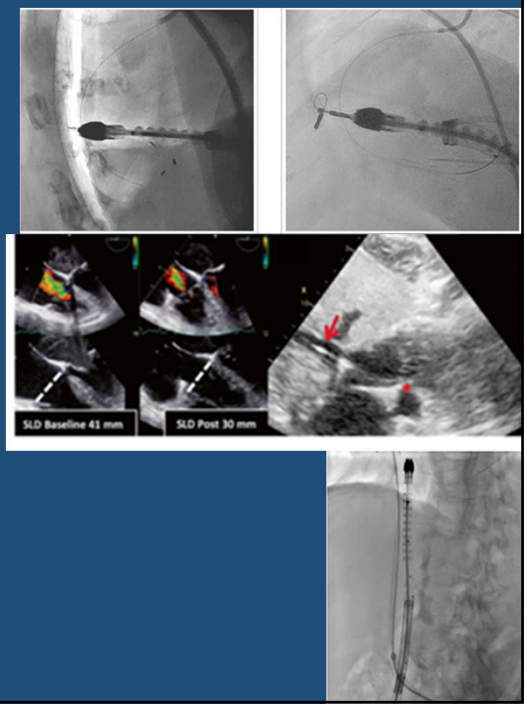






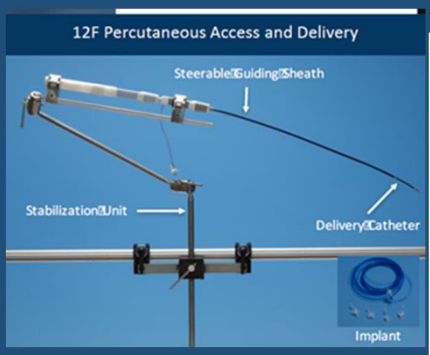
Latib A et al JACC: Cardiovascular Interventions Vol 8, Issue 13, November 2015

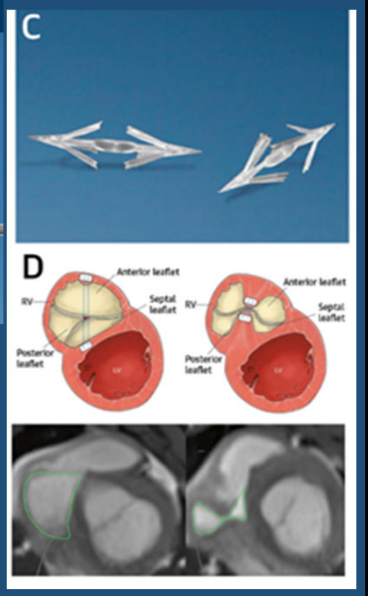
- PREVENT (Percutaneous Treatment of Tricuspid Valve Regurgitation With the TriCinch System) trial
- 24 Patients
- Successful implant in 18 patients (81%)
- Significant (≥1 grade) acute TR reduction in 94% of cases.
- Hemopericardium in 2 patients (8%)
- 5 patients(23%) experienced late annular anchor detachment.
- Preliminary data showed severe 4+ TR reduction
- from ~80% to ~40%,
- Sustained improvement in NYHA and QoL at 6-month follow-up



Minimally Invasive Annuloplasty (MIA Microinterventional Devices, Newton PA

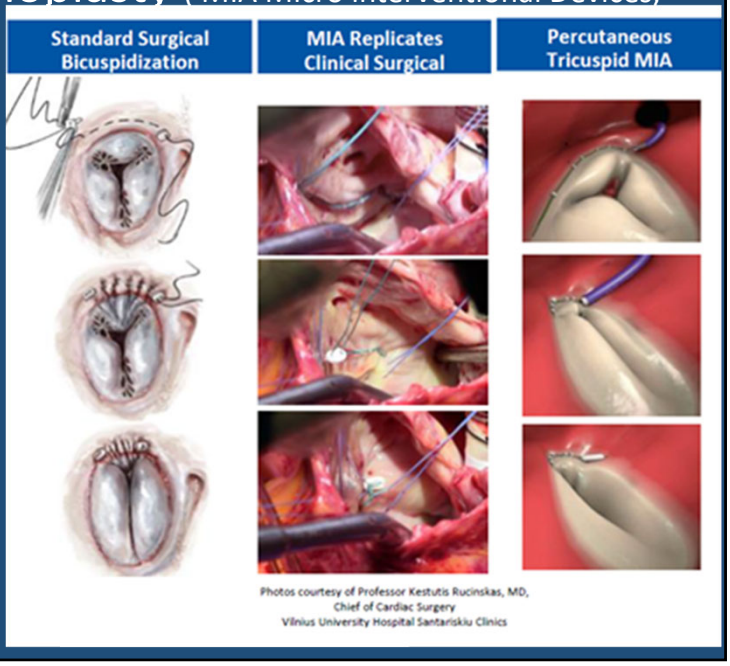
Sutureless Transcatheter annuloplasty system thermoplasty elastomer (Myolast), low mass polymeric self tensioning anchors (Polycor)





Minimally Invasive Annuloplasty (MIA Micro interventional Devices, Newton PA

Via RIJV to the posterior annulus
Fixation elements connected by cable which is cinched and then fixed by locking of a cable
STTAR feasibility Arm
10 patients
No device adverse events
no dehiscence
TR reduced and maintained at 1 yr

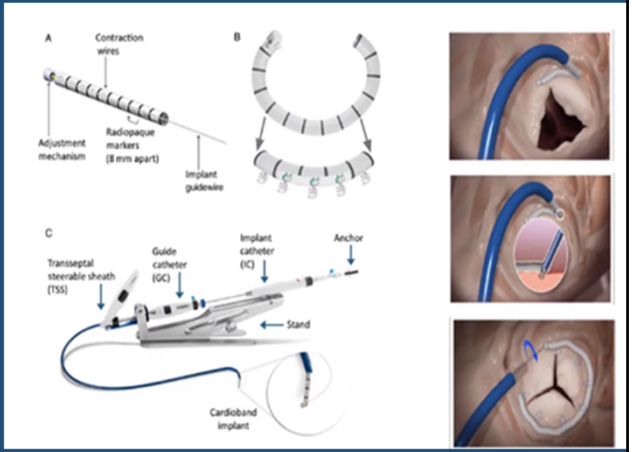


CARDIOBAND (Edwards Lifesciences, Irvine CA)

25F steerable sheath
Sutureless adjustable dacron band

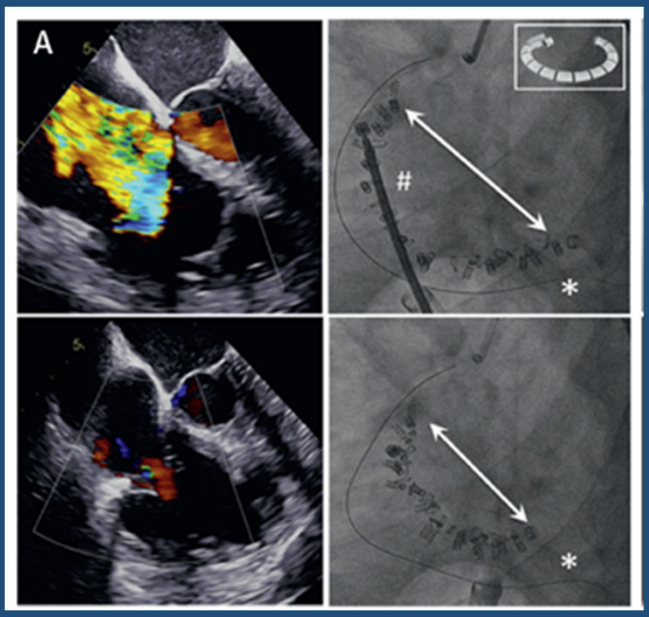
Polyester sleeve with radiopaque markers
Up to 17 stainless steel anchors, 6mm long.
Repositionable and retrievable until deployed
Implant size controlled via a Spool

.

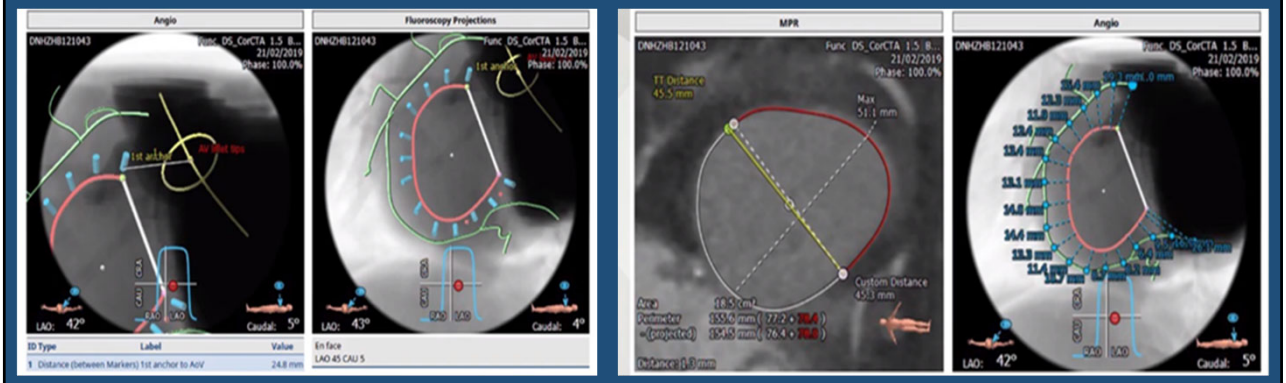


May be limited as a stand alone therapy if -
Severe annular dilation
Severe leaflet tethering (Tethering height >0.51cm)
Primary TR

CT planning - RCA is<2mm to annulus is a contra-indication



Mark first anchor



Understanding the proximity between anatomical landmarks and device to guide procedure and prevent complications

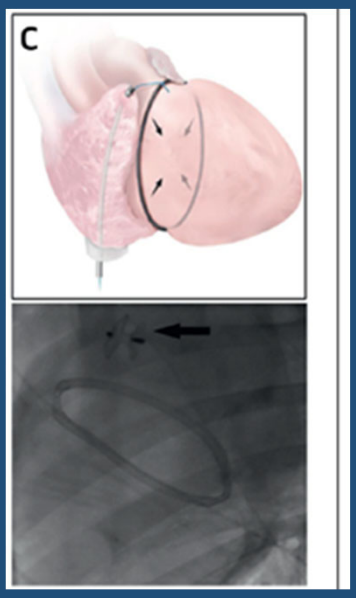
TRI-REPAIR Cardioband

- Single arm study to evaluate safety and efficacy of Cardioband Tricuspid system for (TR 30 patients)
- Excluded patients with device leads impinging the TV
- In early experience the
  - Complications – related to RCA (side branch occlusion, worsening distal RCA lesion, tamponade from anchor in RCA)
  - Significant reduction in EROA through annular reduction at 30d and sustained in 1 year
  - Clinically and statistically significant improvements in functional status, QoL, 6MWT at 30d and through 1 year
  - One year survival 83%
- CE Mark Approval

Trans-atrial intra-pericardial tricuspid annuloplasty system (Cook Medical, Bloomington IN

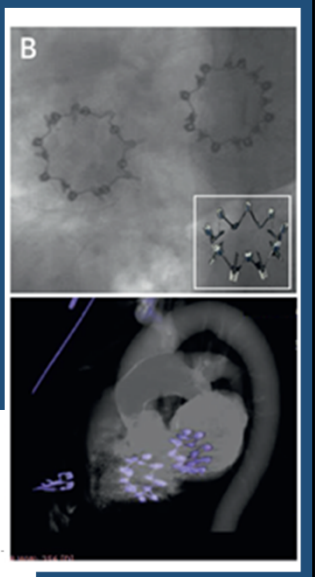
- Memory shaped delivery system
- Access through femoral vein into pericardium vis right atrial appendage (RAA)
- Adjustable circumferential implant along atrioventricular grove externally compressing the TV annulus
- RAA access closed with a nitinol occlude

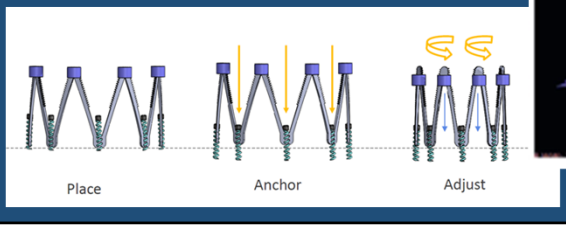
- A newer version of the device—including a balloon anchor pericardial sheath, the annuloplasty system, and a bioresorbable closure device—for human use is currently being developed by the National Institutes of Health and Cook Medical (EFS is planned



MILLIPEDE IRIS (Boston Scientific, Marlborough, MA)

- Semirigid complete ring
- Customized repositioned and retrievable
- Leave options open for future interventions
- Catheter for Tricuspid is in development
- No anticoagulation needed
- Allows concomitant procedures
- Serves as a dock for TTVR



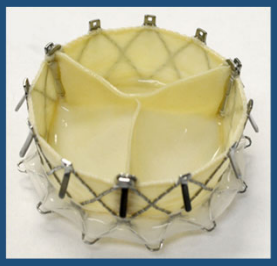


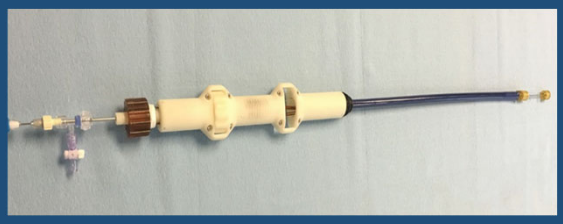
Orthotopic Valve Implantation

- Native Valve
- Valve-in Valve or Valve-in-ring

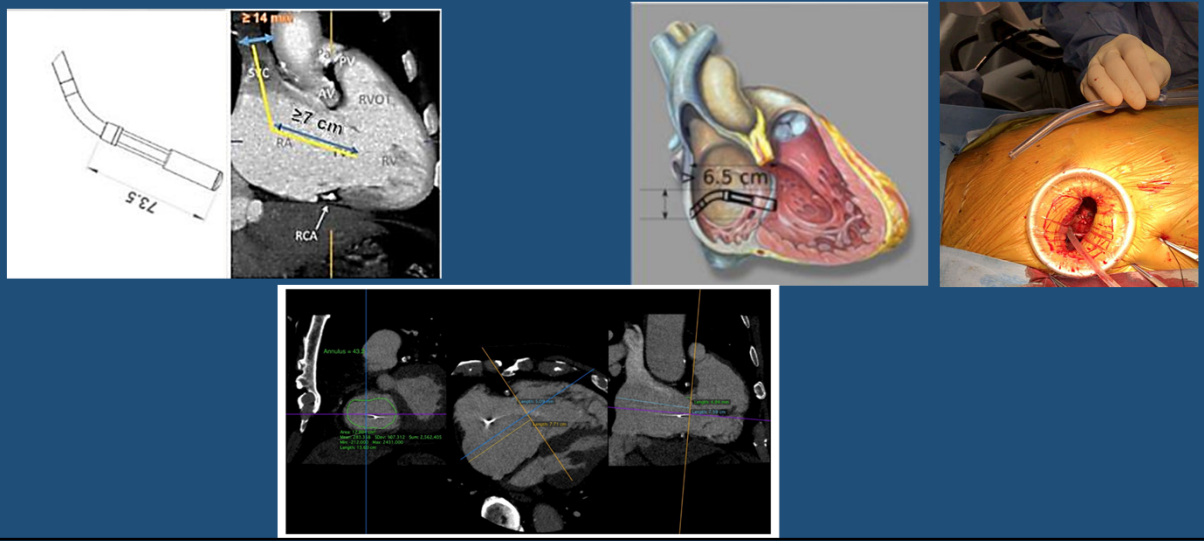
NAVIGATE (Navigate Cardiac Structures, Lake Forest CA)

- Self expanding nitinol tapered stent,
- 3 pericardial valve
- Atrial Winglet and Ventricular graspers
- 21mm Height, truncated cone
- Delivery system
  - 42F sheath in RIJV
  - 35F at distal capsule,
  - 24F shaft
- 2 degrees of motion at the tip
- 80 degrees articulation
- Only one tried in humans yet

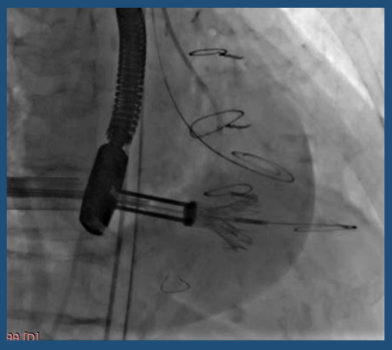




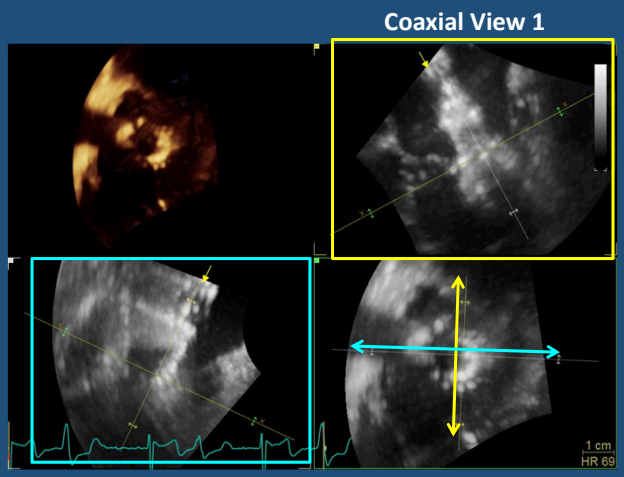
Transjugular and Transatrial



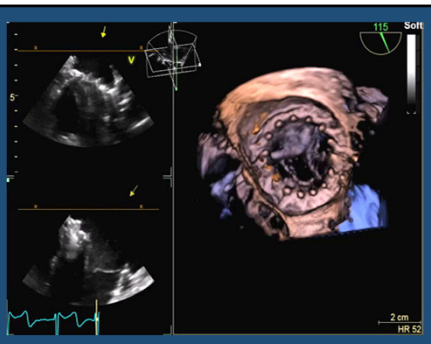
Initial valve deployment with RCA injection

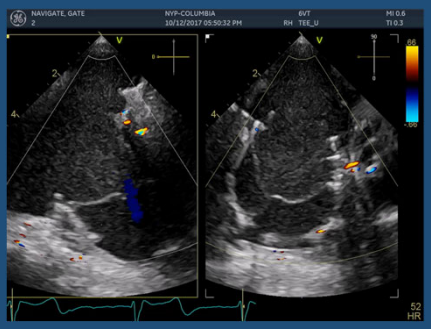


Retracting the capsule:
Exposing Ventricular Tines



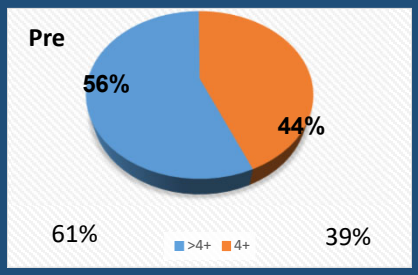
Final Result

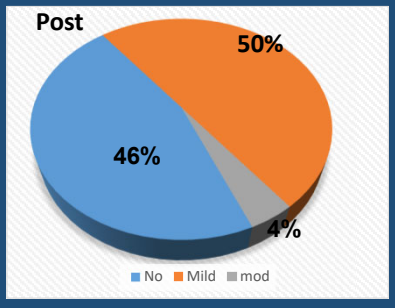




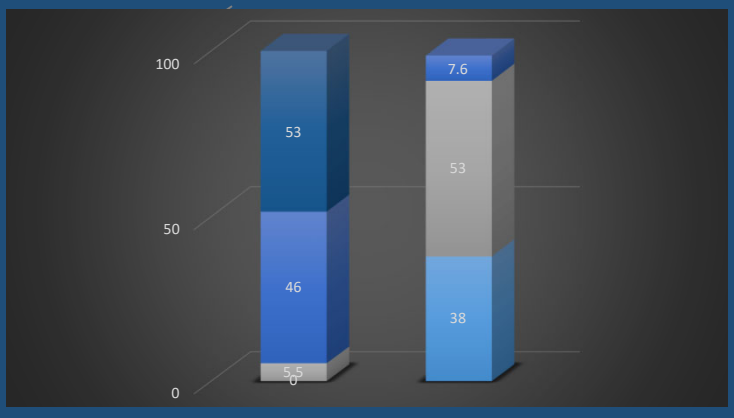
- Trivial central and trivial paravalvular regurgitation
- Peak/mean transtricuspid gradient = 1.5 and 0.3 mmHg

Efficacy and Functional Improvement





Tricuspid Regurgitation Severity



NYHA Class

Complications

30 D mortality – 13%

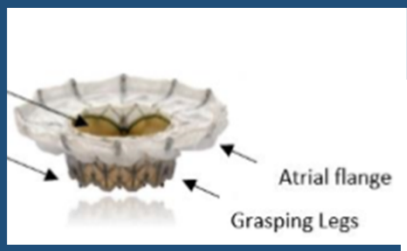
- Trans-atrial
  - D9 VSD, re-operation
  - D28 AKI multiorgan failure
  - D2 Premature deployment, canted valve, ECMO, bioprosthetic valve
- Transjugular
  - D9 AKI, multiorgan failure
- Malpositioning needing surgical conversion
  - gross oversizing ~ 10mm
  - Undersizing and premature deployment
  - Small RA and deep RV deployment in Carcinoid patient
  - Canting while trying to capture septal leaflet
- RV perforation due to guidewire
- HIT
- Pacemaker D2,5,150
- AKI on CKD

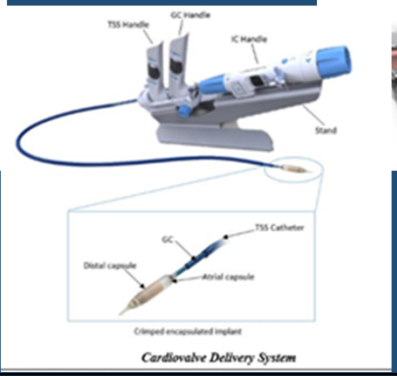
NAVIGATE COMPASSIONATE USE

- Feasible via TA or TJ, coaxial deployment is key
- Low RVOT risk
- Rapid pacing not necessary
- Confirm leaflet insertion
- Confirm sizing with TEE – oversizing VSD or PPM
- Implanted in PPM patients without dislodgment or change in thresholds

CARDIOVALVE

- 3 bovine pericardium leaflets sutured via a Dacron fabric to a dual self-expanding nitinol frame design.
- 24 grasping points that fixate the device to the native tricuspid annulus.
- The Dacron fabric is also used to cover the nitinol frame for promoting atraumatic interface with the heart tissue and enhanced sealing.





Cardiovalve Delivery System

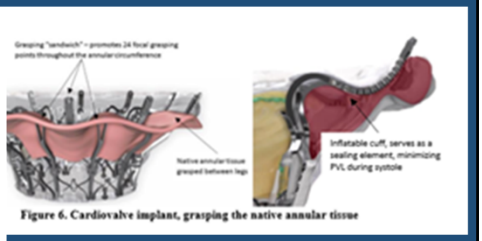


Figure 6. Cardiovalve implant, grasping the native annular tissue

TRISOL

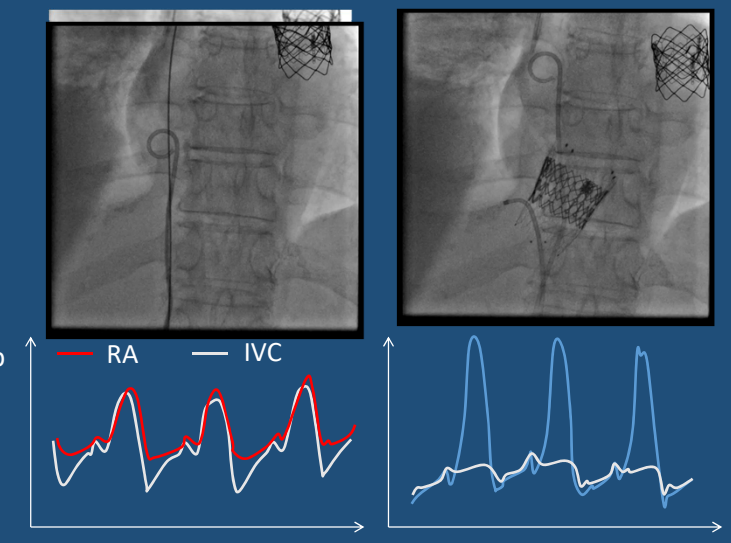
- Single dome shaped leaflet.
- Large diameter and low profile
- Axial anchoring
- Bovine pericardium
- Leaflet

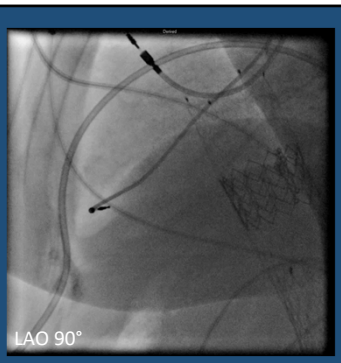
LUX valve (Jenscare Biotechnology Ningbo China)

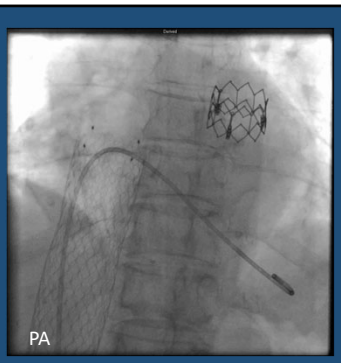
- Self expanding bovine pericardial tissue valve mounted on a nitinol stent frame and inserted trans-atrially
- Adaptive skirt to minimize paravalvular regurgitation
- Special anchoring mechanism for secure anchoring within right ventricle

Rationale of caval valve implantation

- Reduce TR volume by increasing RA pressure
- Decongest hepatic and renal veins by reducing peak IVC pressure
- Prospective, open-label, single center, RCT
- symptomatic TR (NYHA ≥2) despite established optimal medical therapy, age ≥50 years, and IVC diameter <31 mm
- Excluded: LVEF < 30%, severe MR, dialysis







Within 7-48 hours post CAVI – 2 valve dislocations and stent migrations
All surgical bail out
All died - bleeding, RHF, Sepsis 1, 8, 49 and 60 days after the index procedure
Recruitment was stopped prematurely after patient 28 (40 pts. planned)

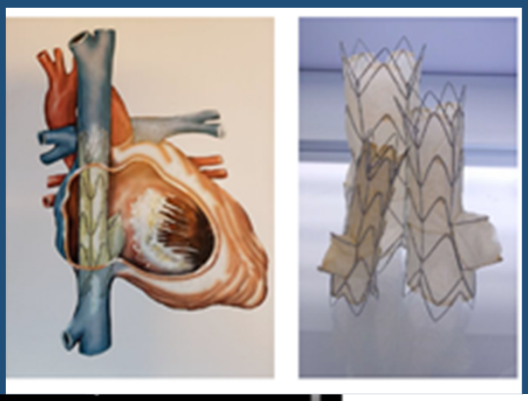
Symptom Relief and QoL improvements
No change in Peak VO2

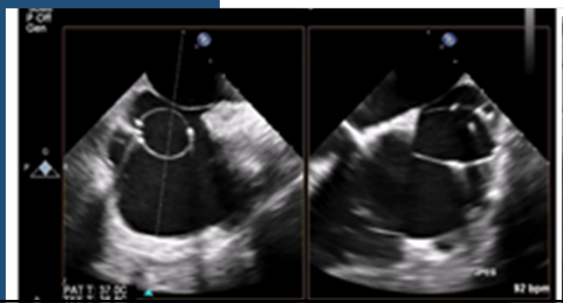
TRICAVAL TRIAL

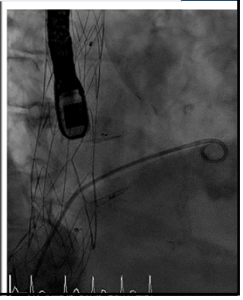
- Prospective, open-label, single center, RCT
- symptomatic TR (NYHA ≥2) despite established optimal medical therapy, age ≥50 years, and IVC diameter <31 mm
- Excluded: LVEF < 30%, severe MR, dialysis
- Primary outcome: Peak VO2 after 3 months
- Secondary : safety, 6MWT, NYHA class, NT-proBNP levels, right heart function, HF hospitalization, QoL

TRICENTO (NVT GmBH, Hechingen)

- Self expanding covered nitinol stent with a bicuspid porcine pericardium valve
- Bicaval anchored
- Custom made with CT measurements
- 24F TF
- Fully repositionable and re-sheathable up to final release







	STAGE 1	STAGE 2	STAGE 3	STAGE 4	STAGE 5
SYMPTOMS	None	None	Vague	Current or previous episodes of RHF	Overt RHF+/- end organ damage from chronic RVVO
TR GRADE	<moderate	≥ moderate	Severe	Severe	Torrential
ANNULAR REMODELING	**Normal <40mm**	Normal or mild	Present	Moderate to severe	Severe
LEAFLET COAPTATION	Normal 5-6mm	mildly abnormal <3mm	Abnormal	Coaptation gap	Large coaptation gap
TETHERING	None	None or mildly abnormal	Abnormal <8mm	Significantly abnormal, varying degrees of tethering >8mm, 1.8cm2	Significantly abnormal
RV FUNCTION AND REMODELING	None	Mildly abnormal	Mild RV dysfunction +/- remodeling	> Moderate dysfunction and remodeling	Severe RV dysfunction and remodeling
MEDICAL TREATMENT	None Surveillance	Normal function Mild remodeling Diuretic	Diuretics	Moderate to high dose diuretics and/or IV diuretic requirements	Multiple RHF hospitalizations. Frequent need for IV diuretics and/or high dose combination diuretics
SURGICAL TREATMENT	No	At time of Left heart (LH) surgery	At time of LH surgery Isolated if symptoms, RV remodeling, comorbidities	Isolated TVR in absence of severe PHTN and comorbidities High risk of peri-operative RV dysfunction	Prohibitive intra-operative and peri-operative risk
TRANSCATHETER TREATMENT	No	Potential future target	Potential candidates for surgery enrolled in IDE RCTs	Currently in EFS if High surgical risk. May require combination annuloplasty + leaflet repair TTVR	Prohibitive risk Potentially futile Palliative procedures in highly selected patients

Taramasso M et al JACC Cardiovasc Imaging. 2019 Apr;12(4):605-621.
Dreyfus GD et al J Am Coll Cardiol. 2015 Jun 2;65(21):2331-6

	STAGE 1	STAGE 2	STAGE 3	STAGE 4	STAGE 5
SYMPTOMS	None	None	Vague	Current or previous episodes of RHF	Overt RHF+/- end organ damage from chronic RVVO
TR GRADE	<moderate	≥ moderate	Severe	Severe	Torrential
TV ANNULUS	**Normal <40mm**	Normal or mild	Present	Moderate to severe	Severe
LEAFLET COAPTATION	Normal	mildly abnormal	Abnormal	Coaptation gap	Large coaptation gap
TETHERING	None 5-6mm	None or mildly abnormal	Abnormal <8mm	Significantly abnormal, varying degrees of tethering >8mm	Significantly abnormal
RV FUNCTION AND REMODELING	None	Mildly abnormal	Mild RV dysfunction +/- remodeling	> Moderate dysfunction and remodeling	Severe RV dysfunction and remodeling
MEDICAL TREATMENT	None Surveillance	Normal function Mild remodeling	Diuretics	Moderate to high dose diuretics and/or IV diuretic requirements	Multiple RHF hospitalizations. Frequent need for IV diuretics and/or high dose combination diuretics
SURGICAL TREATMENT	No	At time of Left heart (LH) surgery	At time of LH surgery Isolated if symptoms, RV remodeling, comorbidities	Isolated TVR in absence of severe PHTN and comorbidities High risk of peri-operative RV dysfunction	Prohibitive intra-operative and peri-operative risk
TRANSCATHETER TREATMENT	**EARLY** RV initial dilation TA subsequent initial dilation Leaflet – mild coaptation defects • Annuloplasty • Leaflet approximation • Replacement (Orthotopic)		**PROGRESSIVE** RV progressive dilation TA progressive dilation Leaflet – lack of coaptation • Leaflet approximation • +/-Annuloplasty • Replacement (Orthotopic)	**LATE** RV and TA severe dilation Leaflet tethering • Annuloplasty • +/- Leaflet approximation • Replacement (Orthotopic or Heterotopic)	

Taramasso M et al JACC Cardiovasc Imaging. 2019 Apr;12(4):605-621.
Dreyfus GD et al J Am Coll Cardiol. 2015 Jun 2;65(21):2331-6

SUMMARY

- Tricuspid regurgitation is BAD, Early diagnosis is key for successful therapies.
- Careful echocardiography and use of cross sectional imaging is crucial for diagnosis.
- Transcatheter tricuspid interventions is rapidly developing and shows promise in early feasibility studies
- Standardization of outcomes (Valve Academic Research consortium) and Registry.
- Determination of best timing for intervention “Early TTVI”
- Combination therapies – sequential or simultaneous.
- More Trials

ACKNOWLEDGEMENTS

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- MHIF Research Team, Cath Lab staff, Clinic Nurses and Staff
- Referring Cardiologists
- Patients

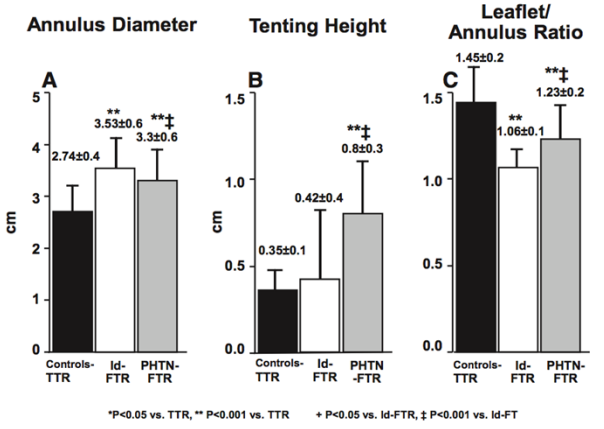
THANKS FOR LISTENING

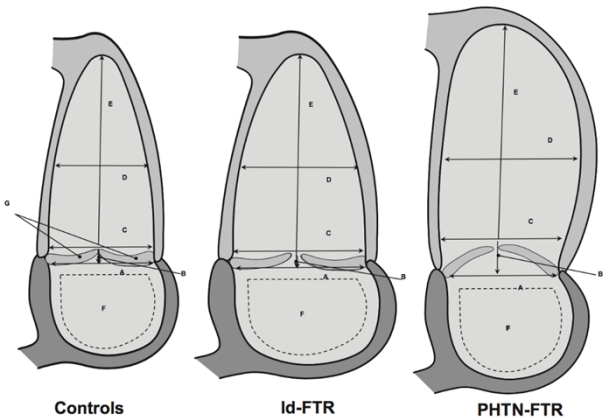
QUESTIONS??

Structure	Device name and typology	Description	Summary	Current clinical experience
	**TRAIPTA** (Trans-Atrial Intra-Pericardial Tricuspid Annuloplasty) [34] *Annuloplasty system*	A delivery device is used to position a suture circumferentially in the atrio-ventricular groove and to deploy a semirigid device, in order to apply direct compression to the tricuspid annulus.	- Good preclinical results - Increase in leaflet coaptation - Challenging procedure with need of pericardial space - Risk of coronary injury	Only preclinical implants performed.
	**Trialign**: system for tricuspid bicuspidization [35] *Annuloplasty system*	Delivery of polyester pledgets via the right ventricle through the tricuspid annulus. Pledgets are plicated and locked directly on the annulus. The system is advanced through a transjugular route.	- Risk of mid-term failure (incomplete plasty) which can be mitigated by implanting 2 pairs of pledgets	15 patients (SCOUT trial) 1. Acute implant success in 100%; 2. Reduced annular dimensions, annular area and EROA; 3. Three late pledget detachments and one right coronary artery damage occurred
	**TriCinch**: catheter-based device to perform tricuspid annular cinching [36] *Annuloplasty system*	The system consists of a corkscrew anchor, a self-expanding stent, and a Dacron band connecting both. Once anchored, the stent is released in the inferior vein cava and tension is applied through the Dacron band.	- Potential risk of leaflet or coronary damage - Single anchor with risk of anchor detachment - Incomplete plasty with risk of TR recurrence	24 patients (PREVENT trial): 1. Successful procedure in 85% patients patients (2 haemopericardium) 2. four late anchor detachments and one right coronary artery damage occurred occurred
	**Millipede**: repositionable and retrievable tricuspid ring [37] *Annuloplasty system*	Collapsible nitinol ring with individually controlled collars. Corkscrew-shaped anchors attach the ring to the annulus. The implant is then contracted, reducing the dilated annulus to a physiological size.	- Complete annuloplasty with potential reduced risk of TR recurrence - Risk of atrio-ventricular block	2 patients (surgical implant): 1. Immediate reduction in tricuspid diameter; 2. Abolishment of TR 3.Positive remodeling of both ventricles.
	**Cardioband**: adjustable, sutureless annuloplasty band [38] *Annuloplasty system*	A flexible implant delivered through a flexible catheter. Anchors are attached to the annulus. Once all anchors are fixed, tension can be applied reducing the annular diameters.	- Complete annuloplasty with potential reduced risk of TR recurrence - It could be effective in the reduction of the annular diameters - Risk of anchor detachment & coronary injury	5 patients (compassionate use): 1. Reduction in TR grade, septo-lateral and antero-posterior diameter; 2. Reduction in EROA, PISA radius, and VC.
	**FORMA**: spacer anchored at the right ventricular apex [39] *Coaptation device*	A foam-filled polymer balloon and rail that is anchored at the right ventricular apex. The device is advanced via left axillary vein access and is fully retrievable.	- Large device not addressing the anatomical changes that occur in functional TR - May have impact on RV pacing lead insertion	Cohort of 18 patients: 1. Implantation success in 89%, with no operative mortality. 2. Less than severe TR grade in 71% at 6-month follow-up; 3. Improvement in NYHA functional class and clinical outcomes at 1-year follow-up.
	**Caval valve implantation**: valve implantation in inferior and superior vein cava.	The *TricValve* device consists of 3 leaflets of bovine pericardium mounted on a self-expandable nitinol frame. The size ranges from 28 to 43 mm.	- Not technically challenging but sizing is an issue - Ventricularization of the right atrium - Optimal relief of symptoms and signs of heart failure in advance patients	4 patients: 1. Technical success in 75% of patients; 2. Clinical improvement at 7-month follow-up.
	**MitraClip**: a v-shaped clip which can grasp contiguous leaflets together [40] *Leaflet plasty device*	A 4-mm-wide cobalt-chromium polyester-covered implant with 2 arms that can grasp 2 leaflets. The delivery system can be advanced through a transjugular or transfemoral access.	- Large interventional experience - Operators are confident with the device - MitraClip does not target the annular dilation - Risk of leaflet detachment, leaflet injury and chordal entanglement	64 patients (compassionate use): 1. Significant reduction in TR grade, EROA, regurgitant volume, septo-lateral diameter; 2. Improvement of clinical outcomes at 9-month follow-up.
	**MIA device:** two Polycor anchors connected by MyoLast elastomer *Annuloplasty system*	The annular reduction is achieved without sutures or other intervention due to the compliant, self-tensioning MIA implant incorporating the PolyCor anchors and MyoLastTM implantable elastomer.	- Replicates the surgical sutures - Encouraging pre clinical data - Reliable and rapid deployment	1. the 2 first-in-man experiences have been successful with proven safety and reduction in annular valve are. 2. In the first 2 patients 9 and 8 MIAs were implanted in a 270-degree ring pattern
	**NAVIGATE valve:** Nitinol tapered stent with a truncated cone configuration and annular winglets for secure anchoring of annulus and tricuspid valve leaflets. *Transcatheter valve prosthesis*	The winglets engage the annulus from both atrial and ventricular sides. The truncated cone enables low height profile	- The valve replacement can virtually minimize the risk of residual regurgitation - The valve replacement can reach a wider patient population with different anatomies and etiologies - Valve replacement can shorter procedural times	1. the first compassionate use was performed with procedural success and no events at short-term follow-up.

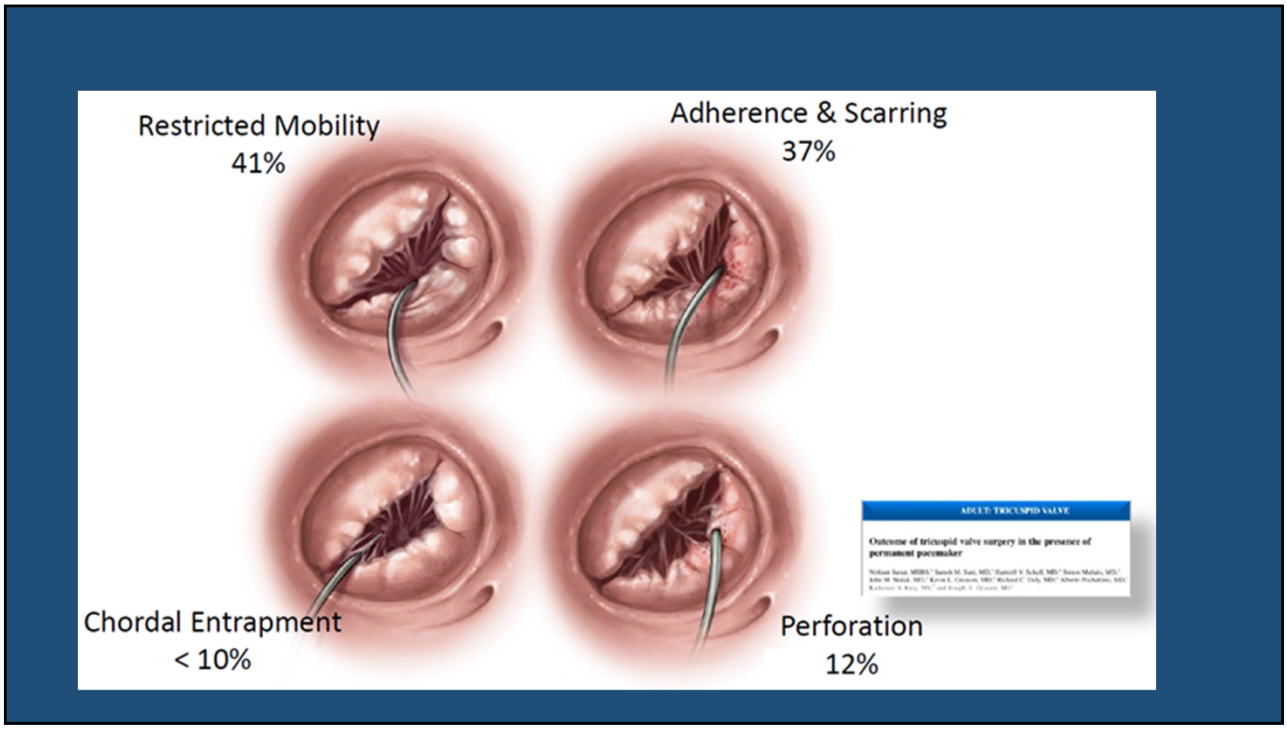
Mangieri A et al Circ Cardiovasc Interv. 2017 Jul;10(7). pii: e005043.

TR PH-related and AF-Related (12%)





Toplisky et al, Circ Cardiovasc Ima 2011


Restricted Mobility
41%
Adherence & Scarring
37%
Chordal Entrapment
< 10%
Perforation
12%
ADULT: TRICUSPID VALVE
Outcome of tricuspid valve surgery in the presence of permanent pacemaker