Echo Beyond 2020: the Brave New World of PC Treatment of the TV Valve

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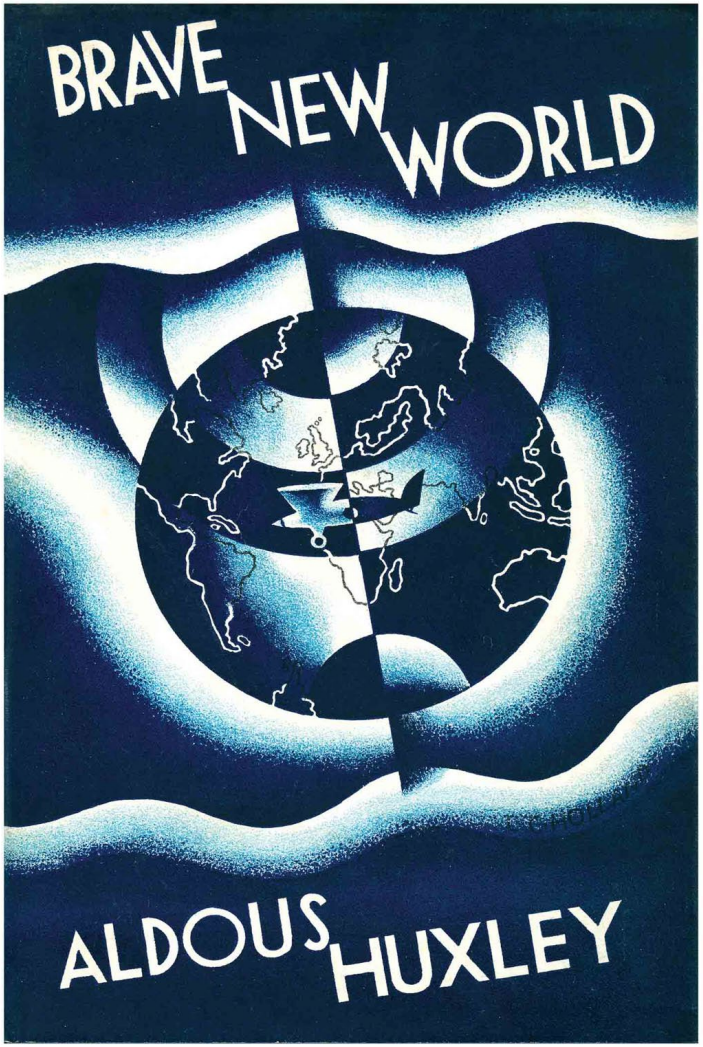

(The Non-Dystopian Edition)

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Tricuspid Regurgitation

Significant tricuspid regurgitation affects more than 1.6 million patients in the United States

More than 80% of these cases are functional in nature

Indolent nature along with concomitant comorbidities were significant barriers in developing therapeutic interest

Association with poor outcomes and the often progressive nature of the disease has lead to increased interest in both surgical and transcatheter management

TR Outcomes: at least moderate TR is independently associated with increased mortality

Aims Tricuspid regurgitation (TR) is a frequent echocardiographic finding; however, its effect on outcome is unclear. The objectives of current study were to evaluate the impact of TR severity on heart failure hospitalization and mortality.

Methods and results We retrospectively reviewed consecutive echocardiograms performed between 2011 and 2016 at the Tel-Aviv Medical Center. TR severity was determined using semi-quantitative approach including colour jet area, vena contracta width, density of continuous Doppler jet, hepatic vein flow pattern, trans-tricuspid inflow pattern, annular diameter, right ventricle, and right atrial size. Major comorbidities, re-admissions and all-cause mortality were extracted from the electronic health records. The final analysis included 33 305 patients with median follow-up period of 3.34 years (interquartile range 2.11–4.54). TR (≥mild) was present in 31% of our cohort. One-year mortality rates were 7.7% for patients with no/trivial TR, 16.8% for patients with mild TR, 29.5% for moderate TR, and 45.6% for patients with severe TR ($P < 0.001$). Univariate and multivariate analyses demonstrated a positive correlation between TR severity and overall mortality and rates of heart failure re-admission after adjustment for potential confounders. The proportional hazards method for overall mortality showed that patients with moderate [hazard ratio (HR) 1.15, 95% confidence interval (CI) 1.02–1.3, $P = 0.024$] and severe TR (HR 1.43, 95% CI 1.08–1.88, $P = 0.011$) had a worse prognosis than those with no or minimal TR.

Conclusions The presence of any degree of TR is associated with adverse clinical outcome. At least moderate TR is independently associated with increased mortality.

Keywords tricuspid regurgitation • echocardiography • prognosis

Chorin EHJ CV Imag 2020

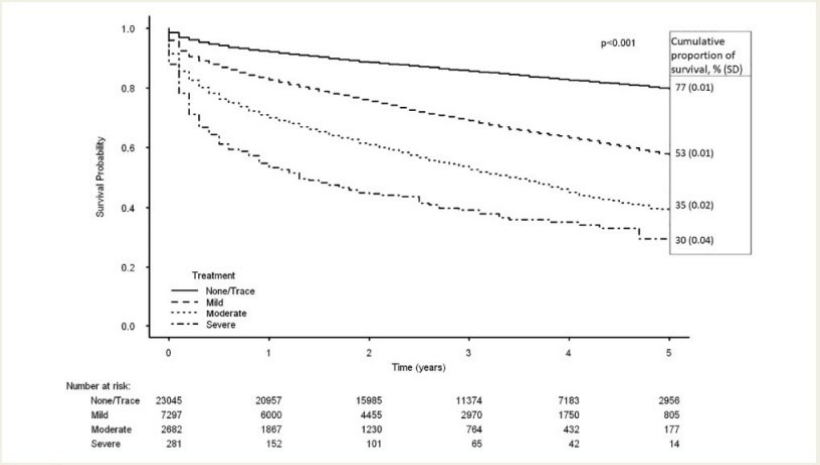


Figure 1 The Kaplan–Meier survival curves of all patients according to TR grade.

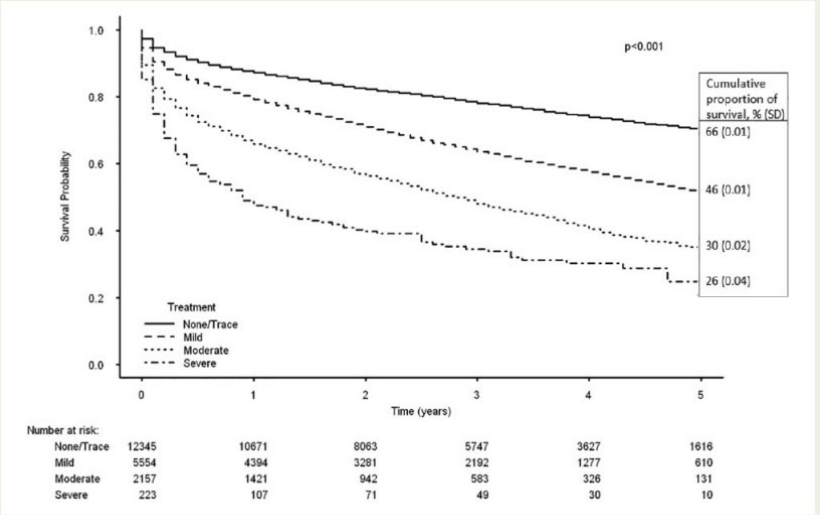
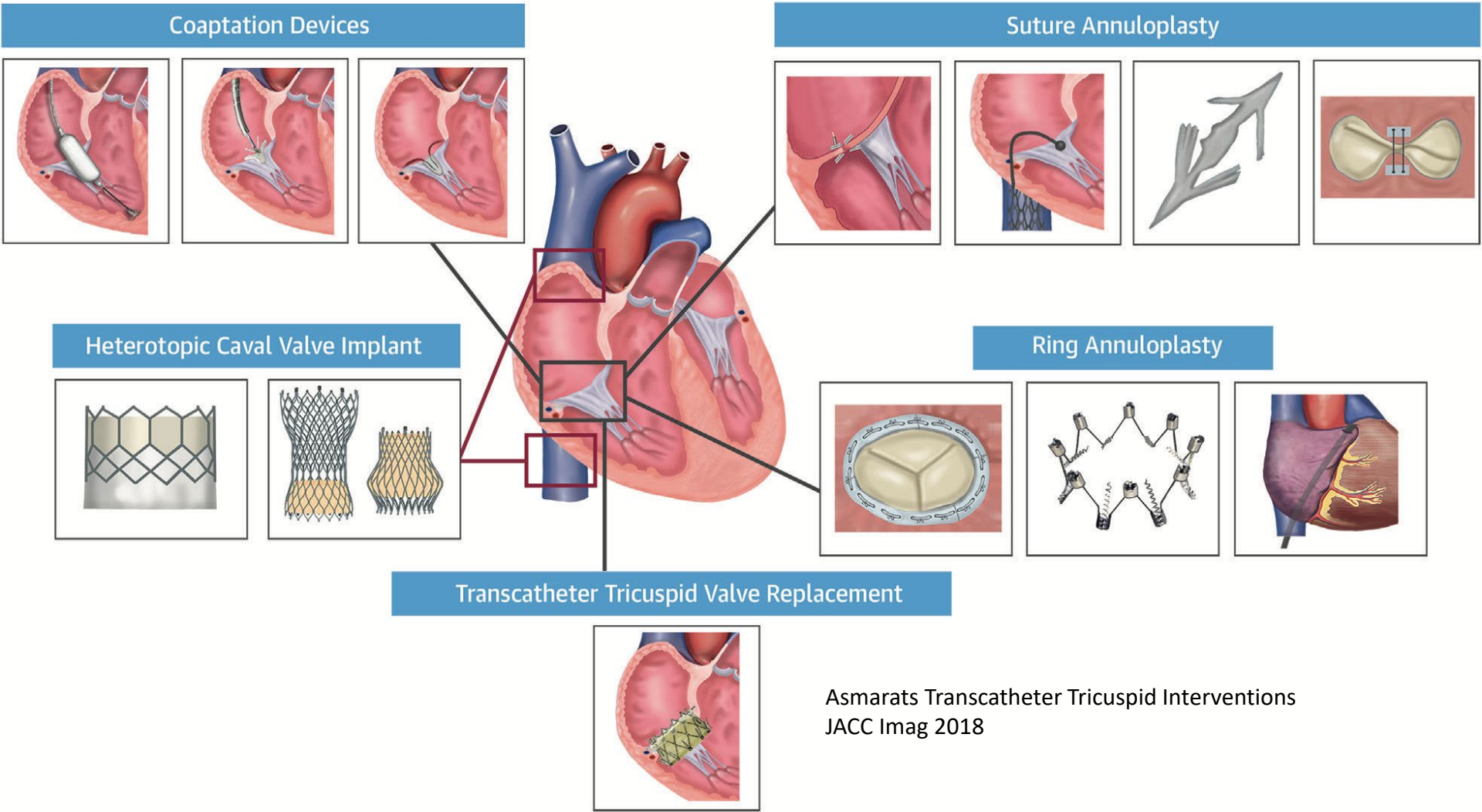
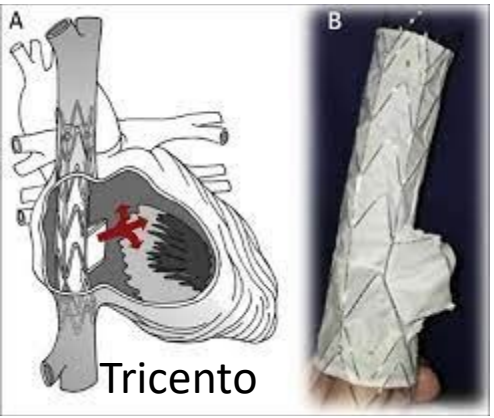


Figure 2 The Kaplan–Meier survival curves of hospitalized patients according to TR grade.

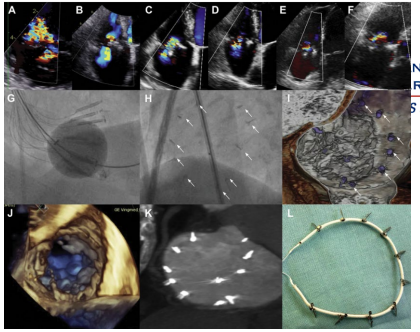


Asmarats Transcatheter Tricuspid Interventions
JACC Imag 2018



Tricento

Navigate



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rdiography
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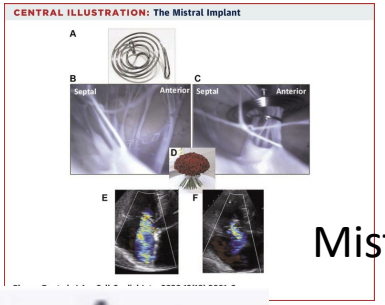
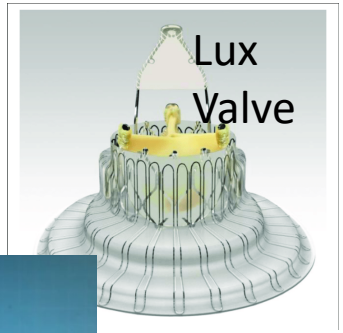
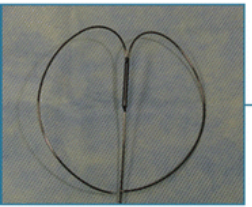
Cardiac Implants LLC
Tarrytown, New York

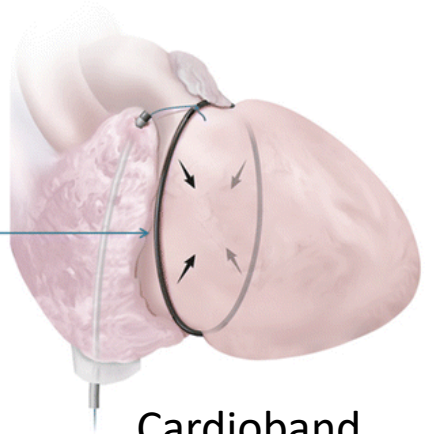


Mistral



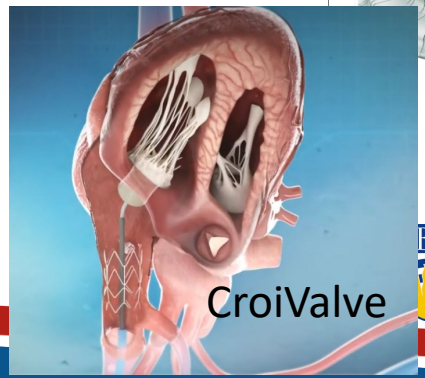


TRAIPTA



Cardioband

Millipede



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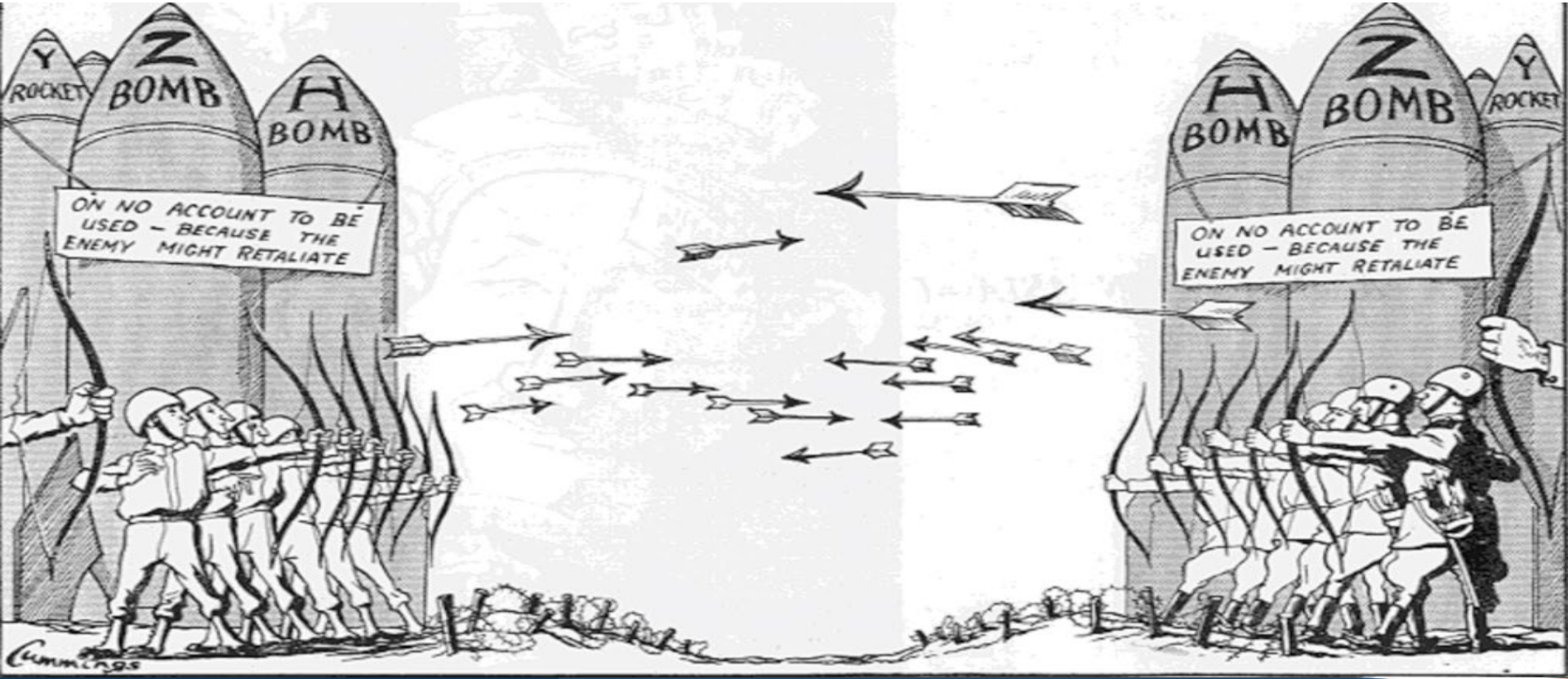
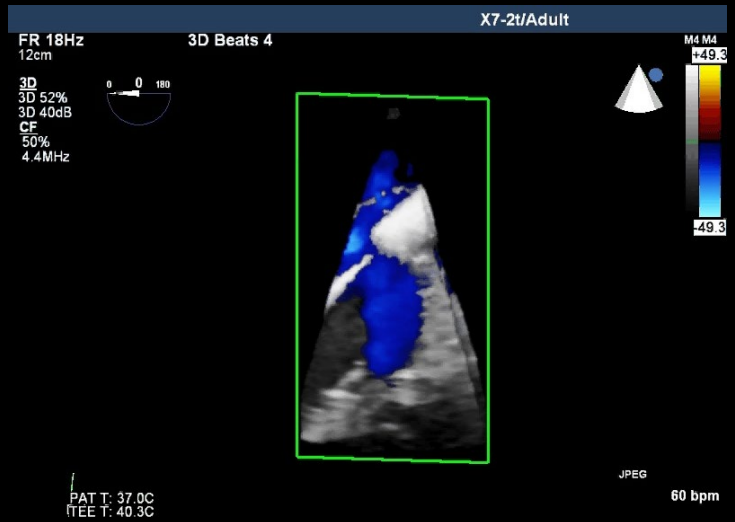
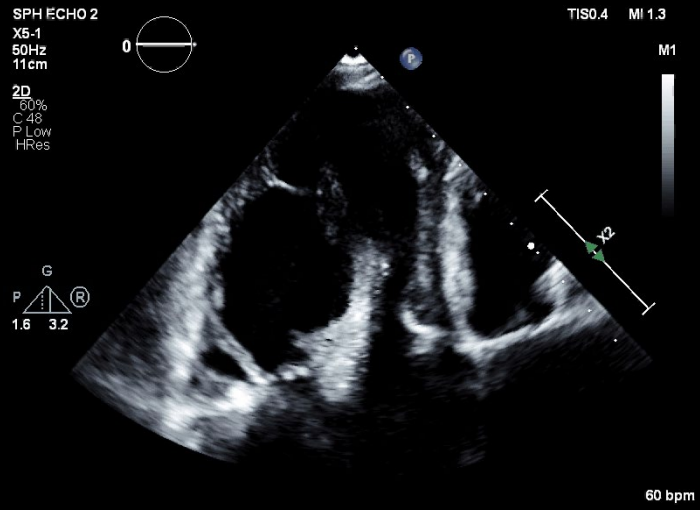
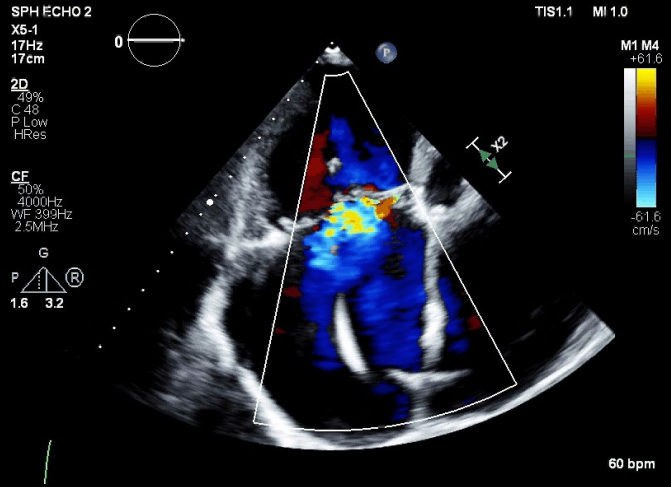
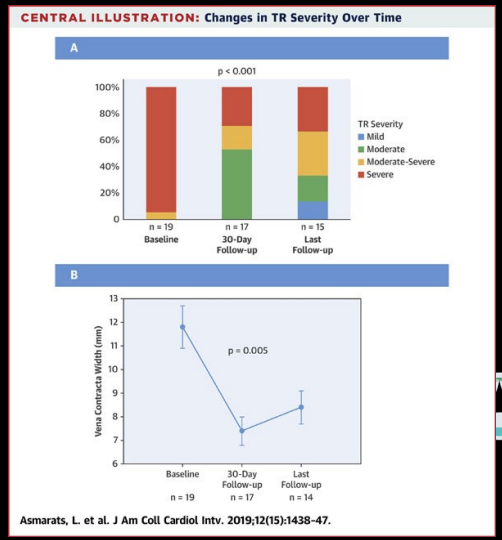
The Tricuspid Arms Race











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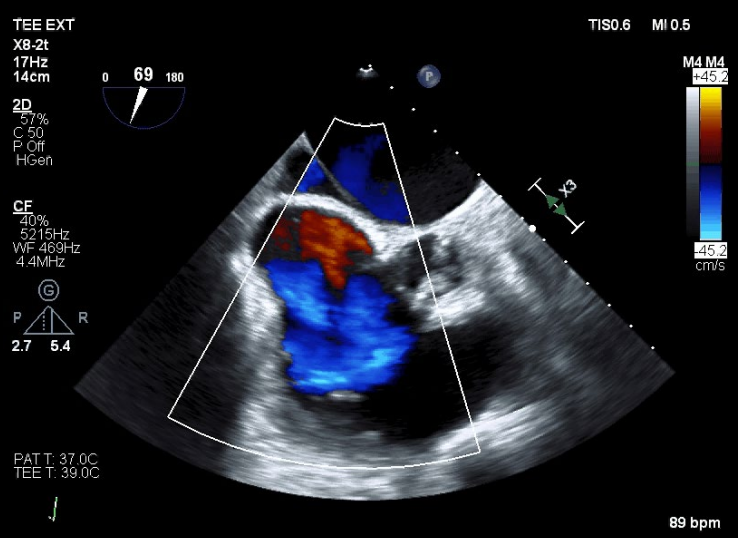
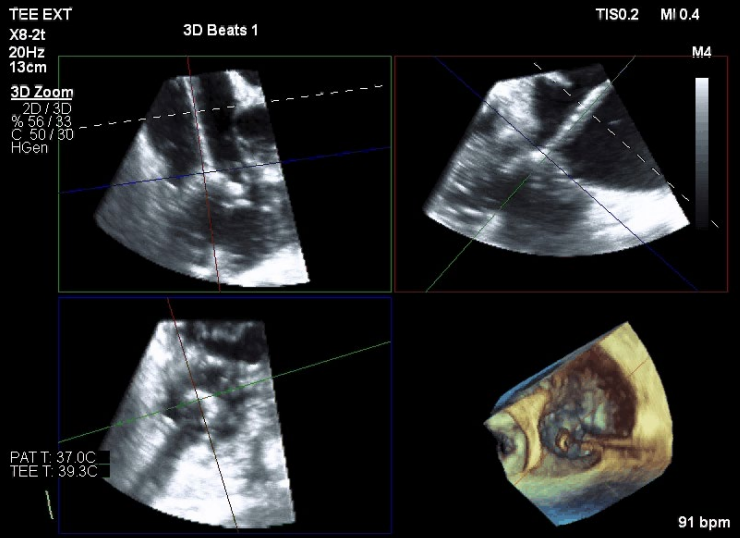
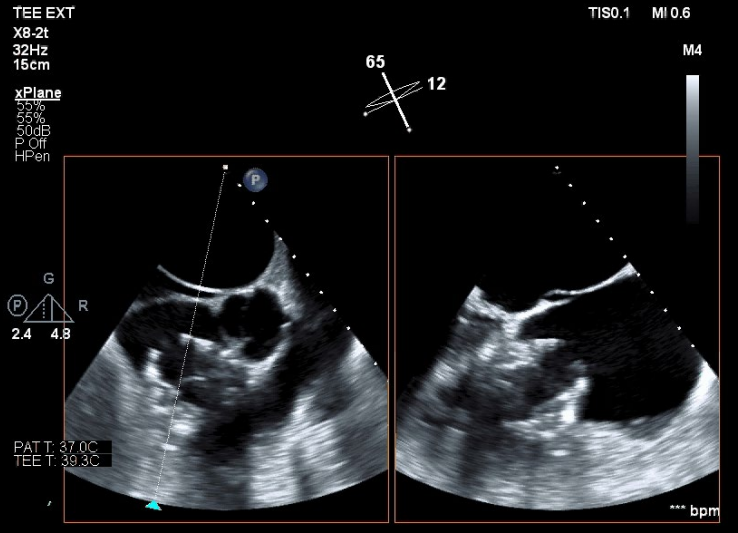
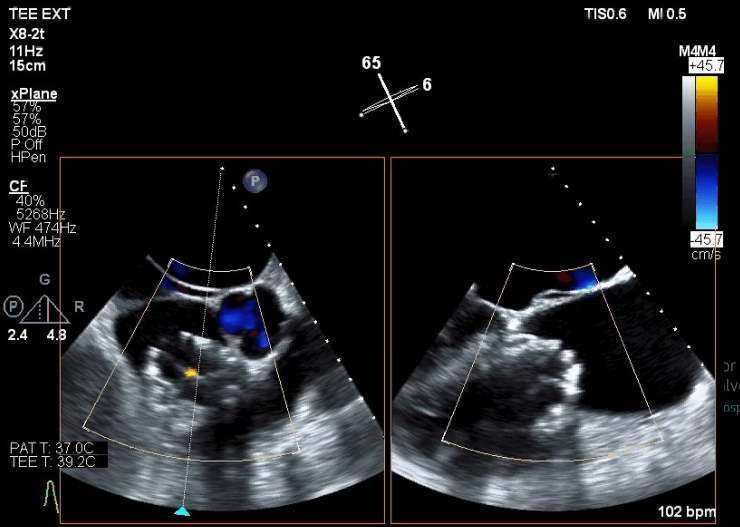
	Annuloplasty systems	Edge to edge repair	TTVI Implant	Heterotopic Caval
Access considerations		Less with Triclip system	IVC RV angle, RV depth	
TEE imaging difficult	-	-	±	±
Anatomic suitability	RCA proximity	adequate leaflet tissue, modest coaptation defect, tethering	Annular dimensions (CT) Sub-valvular structures	Caval size limitations
Advantages and disadvantages	Surgical antecedents and experience	TR correction (RV function) Safety	Full TR correction	RA ventricularization?
PPM leads	++	±	++	?
Conduction disorder	?	±	++	?
RV function	?	++	±	?
TR correction	+	++	++++	NA
Complexity and Procedural time	++++	+++	++	+
Subsequent procedure	Valve in Ring TEER?	?TV implant	TVIV	?
Disease spectrum	Functional	Functional, TVP	Wider applicability?	Wider applicability
Anticoagulation	AF	AF	OAC standard	?
Hybrid Procedures	Yes	Yes	Yes	?

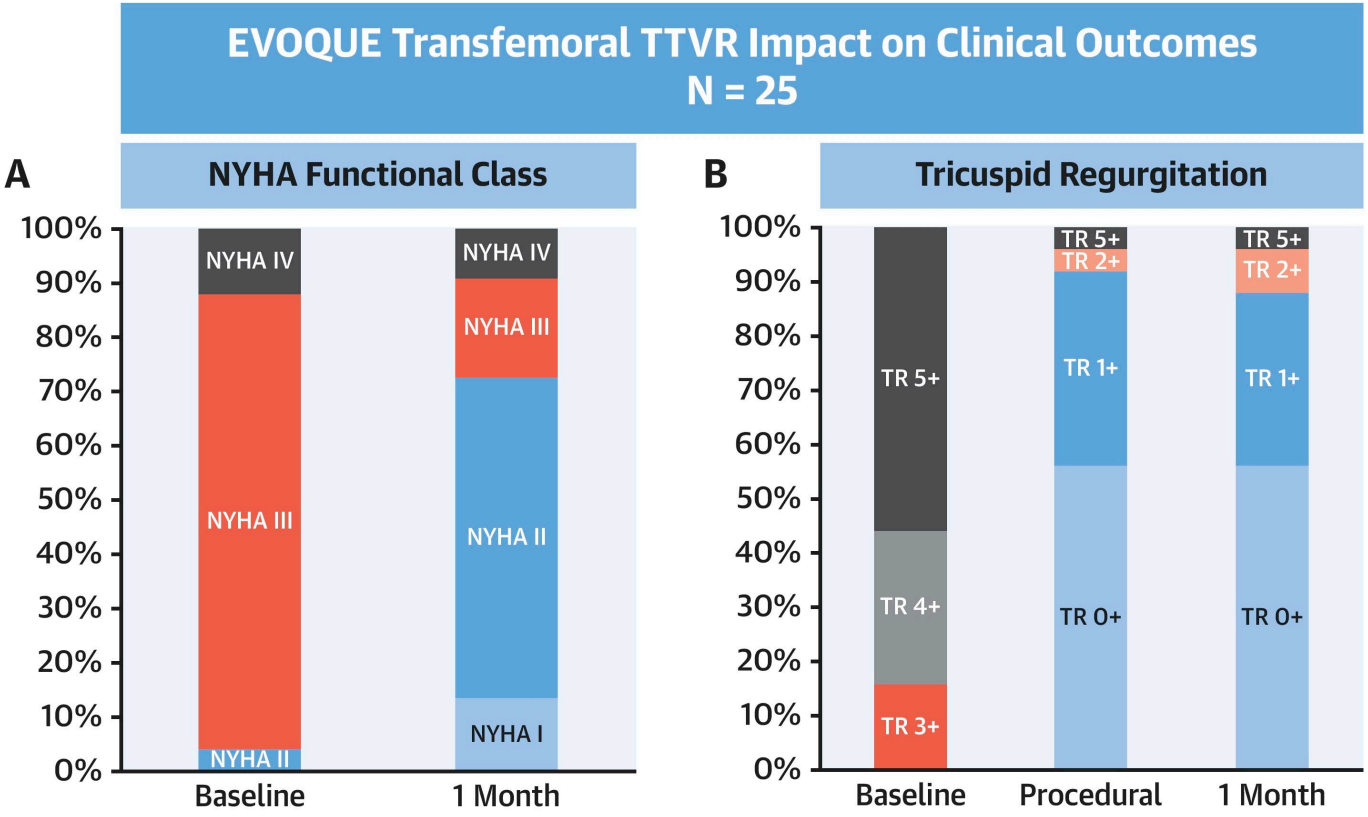

TEE EXT
X8-2t
17Hz
14cm
2D
57%
C 50
P Off
HGen
CF
40%
5215Hz
WF 469Hz
4.4MHz
2.7 5.4
TIS0.6 MI 0.5
M4 M4
+45.2
-45.2
cm/s
PAT T: 37.0C
TEE T: 39.0C
89 bpm


TEE EXT
X8-2t
20Hz
13cm
3D Beats 1
TIS0.2 MI 0.4
M4
3D Zoom
2D / 3D
% 56 / 33
C 50 / 30
HGen
PAT T: 37.0C
TEE T: 39.3C
91 bpm


TEE EXT
X8-2t
32Hz
15cm
xPlane
55%
55%
50dB
P Off
HPen
TIS0.1 MI 0.6
M4
65
12
2.4 4.8
PAT T: 37.0C
TEE T: 39.3C
*** bpm


TEE EXT
X8-2t
11Hz
15cm
xPlane
57%
57%
50dB
P Off
HPen
CF
40%
5268Hz
WF 474Hz
4.4MHz
TIS0.6 MI 0.5
M4M4
+45.7
-45.7
cm/s
65
6
2.4 4.8
PAT T: 37.0C
TEE T: 39.2C
102 bpm

CENTRAL ILLUSTRATION: Outcomes After EVOQUE Transfemoral Transcatheter Tricuspid Valve Replacement for Severe Tricuspid Regurgitation

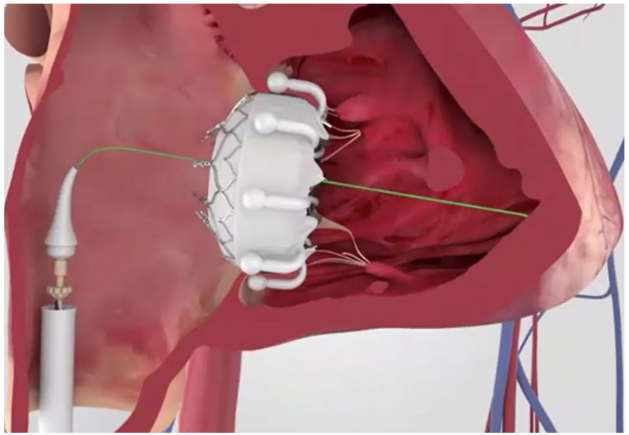


Fam, N.P. et al. J Am Coll Cardiol Intv. 2021;14(5):501-11.

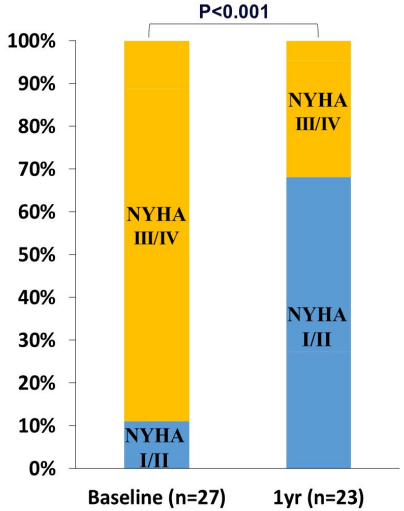
CENTRAL ILLUSTRATION 1-year EVOQUE Transfemoral Transcatheter Tricuspid Valve Replacement for Severe Tricuspid Regurgitation: 1-year clinical and echocardiographic parameters of the first-in-man experience

EVOQUE transfemoral tricuspid replacement

1-year clinical and echocardiographic outcomes



1-year follow-up



27 patients with severe TR
Treated with the EVOQUE system
7 sites (Canada, Europe, USA)
May 2019 to July 2020

All-cause mortality: 8%
HF hospitalization: 8%
New pacemaker: 8% within 30 days,
4% beyond 30 days

Sustained improvement in NYHA class as well a
improvement in TR degree suggesting that the EVO
system is a promising treatment option for this popul

TMVI

Excellent TR reduction

Can be used with interacting pacing leads (with certain caveats)

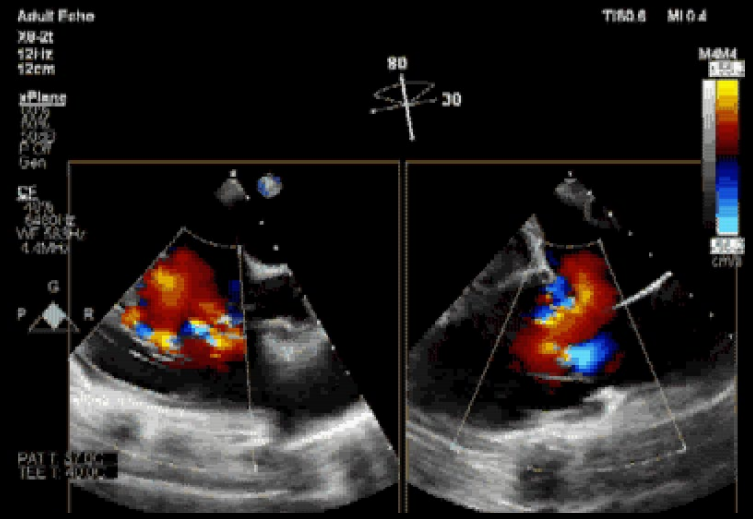
Randomized Long term outcomes (Triscend Pivotal)

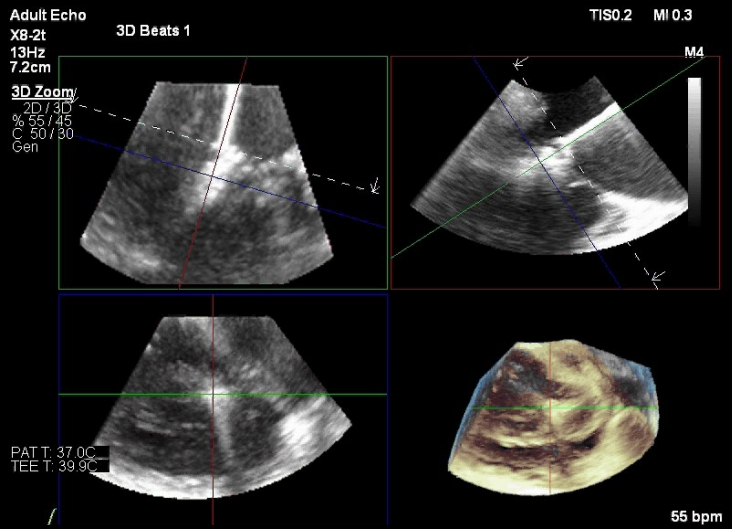
Anatomic constraints

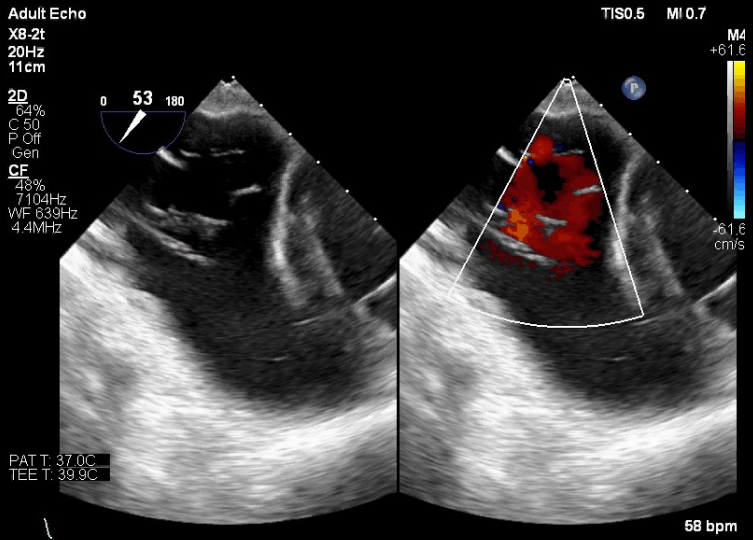
- Annular area, tethering
- Access issues

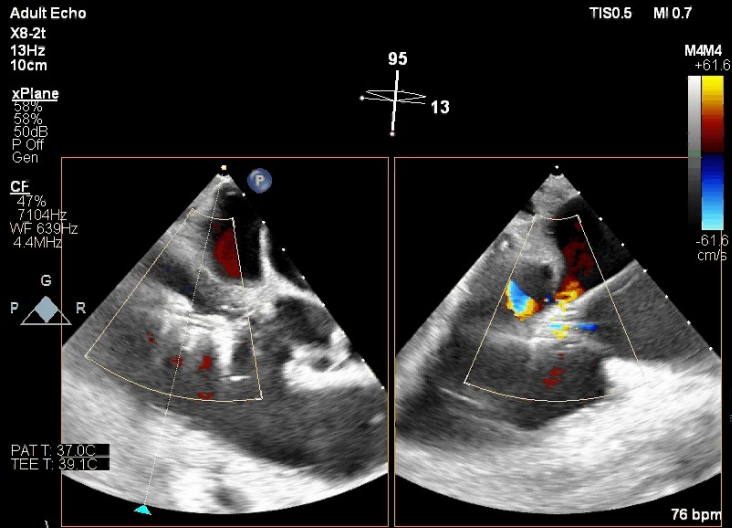
Effect of TMVI on:

- Conduction system and heart block
- Existing pacing Leads
- RV function (afterload increase, mechanical effects of device on longitudinal function)
- Durability (HALT and valve longevity)

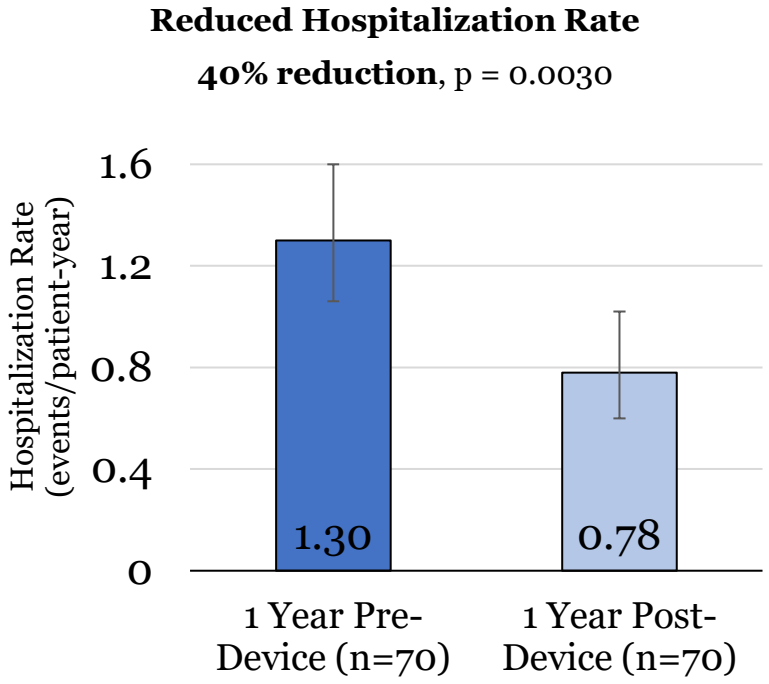

Adult Echo
80
30
M4M4
PAT T: 37.0C
TEE T: 39.9C

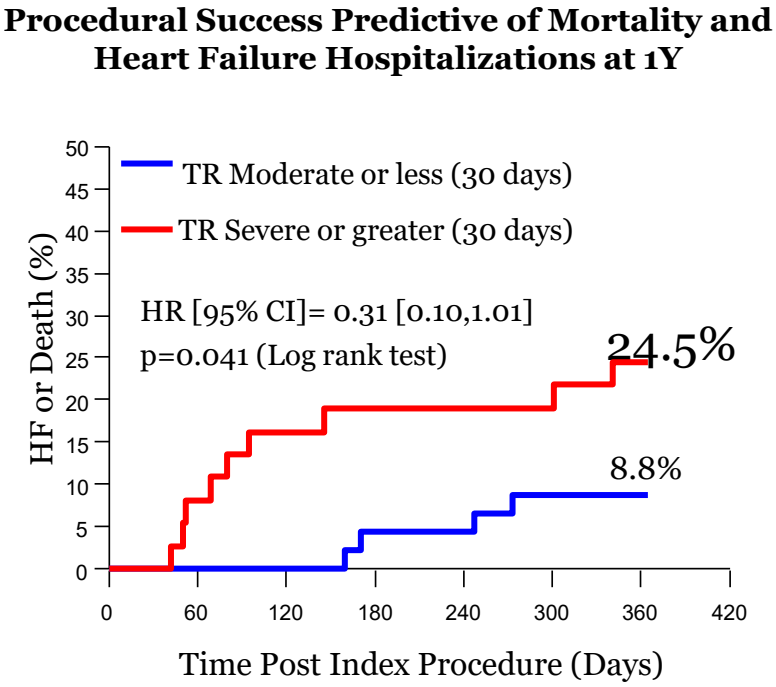

Adult Echo
X8-2t
13Hz
7.2cm
3D Beats 1
TIS0.2 MI 0.3
3D Zoom
M4
PAT T: 37.0C
TEE T: 39.9C
55 bpm


Adult Echo
X8-2t
20Hz
11cm
TIS0.5 MI 0.7
2D
64%
C 50
P Off
Gen
CF
48%
7104Hz
WF 639Hz
4.4MHz
0
53
180
M4
+61.6
-61.6
cm/s
PAT T: 37.0C
TEE T: 39.9C
58 bpm


Adult Echo
X8-2t
13Hz
10cm
TIS0.5 MI 0.7
xPlane
58%
58%
50dB
P Off
Gen
CF
47%
7104Hz
WF 639Hz
4.4MHz
95
13
M4M4
+61.6
-61.6
cm/s
G
P
R
PAT T: 37.0C
TEE T: 39.1C
76 bpm

TRILUMINATE | 40% Reduced Hospitalization at 1 Year





Challenges and Questions: TEER

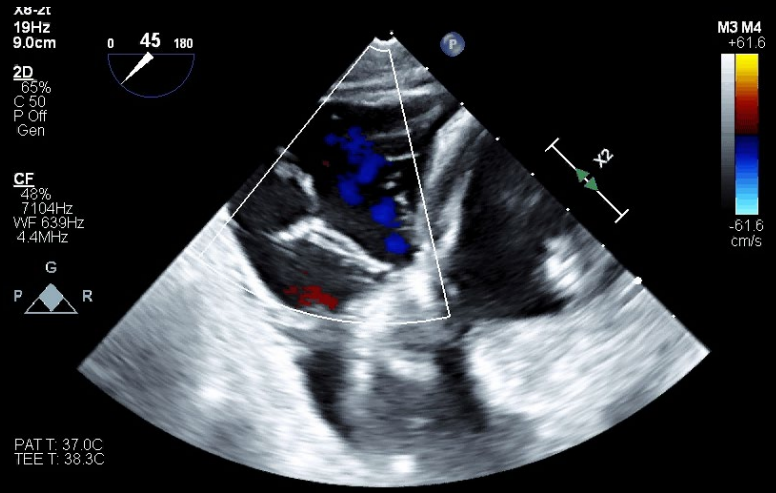
Safe
Effective when anatomically suitable and it works
?Benefits in RV dysfunction

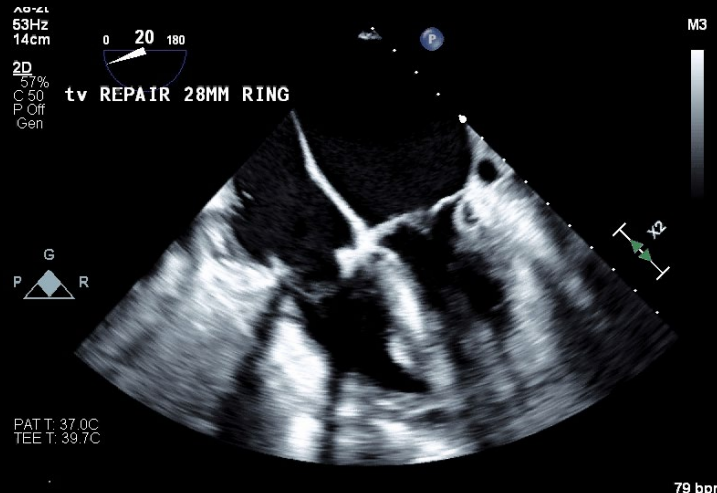
Long term outcomes

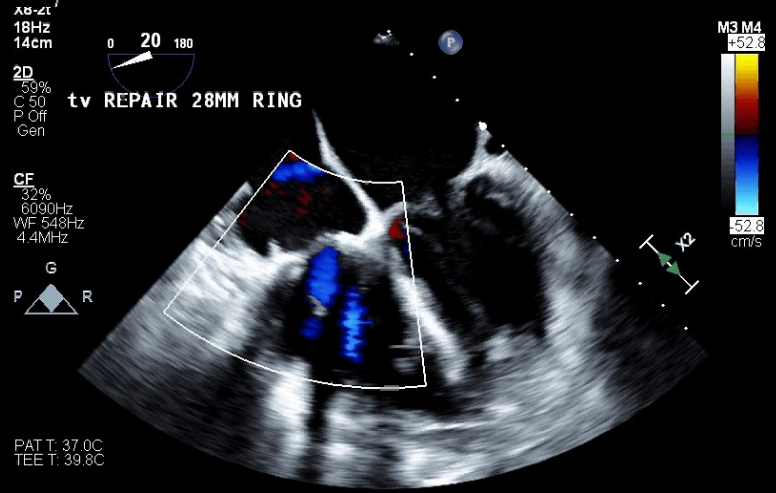
- How much is too much residual TR?
- How much impact can be made on ‘complex’ TR (massive or torrential TR , excess leaflet tethering >7 to 10 mm, and large coaptation gaps?

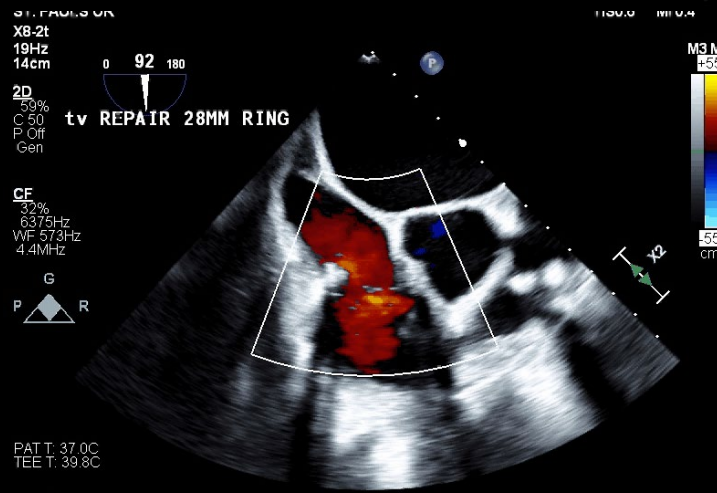
Will complexity and procedural time decrease?

- How might routine ICE impact?
- Will imaging continue to evolve?


19Hz
9.0cm
45
2D
65%
C 50
P Off
Gen
CF
48%
7104Hz
WF 639Hz
4.4MHz
M3 M4
+61.6
-61.6
cm/s
PAT T: 37.0C
TEE T: 38.3C


53Hz
14cm
20
2D
57%
C 50
P Off
Gen
tv REPAIR 28MM RING
M3
PAT T: 37.0C
TEE T: 39.7C

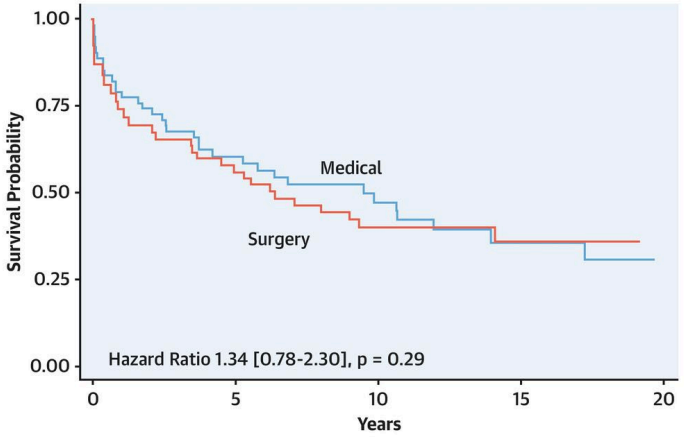

18Hz
14cm
20
2D
59%
C 50
P Off
Gen
tv REPAIR 28MM RING
CF
32%
6090Hz
WF 548Hz
4.4MHz
M3 M4
-52.8
cm/s
PAT T: 37.0C
TEE T: 39.8C
80 bpm


79 bpm
X8-2t
19Hz
14cm
92
2D
59%
C 50
P Off
Gen
tv REPAIR 28MM RING
CF
32%
6375Hz
WF 573Hz
4.4MHz
M3 M4
-55.3
cm/s
PAT T: 37.0C
TEE T: 39.8C
80 bpm

Surgery Does Not Improve Survival in Patients With Isolated Severe Tricuspid Regurgitation

Andrea L. Axtell, Vijeta Bhambhani, Philicia Moonsamy, Emma W. Healy, Michael H. Picard, Thoralf M. Sundt III and Jason H. Wasfy

CENTRAL ILLUSTRATION: Surgery Versus Medical Therapy for Severe Tricuspid Regurgitation



Axtell, A.L. et al. J Am Coll Cardiol. 2019;74(6):715-25.

- Retrospective analysis of 3,276 patients with isolated severe TR at MGH
- 171 (5%) underwent surgery
  - 143 (84% repair)
  - 28 (16% replacement)
- Etiology of the TR was predominantly functional
- Primary outcome was all cause mortality
- Propensity matched comparison accounting for immortal time bias

American Society of Echocardiography
Sound Saves Lives

UBC

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver

Several factors may account for this:

- Poor understanding of natural history and surgical risk
- Delayed referral for operative intervention with accumulation of comorbidities - >25% waited >1 year for referral
- Baseline right heart dysfunction, not well evaluated by current techniques
- Accumulation of comorbidities
- Inflammatory effects of surgery on RH function

ASE American Society of Echocardiography
Sound Saves Lives

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St. Paul's Hospital, Vancouver

"Prediction is very difficult, especially if it's about the future."

-- Niels Bohr
Physics Nobel prize 1922

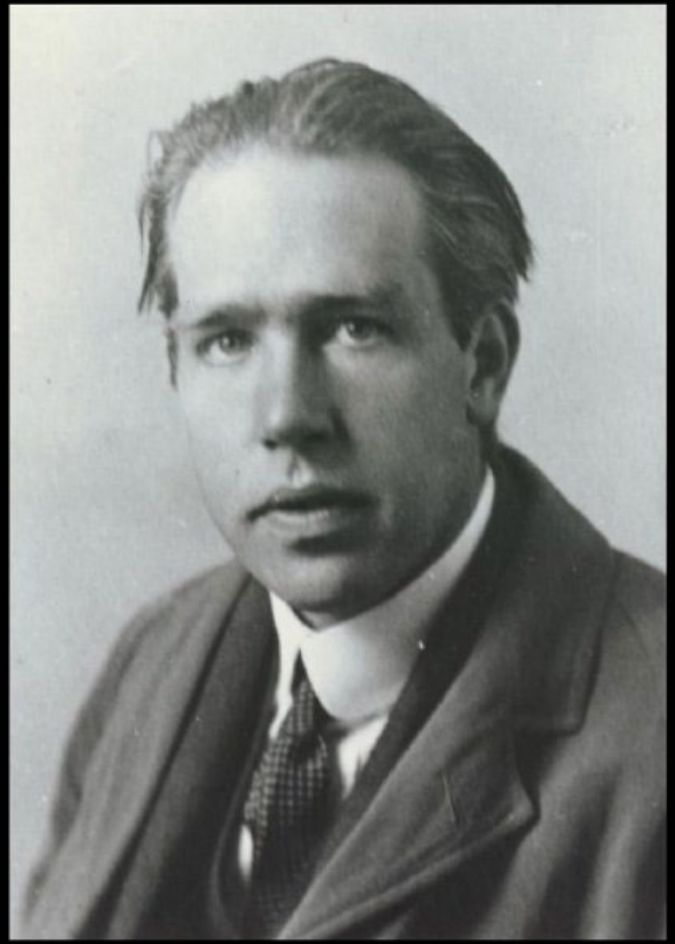
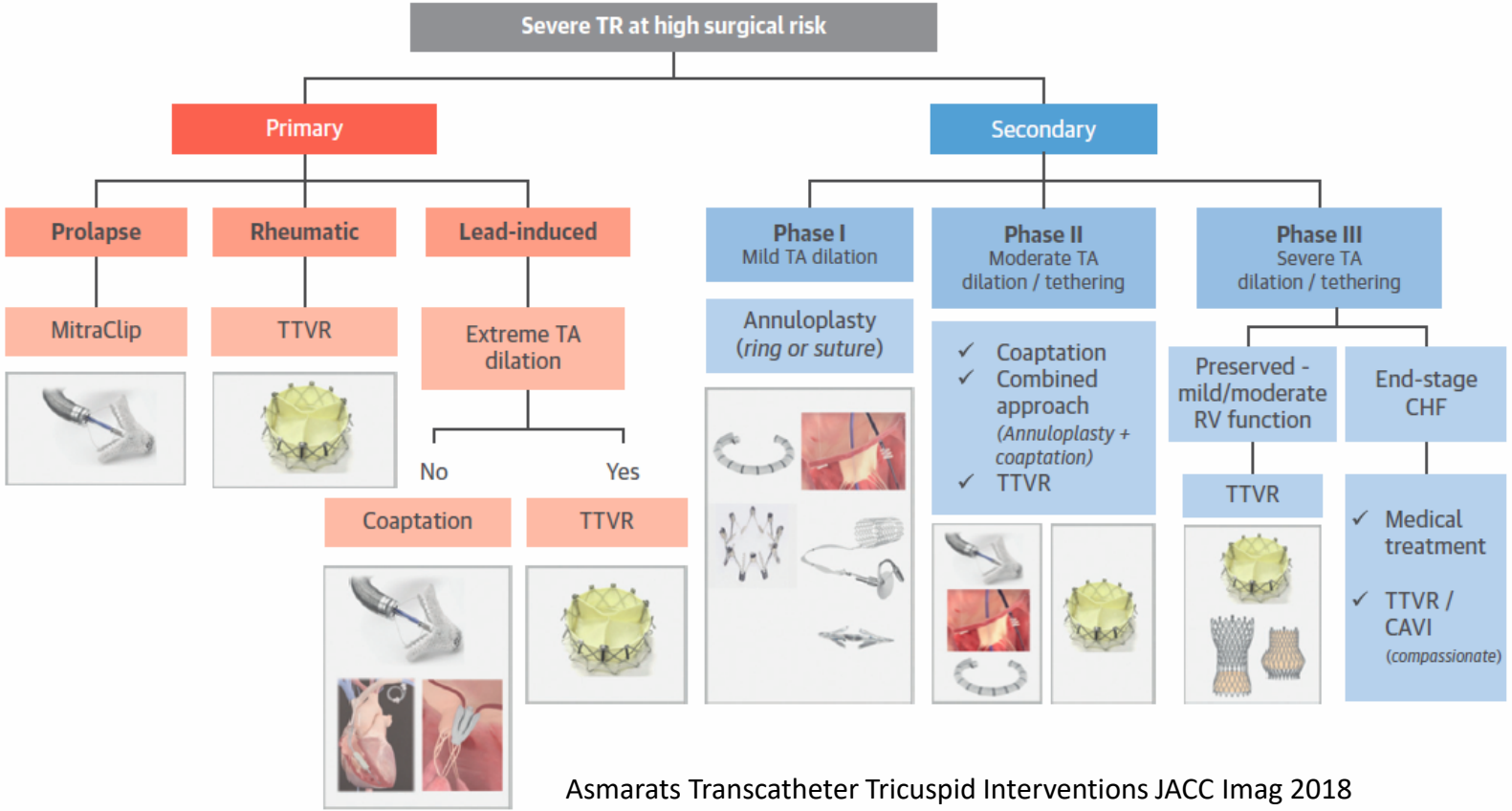


FIGURE 10 Proposed Algorithm for Transcatheter Tricuspid Valve Device Selection Based on Mechanism and Pathoanatomy of Tricuspid Regurgitation



Asmarats Transcatheter Tricuspid Interventions JACC Imag 2018

CAVI = caval valve implantation; CHF = chronic heart failure; RV = right ventricle; TA = tricuspid annulus; TR = tricuspid regurgitation; TTVR = transcatheter tricuspid valve replacement.

Take-homes

All modalities are presently limited by complexity and anatomic suitability

Not one size fits all, therefore:

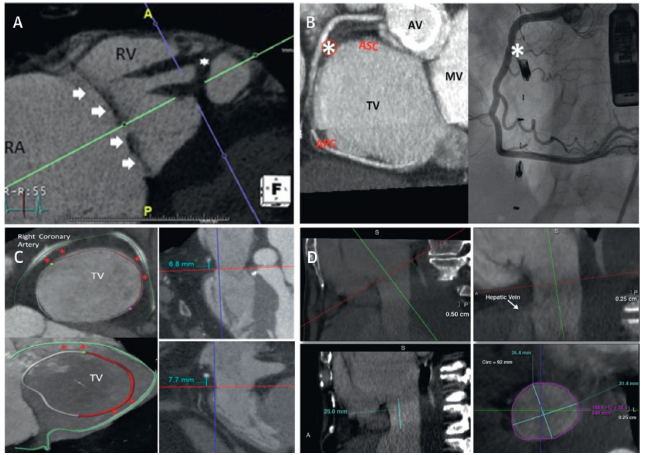
There will be multiple strategies

There will continue to be a role for surgical intervention

Strategy will be based on increasingly careful anatomic characterization (CT, TEE, ICE)

But also clinical considerations

There will be a growth in hybrid procedures



1. Demographic

e.g. age, Sex

2. Clinical symptoms

e.g. NYHA functional class

3. Comorbidities

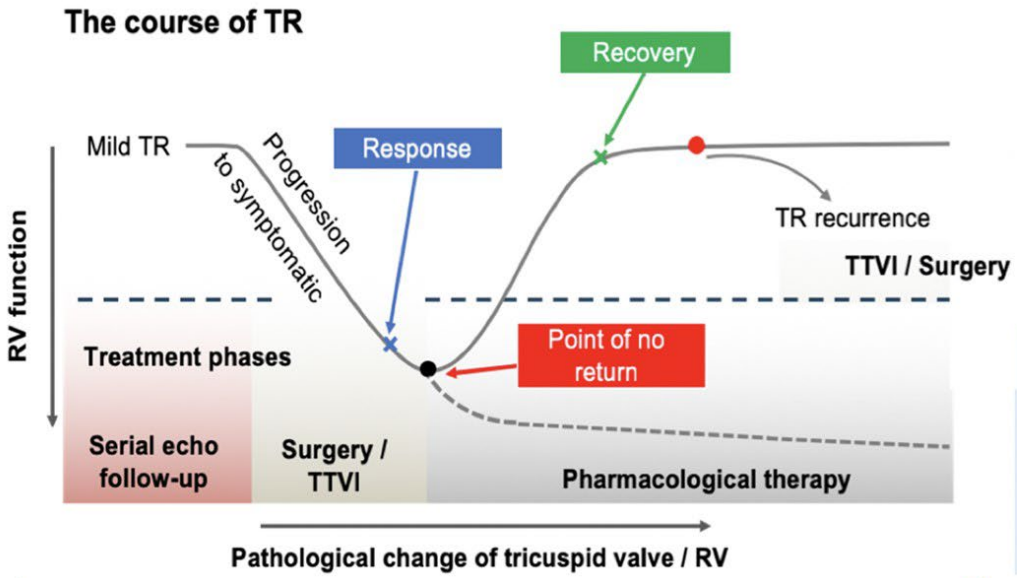
e.g. stroke, COPD, renal, liver failure

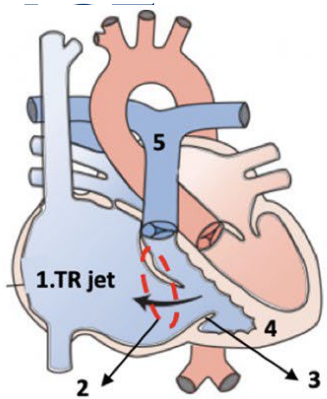
4. Cardiac disease

e.g. combined left-sided disease

5. Surgical characteristics

e.g. isolated, combined





1. TR severity
2. Annulus size
3. Tricuspid valve morphology
4. RV remodelling
5. Pulmonary vascular resistance

Patient risk stratification

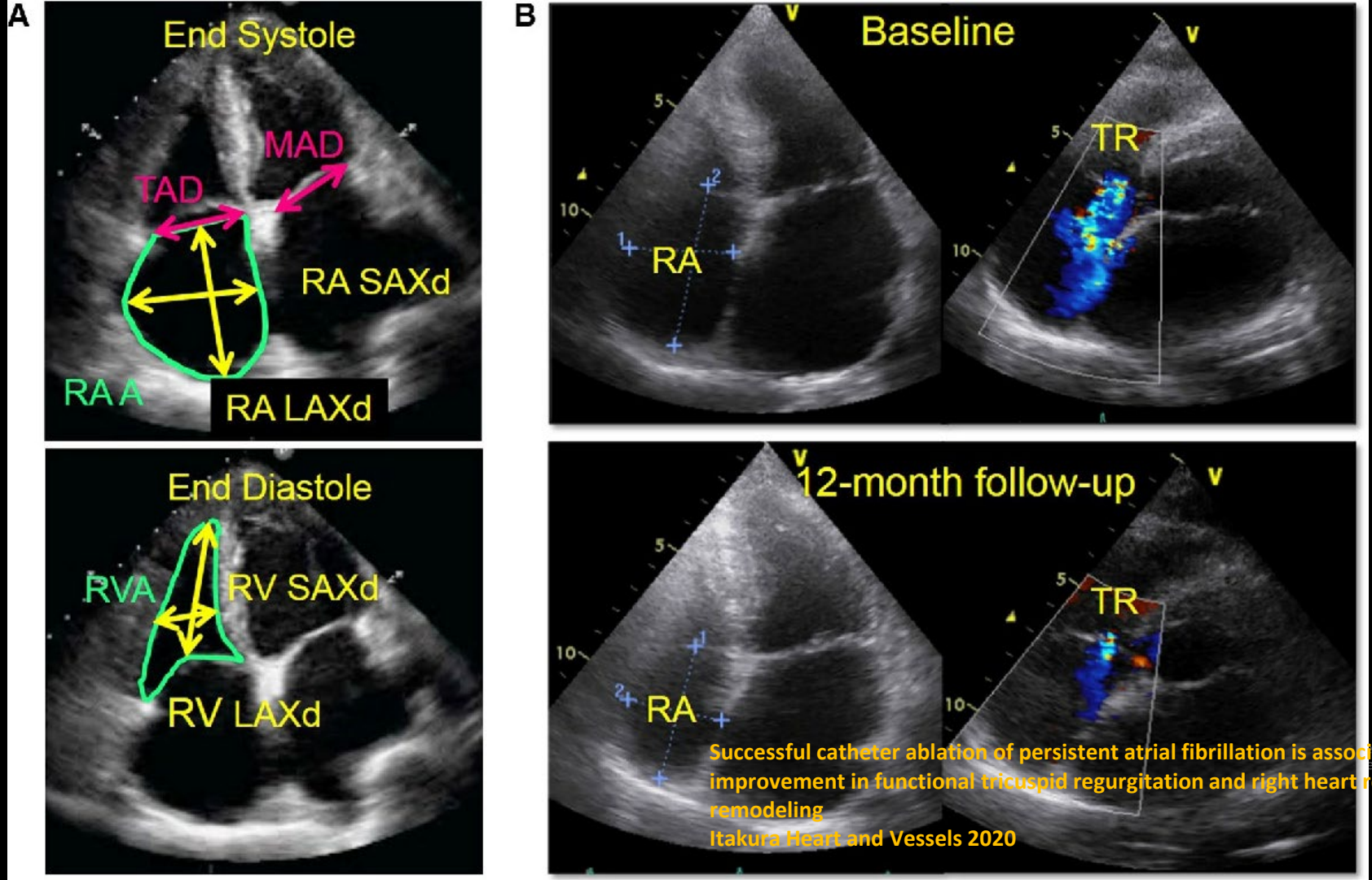
Heart team decision-making

Cardiac pathological remodelling

Chan EHJ 2019

UBC

Centre for Heart Valve Innovation
St. Paul's Hospital, Vancouver



Successful catheter ablation of persistent atrial fibrillation is associated with improvement in functional tricuspid regurgitation and right heart reverse remodeling

Itakura Heart and Vessels 2020

Take-homes

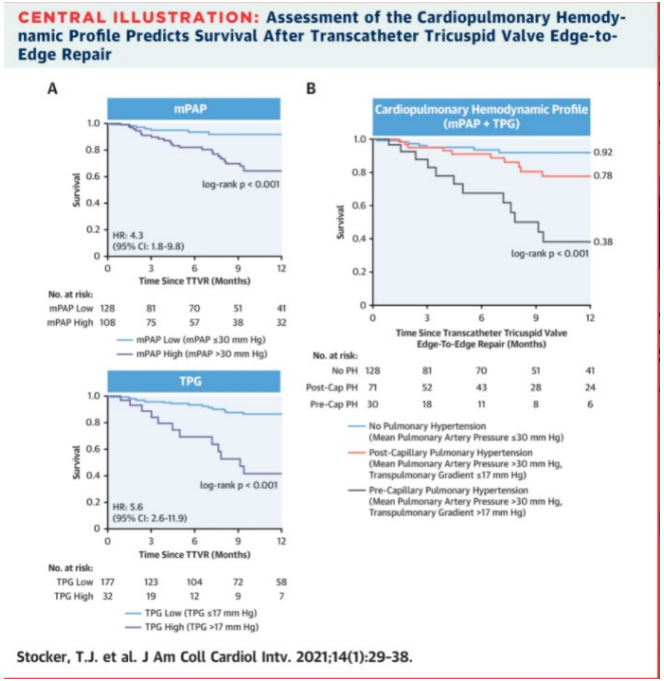
Better need to understand the natural history of TR as well as the impact of interventions so as to improve case selection

TR is a slowly evolving process (decades)

In addition TR is ‘shockingly’ dynamic

We need to get better at:

- Accurate clinical staging, evaluation,
- grading of TR
- Accurate evaluation of RV dysfunction,
- Understanding the impact of PHT



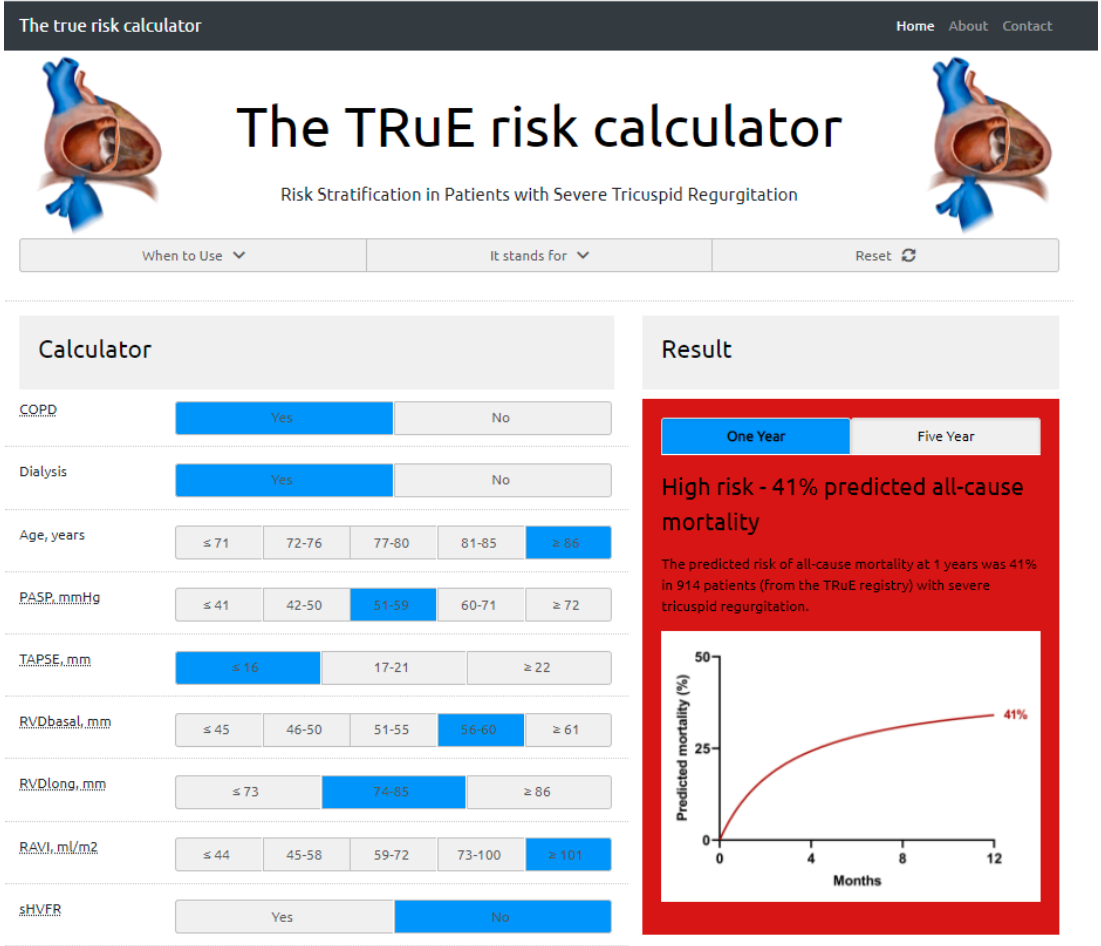
Take-homes

When do we intervene?

- What is too early?
- What is too late?
- Tricuspid Risk Scores?

Risk factors include: age, anemia, NYHA III or IV, liver disease, CKD, COPD, PHT, RV dysfunction

Solutions will continue to innovate, some will fail



American Society of Echocardiography
Sound Saves Lives

Centre for
Heart Valve Innovation
St. Paul's Hospital, Vancouver

Transfemoral transcatheter tricuspid valve replacement with the EVOQUE system for severe tricuspid regurgitation: A multicenter, observational, first-in-human experience

All patients suffered from right heart failure due to severe TR and were deemed inoperable and unsuitable for transcatheter leaflet repair by the institutional heart teams

The primary outcome was technical success, with secondary outcomes of New York Heart Association (NYHA) functional class, TR grade and major adverse cardiac and cerebrovascular events at 30 day follow-up

Concomitant Tricuspid Repair in Patients with Degenerative Mitral Regurgitation

Among patients undergoing mitral-valve surgery, those who also received TA had:

a lower incidence of a primary-end-point event than those who underwent mitral valve surgery alone at 2 years, a reduction that was driven by less frequent progression to severe tricuspid regurgitation.

Tricuspid repair resulted in more frequent permanent pacemaker implantation.

Whether reduced progression of tricuspid regurgitation results in long-term clinical benefit can be determined only with longer follow-up.

Gammie NEJM 2021

Evoque Tricuspid Early data

Why?

- While transcatheter leaflet repair is an option for some patients, transcatheter tricuspid valve replacement (TTVR) may offer a more definitive solution

What?

- We assessed technical success of EVOQUE transfemoral TTVR in patients with severe TR, with device and clinical outcomes at 30 days

How?

- Twenty patients with symptomatic severe TR were treated with the EVOQUE system in a compassionate use experience at six centers

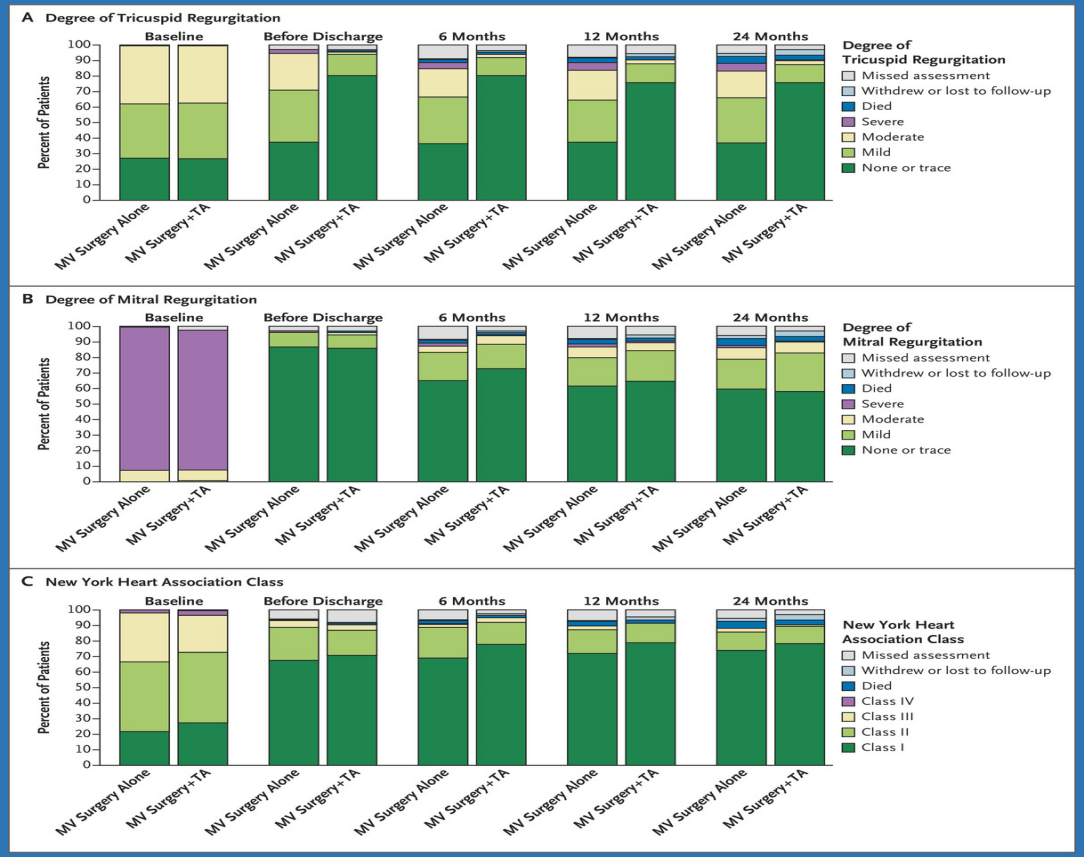
What are the results?

- Technical success was 95%, mortality was 0%, 85% of patients were in NYHA functional class I/II, with TR grade ≤ 2+ in 100% at 30 days

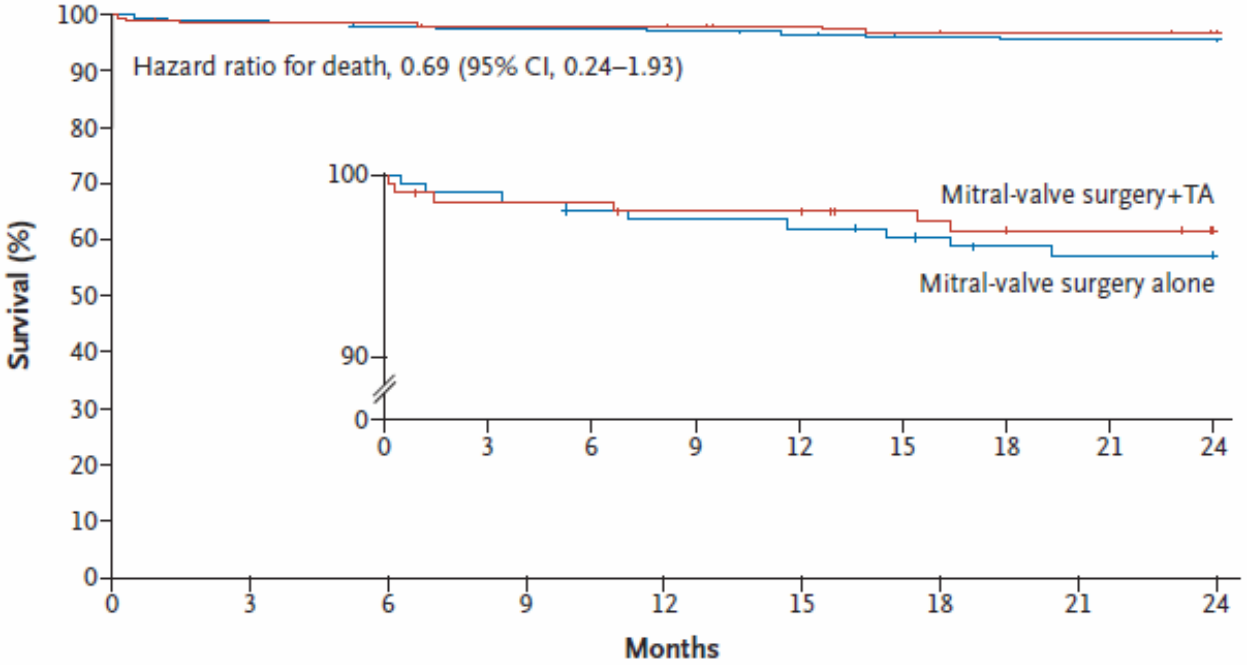
Why is this important?

- EVOQUE transfemoral TTVR utilizes a completely percutaneous approach, with potentially superior efficacy and safety to either TTVR via thoracotomy or transcatheter leaflet repair

Echocardiographic and Functional Status



JS Gammie et al. N Engl J Med 2021. DOI: 10.1056/NEJMoa2115961



No. at Risk									
Mitral-valve surgery+TA	198	194	194	192	192	189	187	186	184
Mitral-valve surgery alone	203	201	198	197	196	194	191	190	190

Figure 1. Overall Survival.

Shown are Kaplan–Meier estimates of overall survival during the 2 years after randomization among patients with moderate or less-than-moderate tricuspid regurgitation who were undergoing mitral-valve surgery alone or surgery with placement of a tricuspid annuloplasty (TA) ring. The inset shows the same data on an expanded y axis. The tick marks indicate censored data.