Tricuspid Valve Regurgitation- The New Frontier:

Results of Recent Interventions

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Disclosures

CoreLab *(grants assigned to employer):* Mitral Trial (CT), NIH LAMPOON (CT and Echo)

Research Grants *(assigned to employer):* Boston Scientific, Ford Motor Foundation

Consultant: Edwards LifeSciences, Materialise, Boston Scientific, Neochord, Abbott

Patents *(assigned to employer HFHS)*: software for TMVR LVOT prediction modeling and LAA planning

Goals

Discuss transcatheter strategies for tricuspid regurgitation

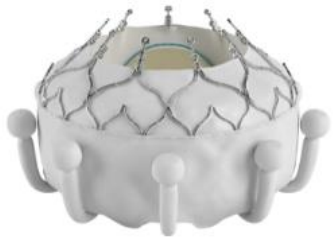
Identify future right heart technologies

Discuss our understanding of ‘ right heart size’

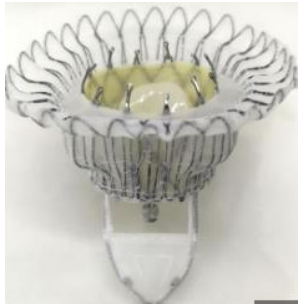
Tricuspid Regurgitation Therapies

Annular Dilatation

- Edwards LifeSciences
  Evoque



- Jenscare
  LUx Valve

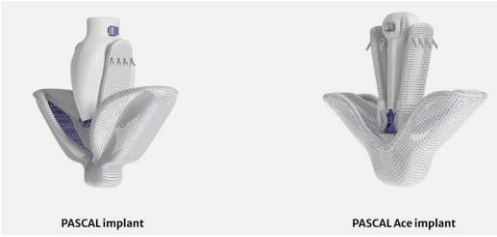


Coaptation Devices

- Abbott

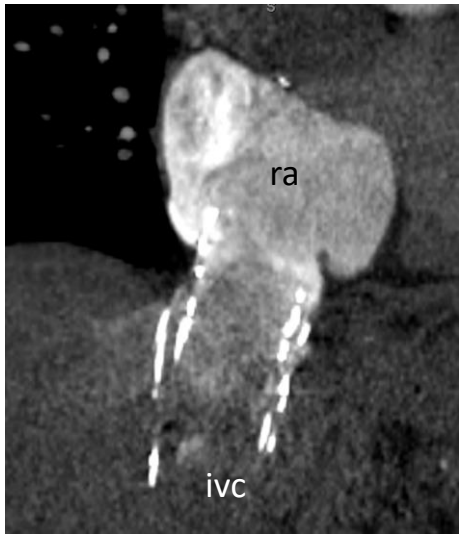
TriClip TTVr device

- Edwards LifeSciences
  PASCAL



Advanced disease, Pacer interference

- Caval valve implant



Edwards PASCAL Transcatheter Valve Repair System Pivotal Clinical Trial (CLASP II TR)

ClinicalTrials.gov Identifier: NCT04097145

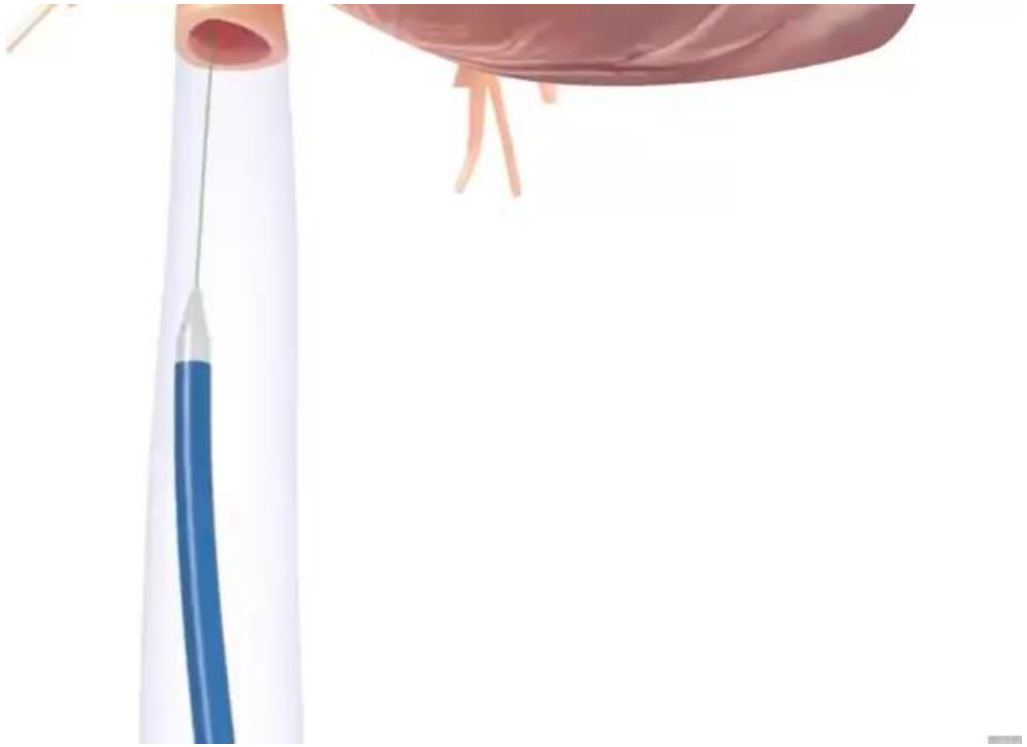
Recruitment Status : Recruiting
First Posted : September 20, 2019
Last Update Posted : November 22, 2021

See **Contacts and Locations**

Sponsor:
Edwards Lifesciences

Information provided by (Responsible Party):
Edwards Lifesciences

Edge to Edge repair: CLASP TR Pivotal clinical trial



Surgical risk: none, local heart team deems appropriate

Inclusion:

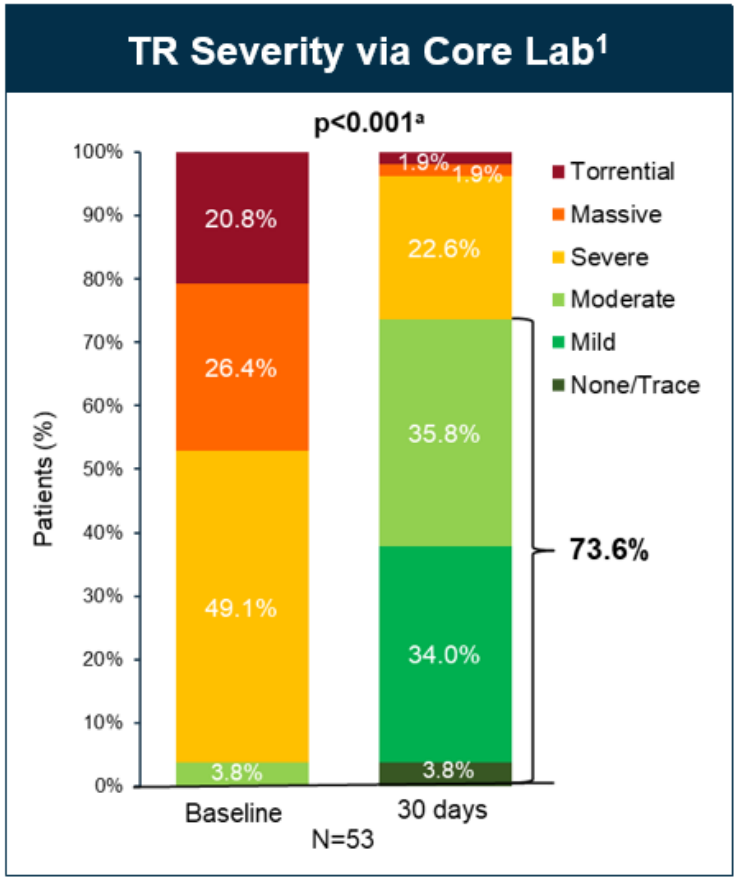
1. Symptomatic (NYHA II, III, IV)
2. Severe TR
3. Heart failure hospitalization in prior 12 months

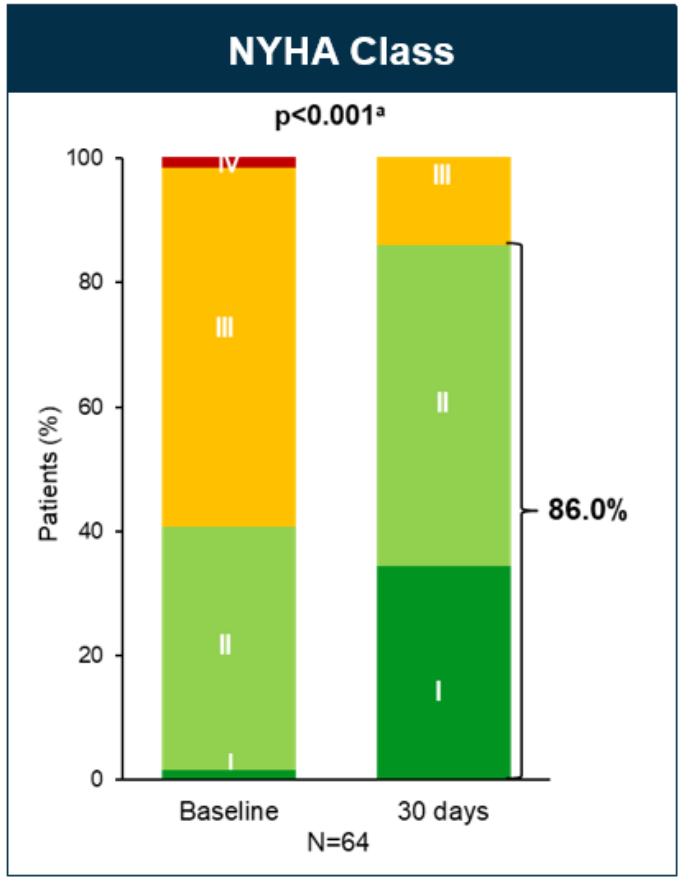
Exclusion

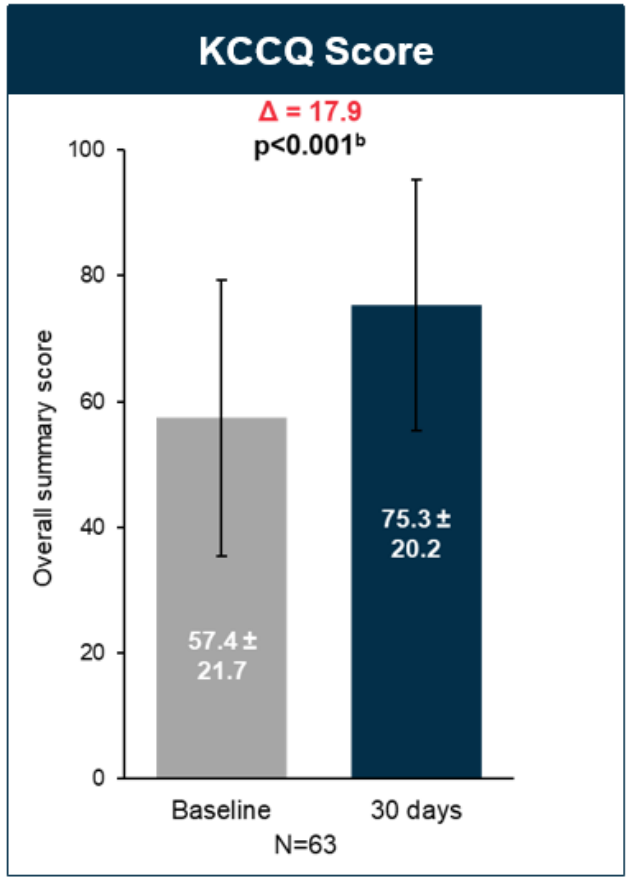
1. Anatomy precludes proper device deployment & function
2. LVEF< 25%
3. Untreated severe MR

THE CLASP II TR TRIAL

TR Reduction with Clinical and Quality-of-Life Improvements







83.0% improved by ≥ 1 TR grade, 62.3% by ≥ 2 grades, and 73.6% reached ≤ moderate TR at 30 days

[1]Core laboratory: Cardiovascular Research Foundation. [a]Wilcoxon signed-rank test. [b]Paired t-test. *TR*, tricuspid regurgitation; *NYHA*, New York Heart Association; *KCCQ*, Kansas City Cardiomyopathy Questionnaire

TRISCEND II Pivotal Trial

ClinicalTrials.gov Identifier: NCT04482062

Recruitment Status : Recruiting
First Posted : July 22, 2020
Last Update Posted : October 28, 2021

See **Contacts and Locations**

Sponsor:
Edwards Lifesciences

Information provided by (Responsible Party):
Edwards Lifesciences

TTVR: TRISCEND Clinical trial with Evoque

Surgical risk: none, local heart team deems appropriate for TTVR

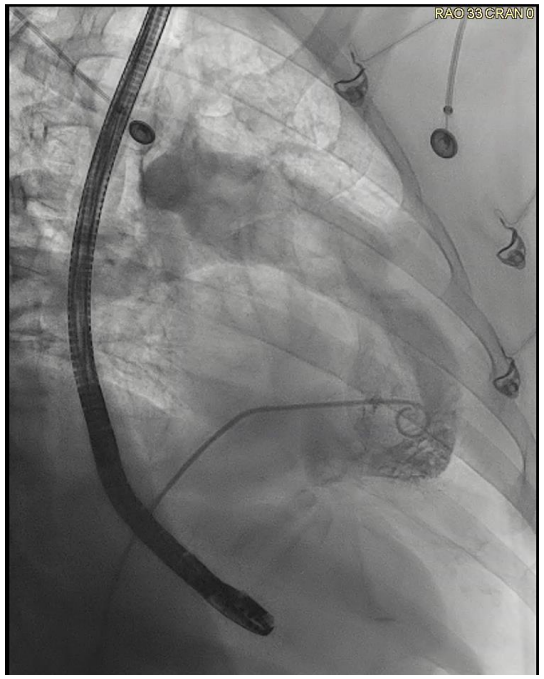
Inclusion:

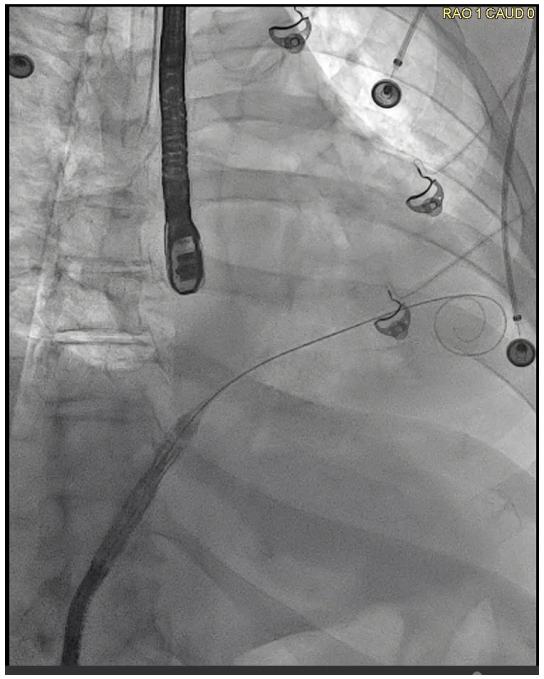
1. Symptomatic (NYHA II, III, IV)
2. Severe TR by TTE
3. Despite OMT, signs of severe TR, hospitalization from TR, or prior heart failure

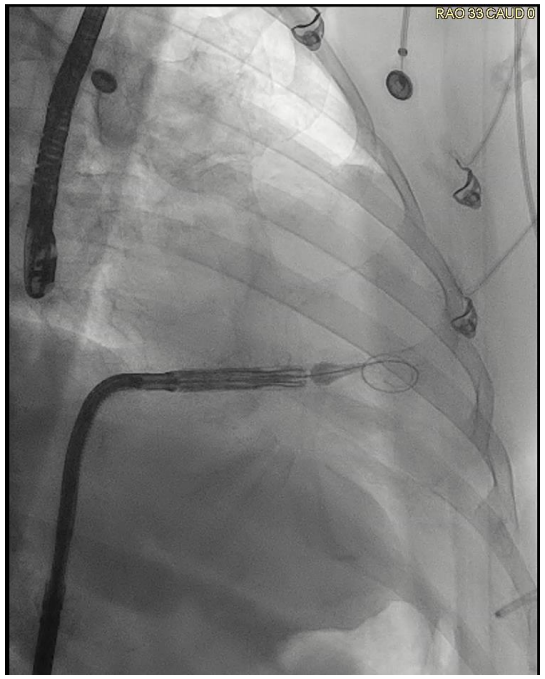
Exclusion

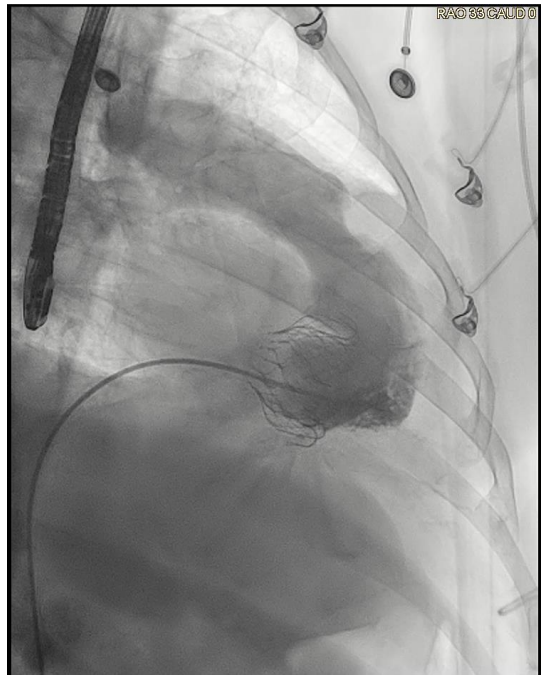
1. Anatomy precludes delivery of dock/valve
2. Inability tolerate antiplatelet or anticoagulation therapy
3. Severe MR
4. LVEF < 25%, severe RV dysfunction, PASP>70mm Hg

TRISCEND: transfemoral approach TTVR

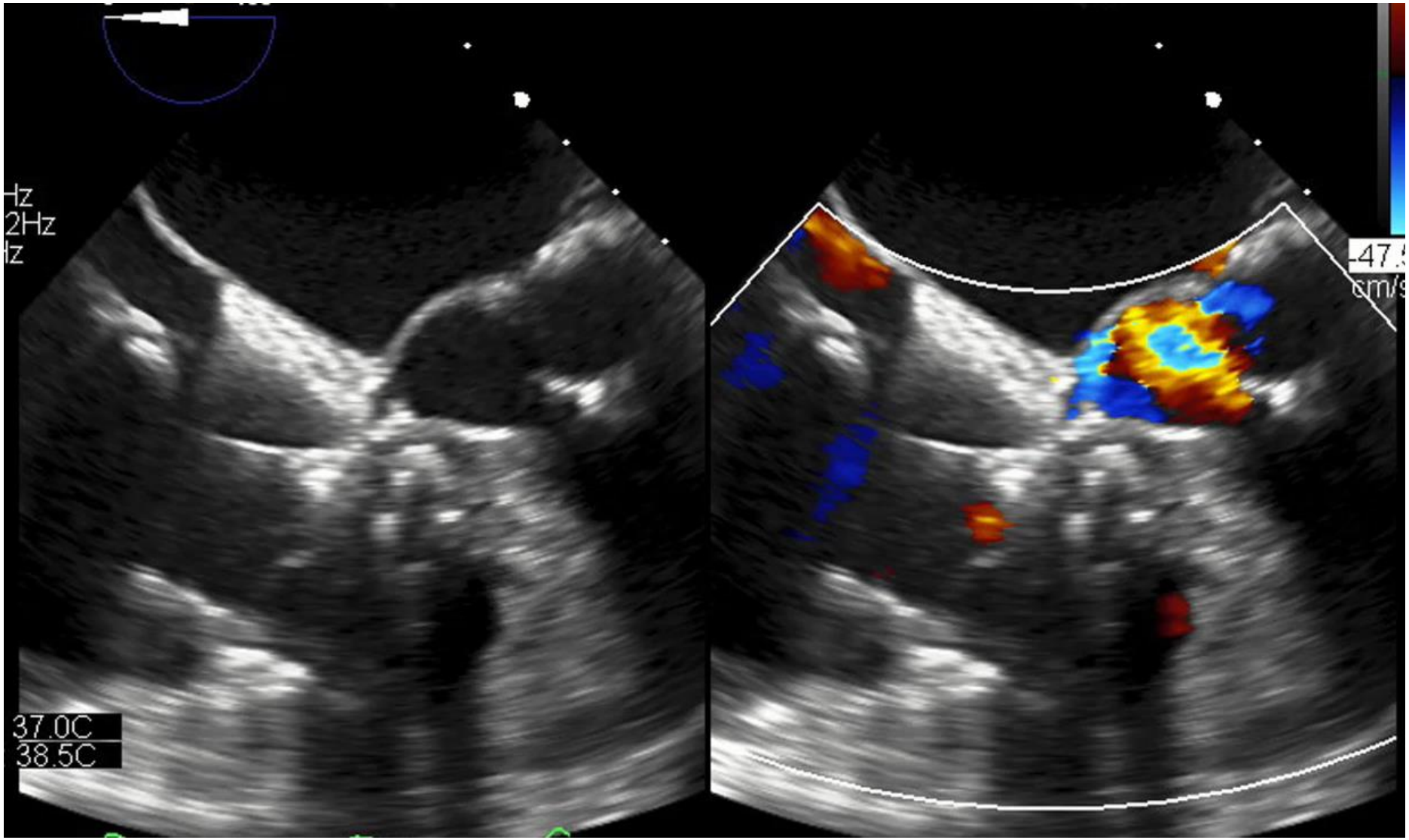




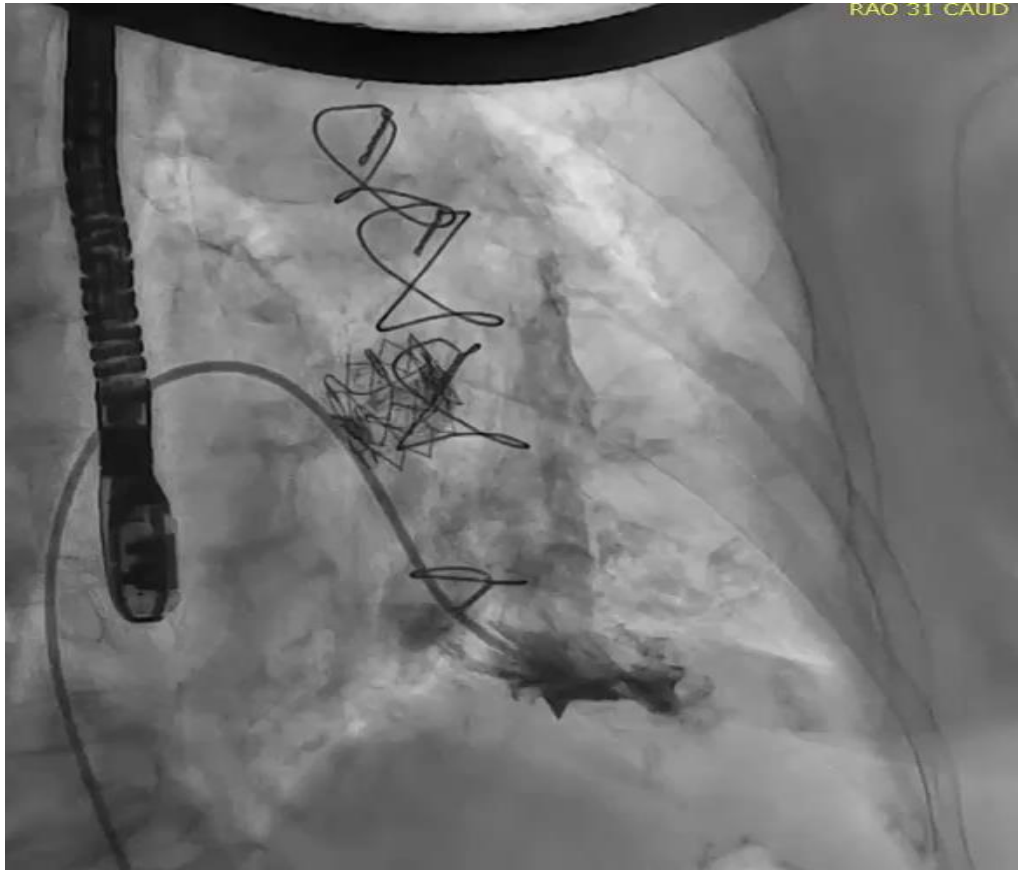


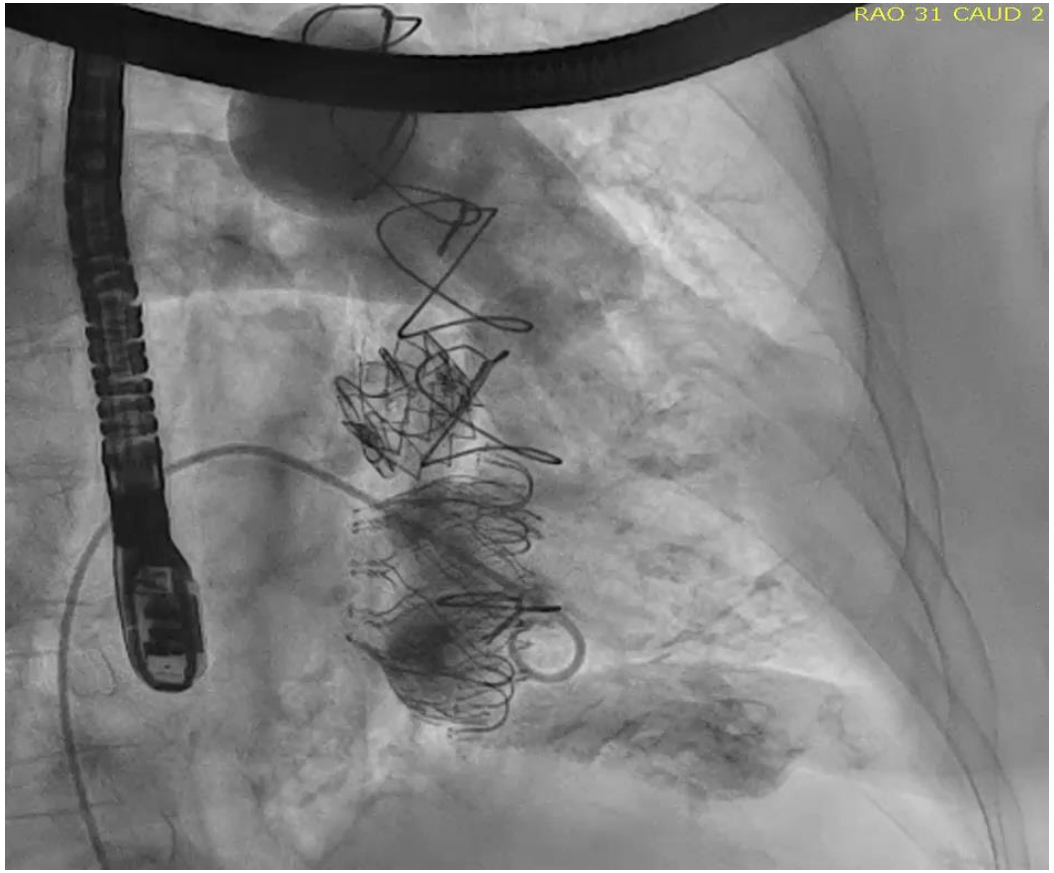


J Am Coll Cardiol Intv 2022;15:471–480.


Hz
2Hz
Hz
37.0C
38.5C

Pre and post RV gram





Procedural Characteristics and Hospital Disposition

Procedural Characteristics	n/N (%) or Mean ± SD (N)
Percutaneous	132/132 (100%)
• **Right femoral vein access**	125/132 (94.7%)
• **Left femoral vein access**	7/132 (5.3%)
Device success (per device)*	128/133 (96.2%)
Device time (implant insertion to release), mins	72.8 ± 28.15 (130)

Hospital Disposition	n/N (%) or Median (Min,Max)
Length of Stay (days)	3 (0,35)
Discharge Location	
Home	114/129 (88.4%)
Home with Services	6/129 (4.7%)
Skilled Nursing Facility	6/129 (4.7%)
Other	3/129 (2.4%)

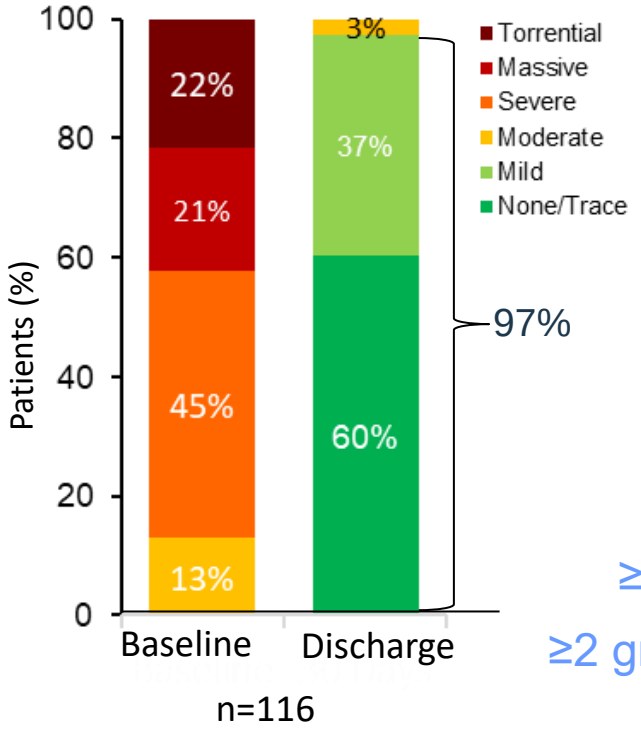
Slides courtesy S. Kodali

*Device deployed and delivery system retrieved at exit from the cardiac catheterization laboratory. One patient had two device attempts.

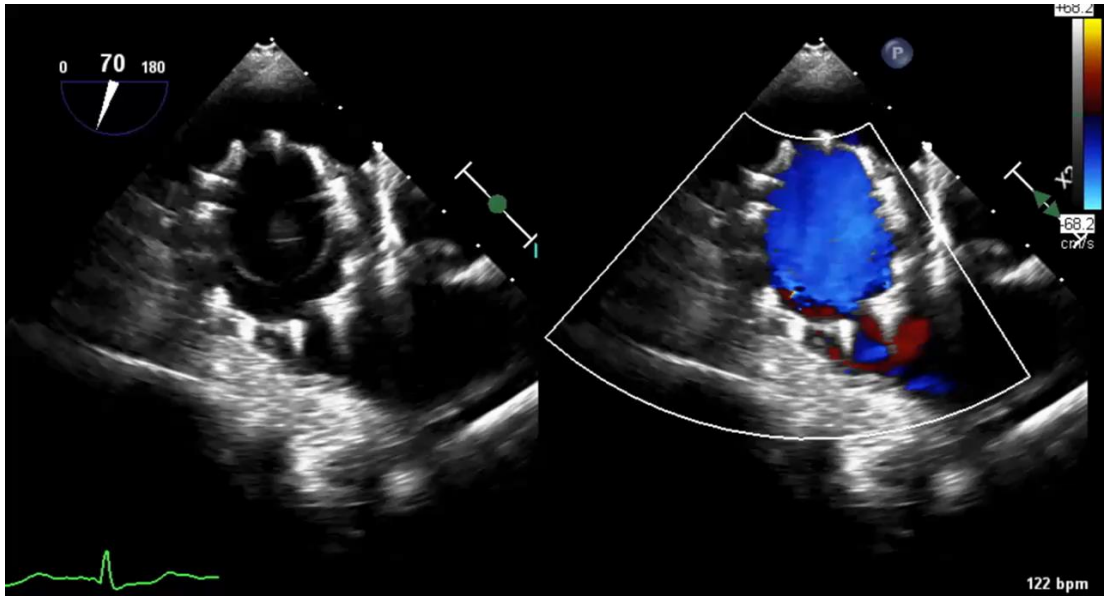
Significant Reduction in TR Severity by Core Lab[1] at 6 Months

TR Severity at Discharge

p < 0.001[a]



n=116



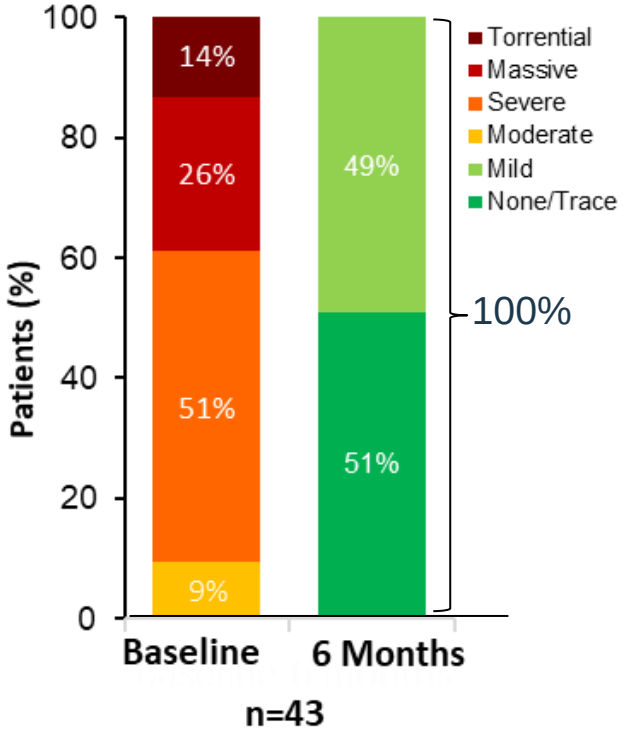
No residual TR post implant with EVOQUE valve

≥1 grade reduction in 100% at discharge and 6 months

≥2 grade reduction in 95% at discharge and 98% at 6 months

TR Severity at 6 Months

p < 0.001[a]



n=43

[1]Core lab: Baylor, Scott and White Research Institute; [a]Wilcoxon signed-rank test. TR, tricuspid regurgitation

Slides courtesy S. Kodali

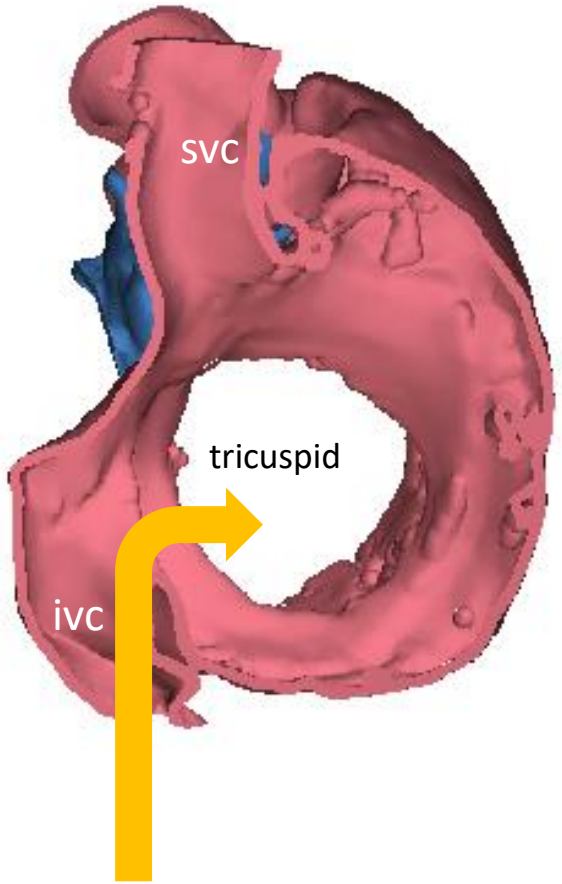
Goals

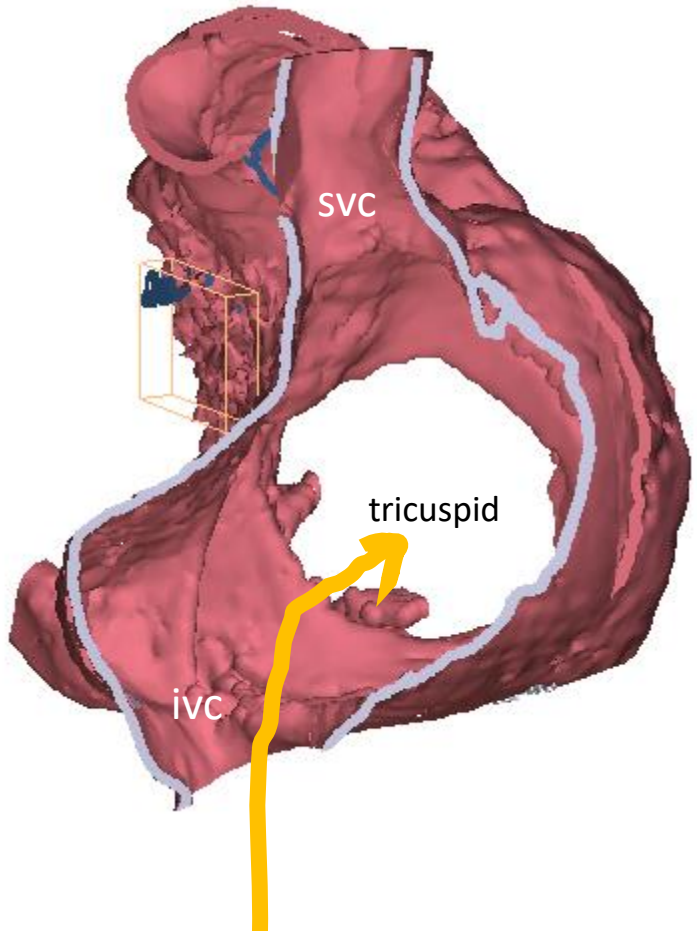
Discuss transcatheter strategies for tricuspid regurgitation

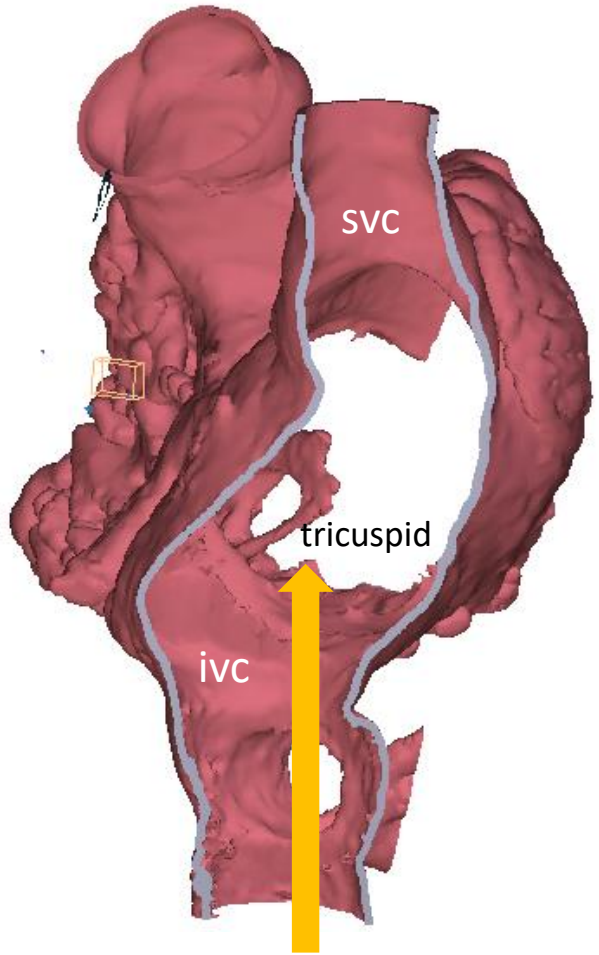
Identify future right heart technologies

Discuss our understanding of ‘size’

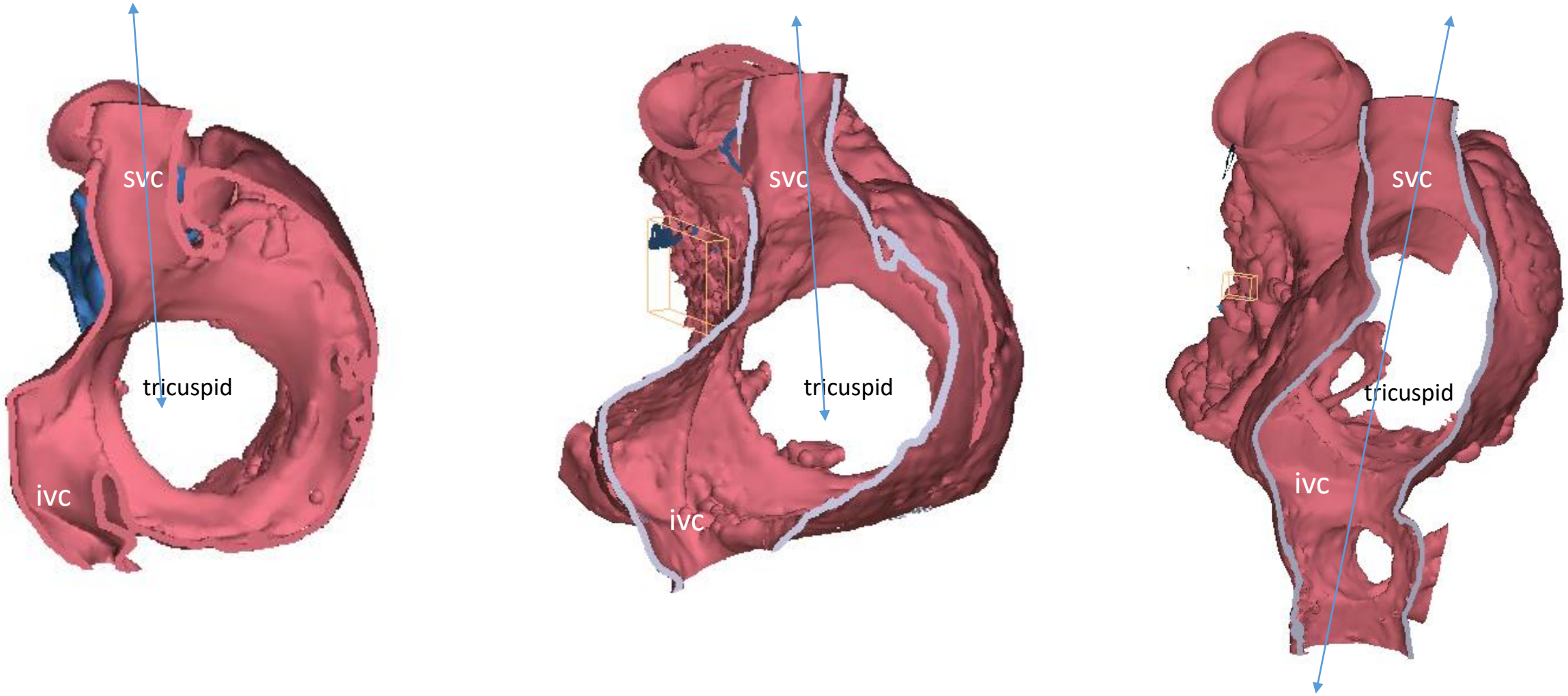
Challenges of transfemoral access to the tricuspid annulus



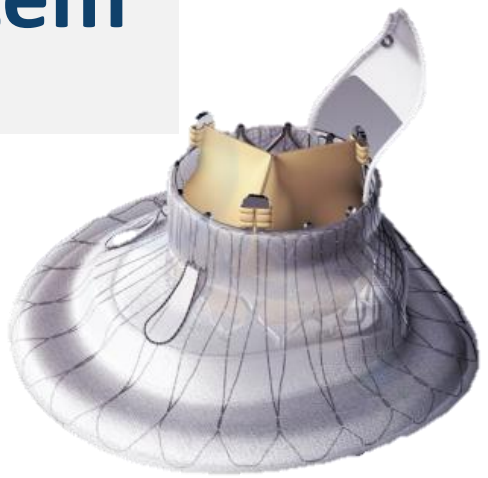




Importance of access coaxiality in Tricuspid



LuX Valve Plus: Transjugular Delivery System



Nitinol, self expanding 30mm tri-leaflet valve

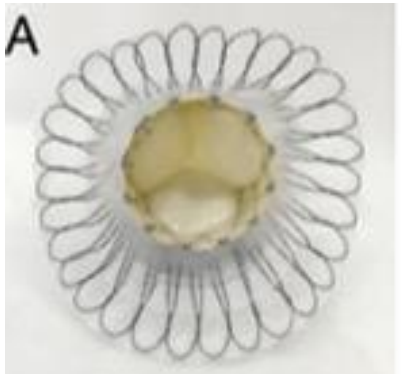
Fixation with 2 sub-annular tabs (ant and post) and a septal anchor

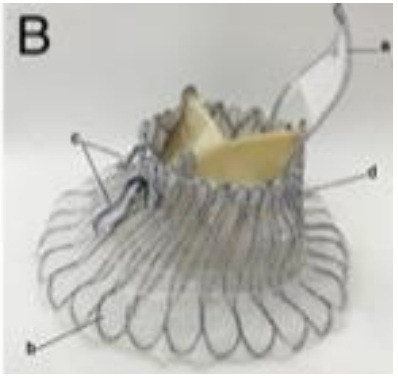
6 valve sizes (mean annular diameter 35 to 70mm)

Multi-plane steerable 31F transjugular delivery catheter

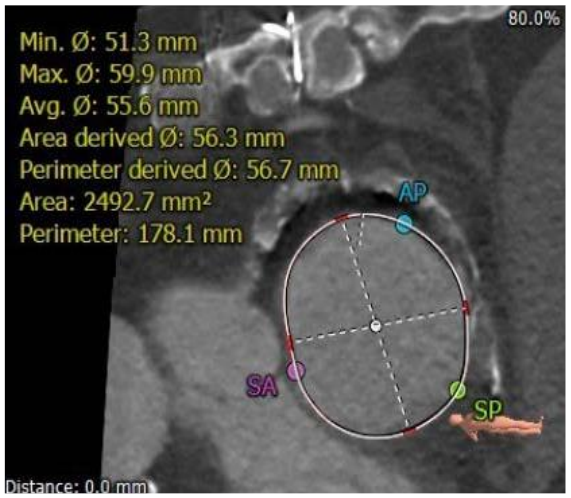
TEE and fluoroscopic guidance

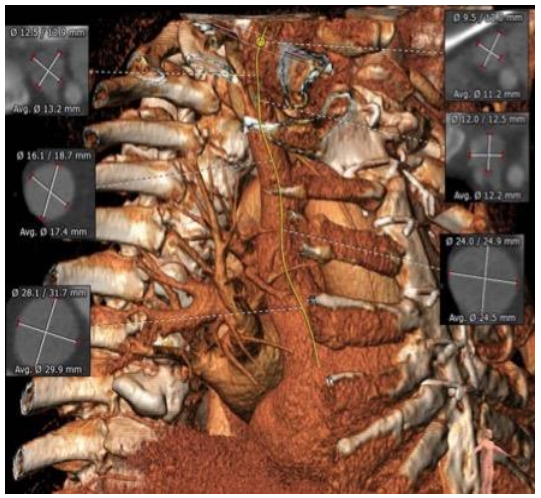
No rapid pacing required for implant

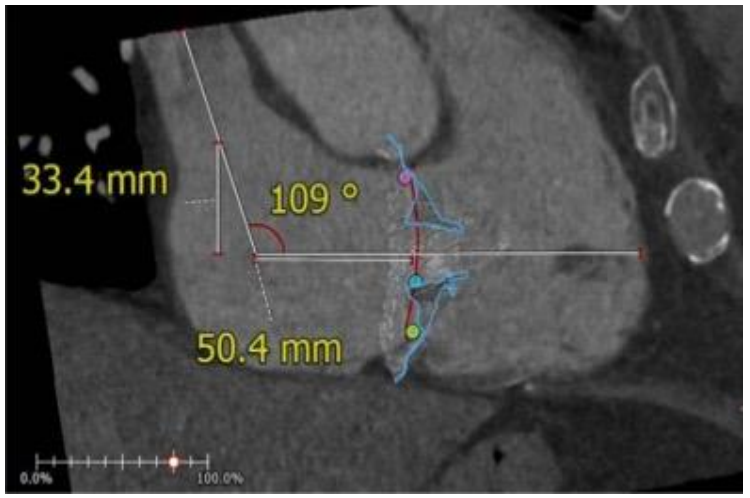


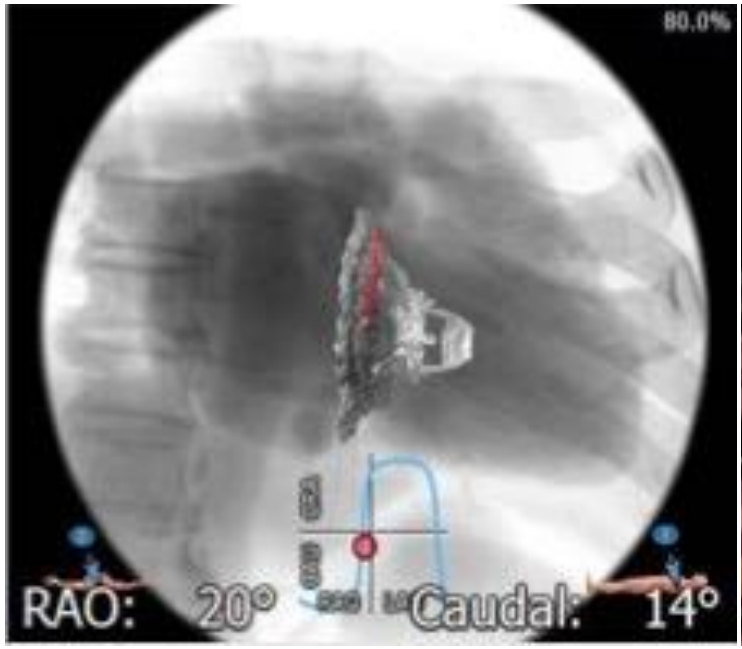


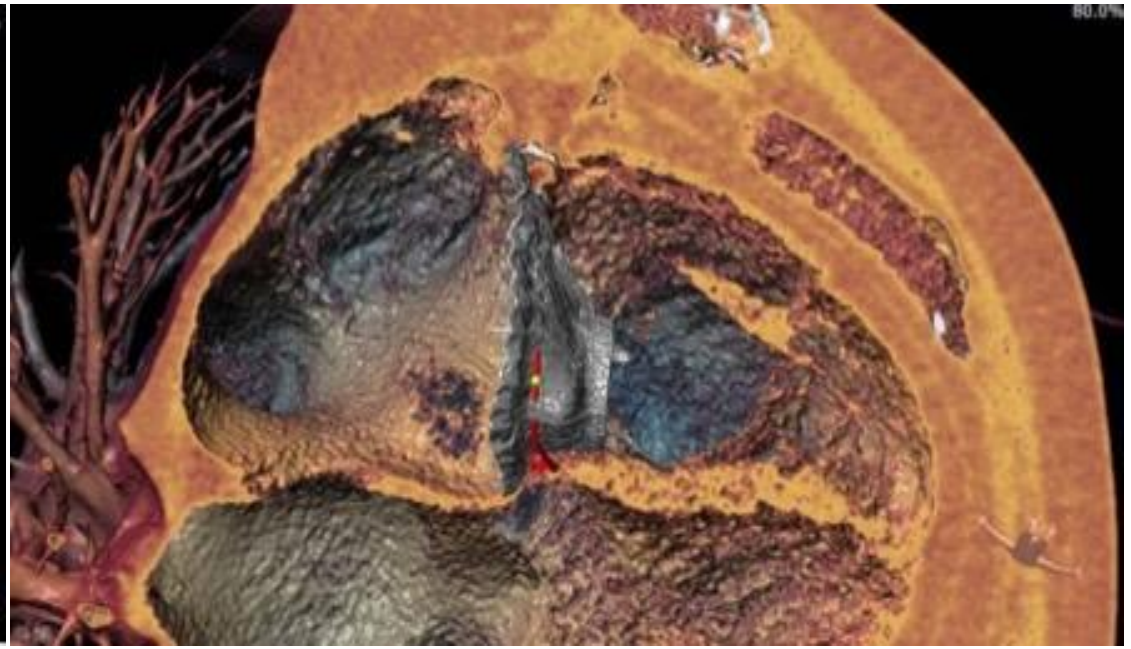
Pre-implant Analysis (TTE, TEE, CT)











LuX-Valve Plus Patient Enrollment

- ✓ Heart team assessment
- ✓ All Compassionate cases
- ✓ Too high risk for conventional surgical TVR
- ✓ Not candidates for commercially available transcatheter devices

Centre	Clinical Leads	Number of Procedures Total (n=18)
St. Paul's Hospital Vancouver, Canada	*Anson Cheung Robert Boone*	*8*
Changhai Hospital Shanghai, China	*Fanglin Lu Zhiyun Xu*	*5*
Zhongshan Hospital Shanghai, China	*Junbo Ge Daxin Zhou*	*5*

Patient Demographics (N=18)

Mean Age (range)	73 ± 10 (50 - 89)
Female Gender	9 (50%)
NYHA Class III	13 (72%)
NYHA Class IV	5 (18%) *1 on inotrop
Mean STS Risk Score (range)	12.2 ± 7.8 (5.4 - 35.9)
Mean EuroSCORE II (range)	14.5 ± 14.4 (4.7 – 51.1)
Chronic Kidney Disease	13 (72%)
Prior Cardiac Surgery	12 (67%)
Atrial Fibrillation	17 (94%)
PPM/AICD/CRT	5 (28%)

Echocardiographic and CT Data (N=18)

Massive/Torrential TR	18 (100%)
Mean Systolic PAP (mmHg)	45.8 ± 7.5
Mean LV Ejection Fraction (%)	59.3 ± 10
>= Moderate RV Dysfunction	10 (56%)
Mean TV annular diameter (mm)	49 ± 6 (40.4 - 60.1)
Mean TV annular area (mm^2)	1850 ± 393 (1258 - 2471)

Clinical Results: Safety and Performance of LuX-Valve Plus

Procedural Outcomes (VARC-3) (N = 18)

Procedural Success	**18 (100%)**
Malposition/Migration	**0 (0%)**
Freedom from Emergency Surgery/Reintervention	**0 (0%)**
Vascular Access Complication	**0 (0%)**
Extubated in OR	**8 (44%)**

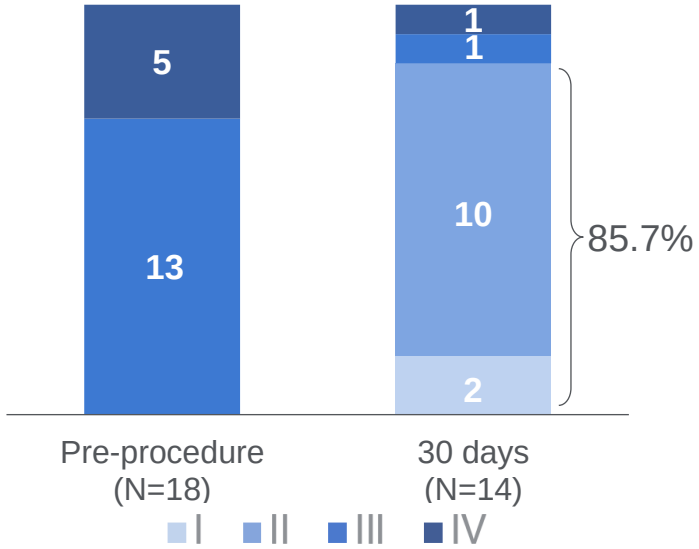
Perioperative Clinical Outcomes (N=18)

In Hospital Mortality	**0 (0%)**
Cerebrovascular Accident	**0 (0%)**
Myocardial Infarction	**0 (0%)**
Reintervention	**0 (0%)**
New Pacemaker	**1 (6%) D10 AF with slow HR**
Median Post-procedural LOS (days)	**5.9 ± 5.2 (6/8 Canadian pts was D/C on day 1)**

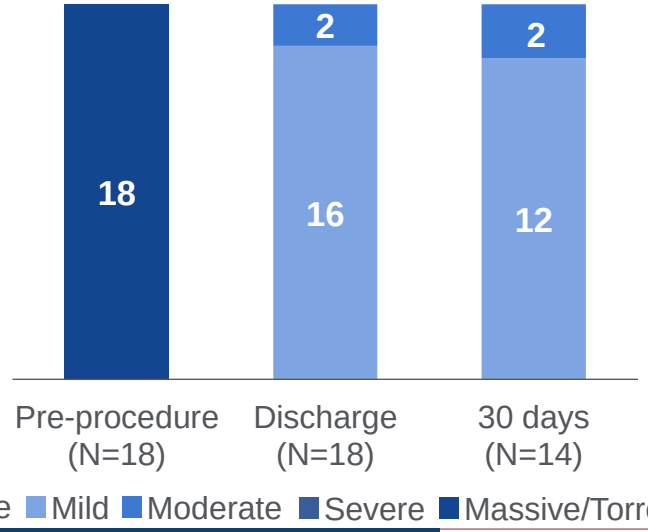
30-Day Clinical Outcomes (N = 18)

All Cause Mortality	**1 (5.6%) *Undiagnosed gastric CA**
Cardiovascular Mortality	**0 (0%)**
Cerebrovascular Accident	**0 (0%)**
Myocardial Infarction	**0 (0%)**
Reintervention	**0 (0%)**

Cardiac Functions Under the NYHA Classification

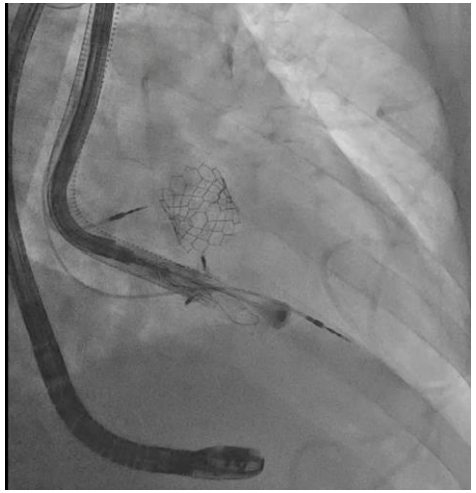


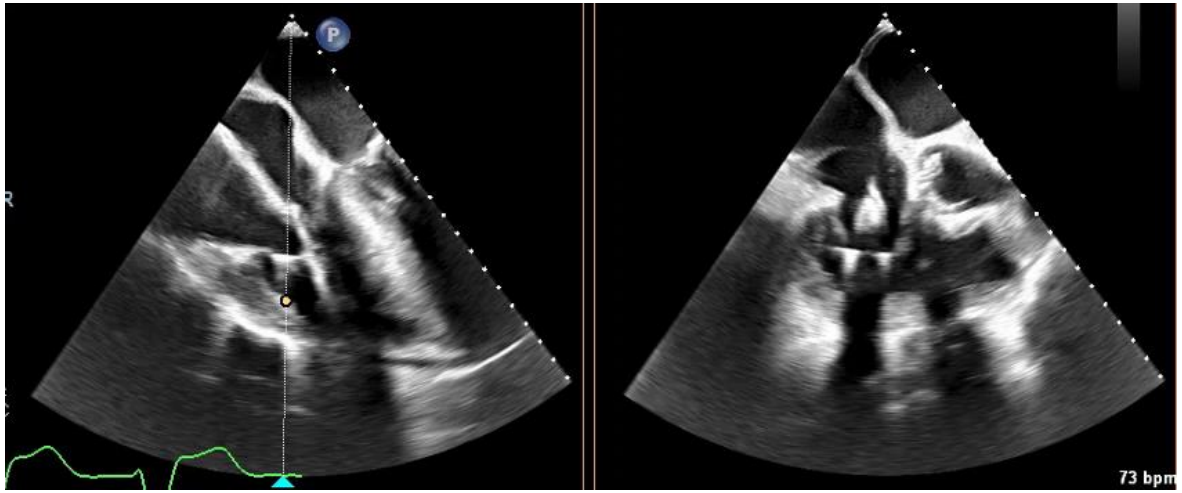
Severity of Tricuspid Regurgitation



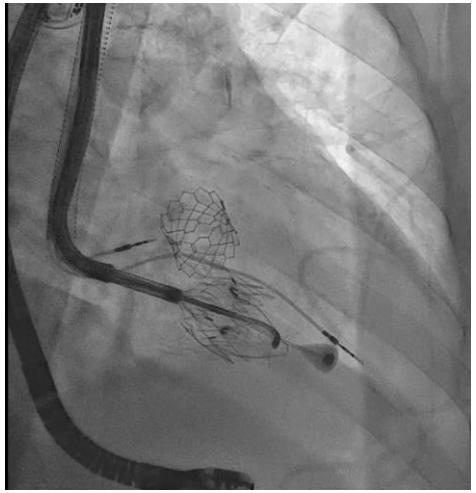
First 7 United States LuX transcatheter tricuspid implants: Henry Ford Structural Heart

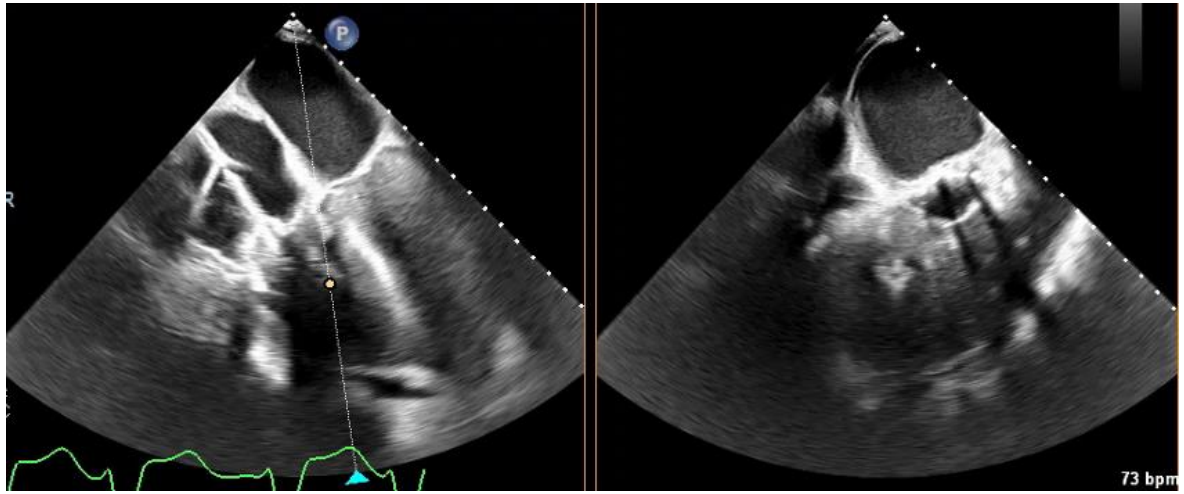
1. Tab positioning



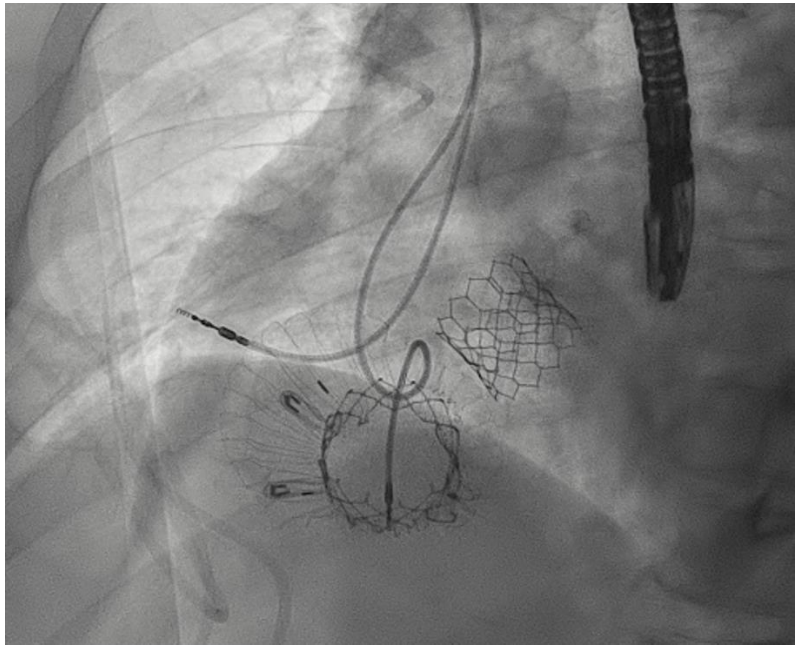


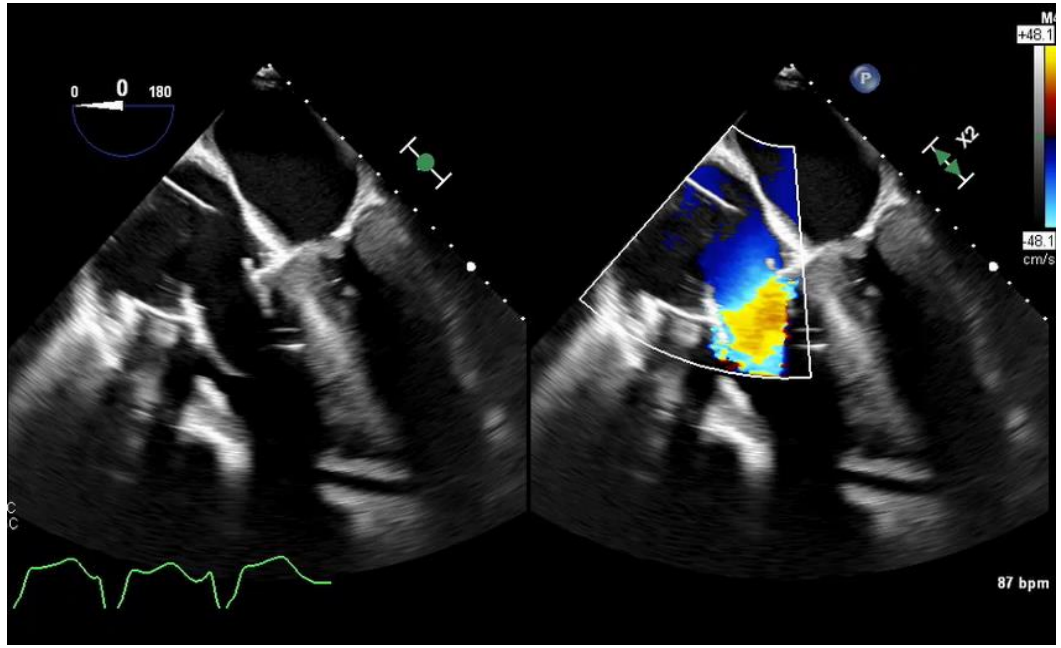
2. Septal anchoring

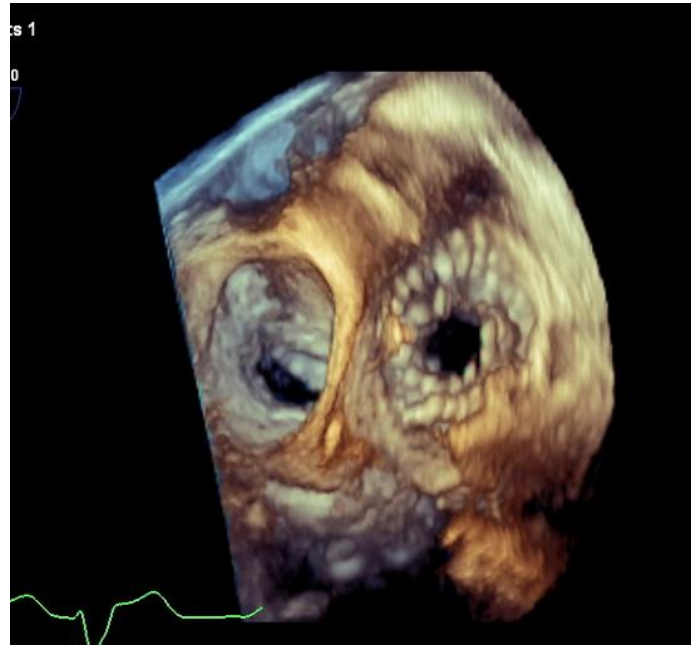




First 7 United States LuX transcatheter tricuspid implants:
Henry Ford Structural Heart







Villablanca P, O'Neill WW, O'Neill BP et al.

Future: LuX-Valve Plus (2nd-Gen, Trans-Jugular), TRINITY, EU Pivotal Study

LuX-Valve Plus TRINITY, EU Pivotal Study	A prospective, single-arm, multi-center study to evaluate the safety and performance of LuX-Valve Plus System for tricuspid replacement in Patients with Severe or Greater Tricuspid Regurgitation
Trial Design	Prospective, single-arm, multi-center trial. All subjects will be evaluated at baseline, discharge, 30 days, 6 months, 1 year, 2 years, 3 years, 4 years and 5 years post-procedure
Primary Safety Endpoint	A composite endpoint of Major Adverse Event (MAE) at 30 days post procedure, as listed below: • Cardiovascular Mortality • Myocardial Infarction (MI) • Stroke • New onset renal failure requiring renal replacement therapy • Severe Bleeding (includes fatal and life-threatening bleeding as defined by MVARC) • Non-selective tricuspid valve surgery or transcatheter re-intervention post procedure • Major access site and vascular complications • Major cardiac structural complications • New pacemaker implantation due to AV block
Primary Performance Endpoint	TR≤2+ without clinically significant paravalvular leak (PVL) on a transthoracic echocardiography (TTE) at 30 days post-procedure. (Assessed by the echo core lab)

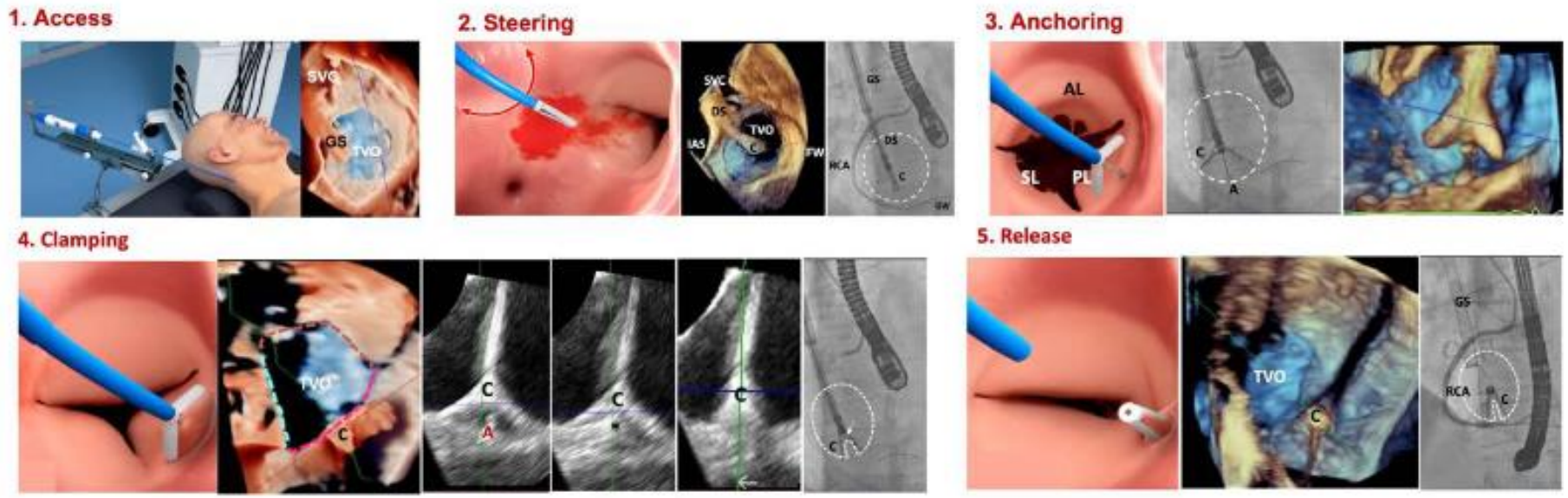
Introducing the K-Clip

Right IJ TTVr annuloplasty device

Clamp annulus with clip & anchor

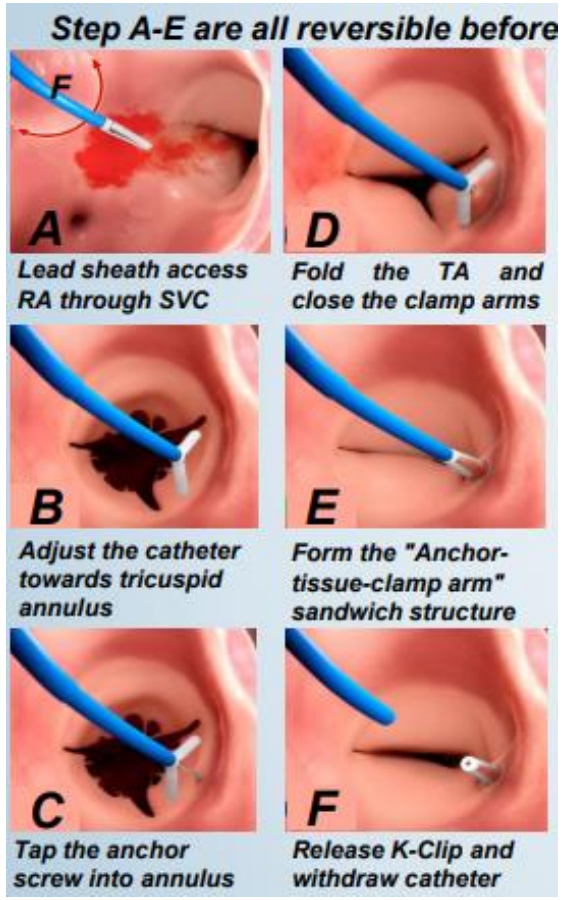
reduces annulus perimeter

reduces regurgitant orifice area



Alex Pui-Wai Lee, MBChB, MD; Yiming Ni, MD; Yat-yin Lam, MBBS, MD

Step-by-step


Step A-E are all reversible before
F
A
Lead sheath access RA through SVC
D
Fold the TA and close the clamp arms
B
Adjust the catheter towards tricuspid annulus
E
Form the "Anchor-tissue-clamp arm" sandwich structure
C
Tap the anchor screw into annulus
F
Release K-Clip and withdraw catheter


汇禾医疗
HuiHe Healthcare

JACC: BASIC TO TRANSLATIONAL SCIENCE

PRECLINICAL RESEARCH

Feasibility Study of a Novel Transcatheter Tricuspid Annuloplasty System in a Porcine Model

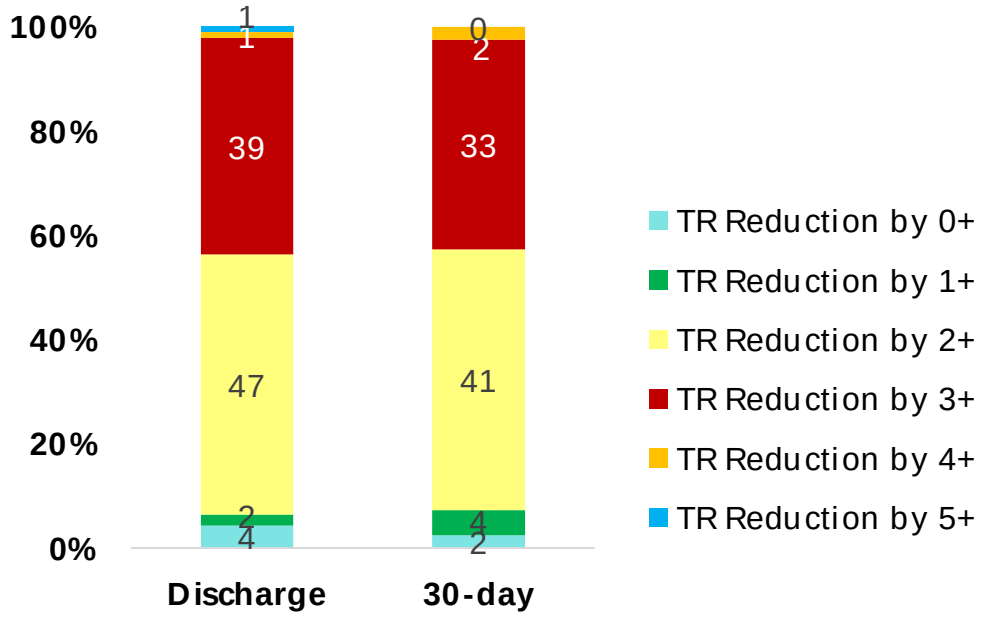
Wenzhi Pan, MD,[a,b,*] Yuliang Long, MD,[a,b,*] Xiaochun Zhang, MD,[a,b,*] Shasha Chen, MD,[a,b] Wei Li, MD,[c] Cuizhen Pan, MD,[c] Yingqiang Guo, MD,[d] Daxin Zhou, MD,[a,b] Junbo Ge, MD[a,b]

- Procedural success rate 100%.
- Procedural time 23.67 +- 4.21 min.
- No bleeding, cardiac perforation, pericardial effusion or any other procedure-related complication
- 69.2% experienced a decline of 1 grade and 23.1% experienced a decline of 2 grades.
- Rapid significant reduction in annular area

K-Clip® Pivotal in China NMPA

Trial completed enrolling (N=96) in Oct. 2022, 132 Clips implanted.

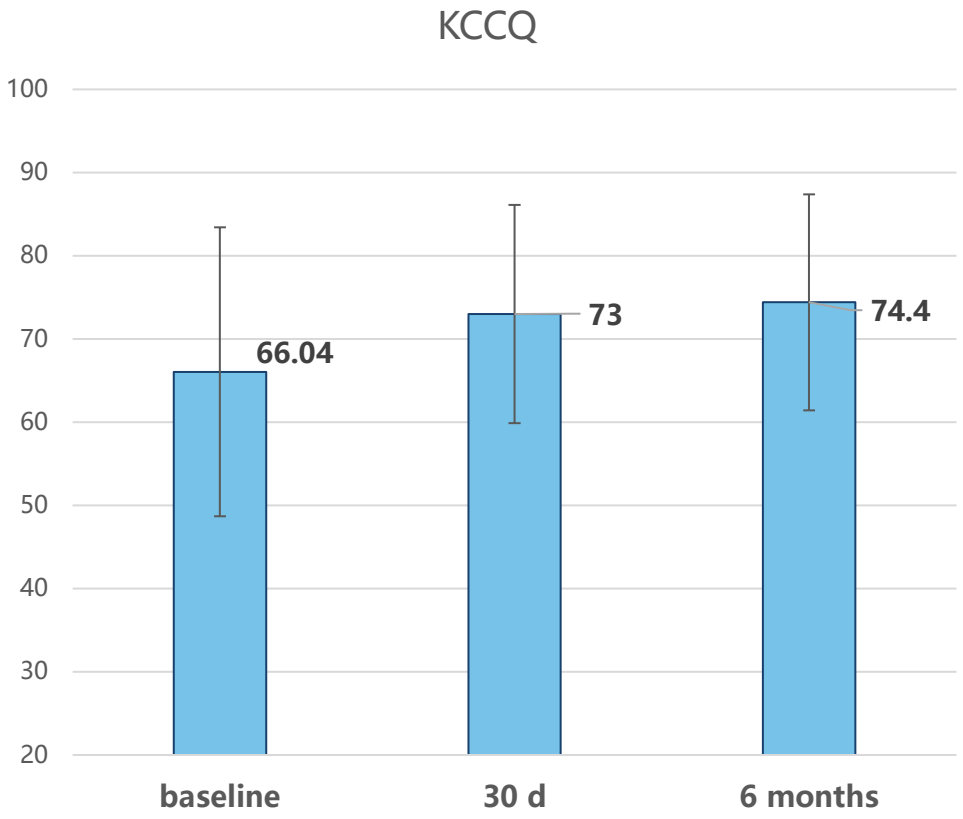
Endpoint	Discharge(n=94)	30 Day(n=82)
TR Reduction by 0+	4 (4.26%)	2(2.44%)
TR Reduction by 1+	2 (2.13%)	4(4.88%)
TR Reduction by 2+	47 (50.00%)	41(50%)
TR Reduction by 3+	39 (41.49%)	33(40.24%)
TR Reduction by 4+	1 (1.06%)	2(2.4%)
TR Reduction by 5+	1 (1.06%)	0(0%)

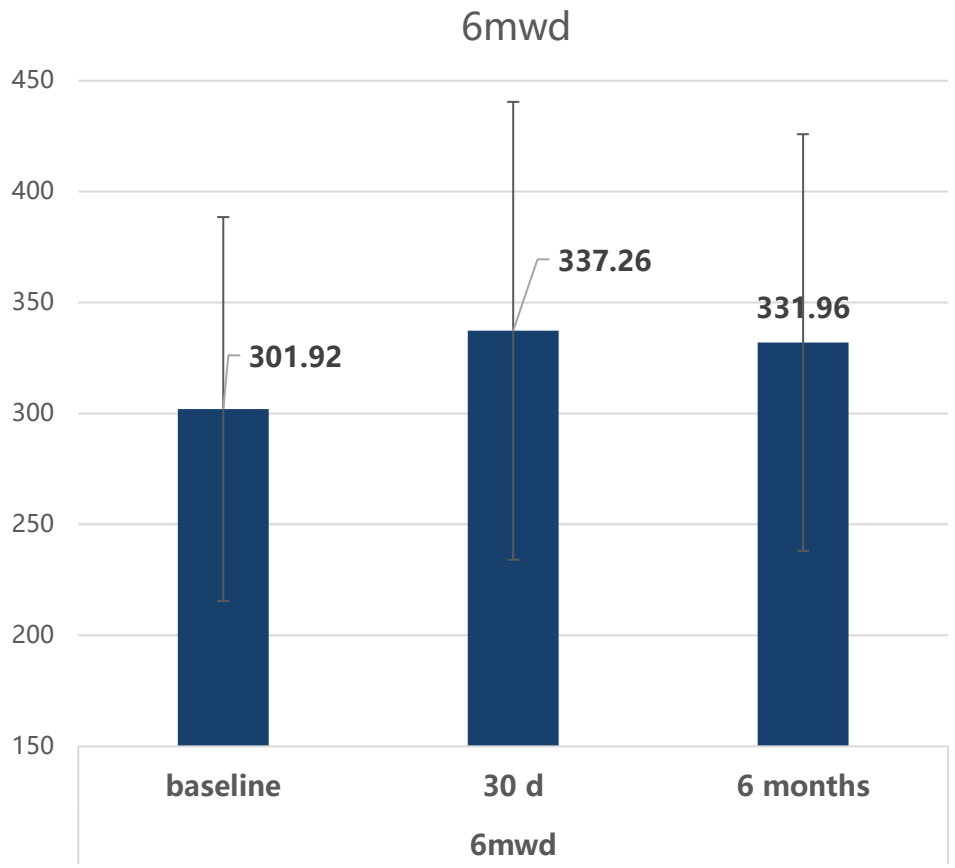


MACE (n,%)	Discharge (n=94)	30 Day (n=94)
Recurred heart failure	0	2 (2.13)
Myocardial infarction	0	0
Stroke	0	0
Renal deterioration	0	0
Severe bleeding	0	0
Recurred AF/Af	0	2 (2.13)
Major access site and vascular complications	0	0

SAE (n,%)	Discharge (n=94)	30 Day (n=94)
Gastrointestinal bleeding	5 (5.32)	0
Pulmonary infection	0	2 (2.13)
Recurred heart failure	0	2 (2.13)
Recurred AF	0	2 (2.13)
PCI	0	0
Pacemaker Implant	0	0

Functional and QoL results

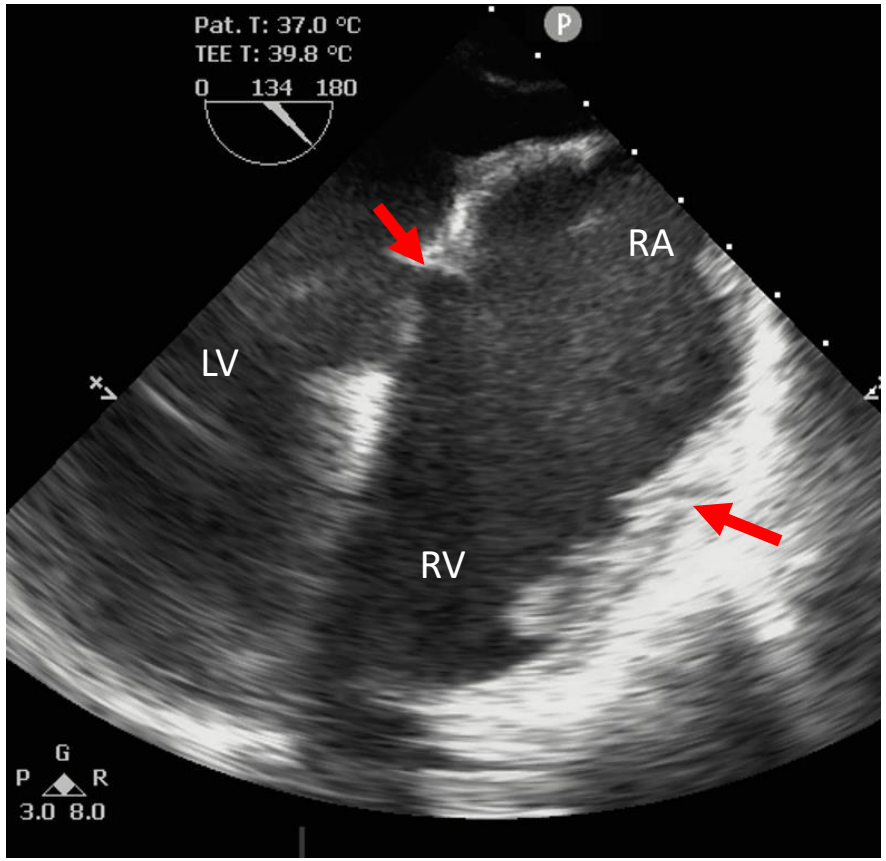


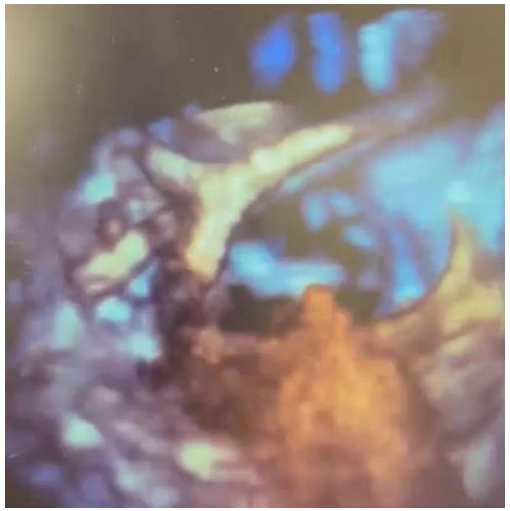


- Safe procedure
- Durable TR reduction at 6 months
- Improvements in KCCQ and QoL.
- Short learning curve
- Promising technique in treating functional TR and can be used as adjunct therapy w/ TEER

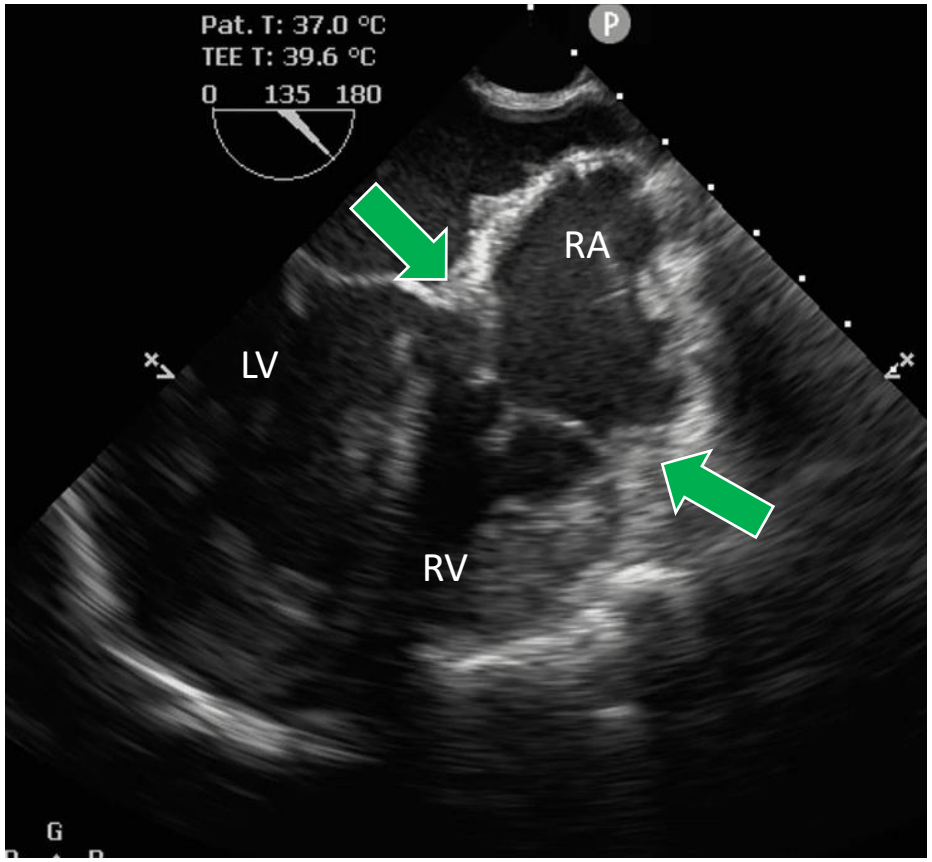
US preclinical: K-Clip evaluation

Baseline tricuspid annulus between Red arrows





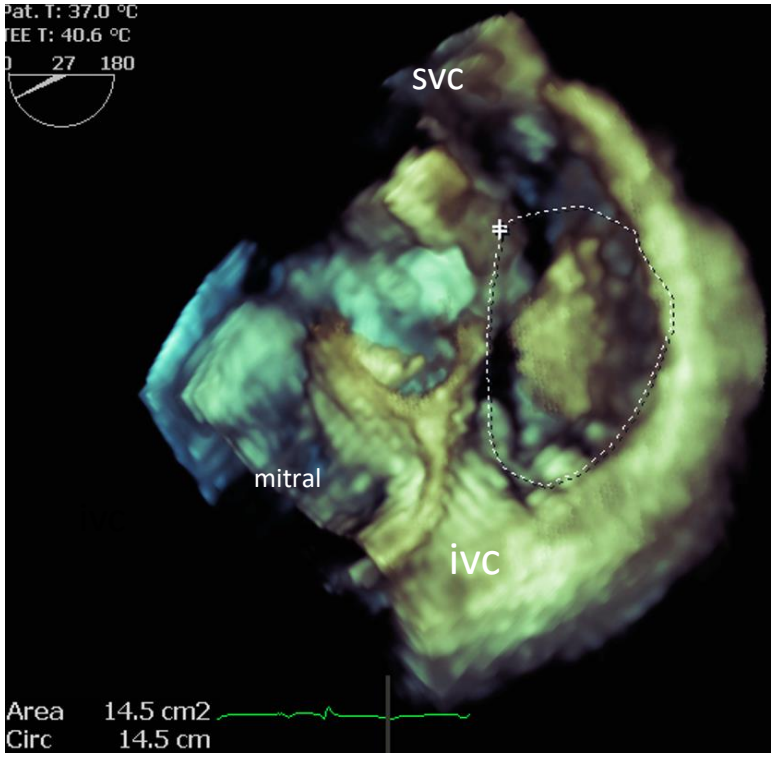
Post K-Clip. tricuspid annulus reduced in size between Green arrows



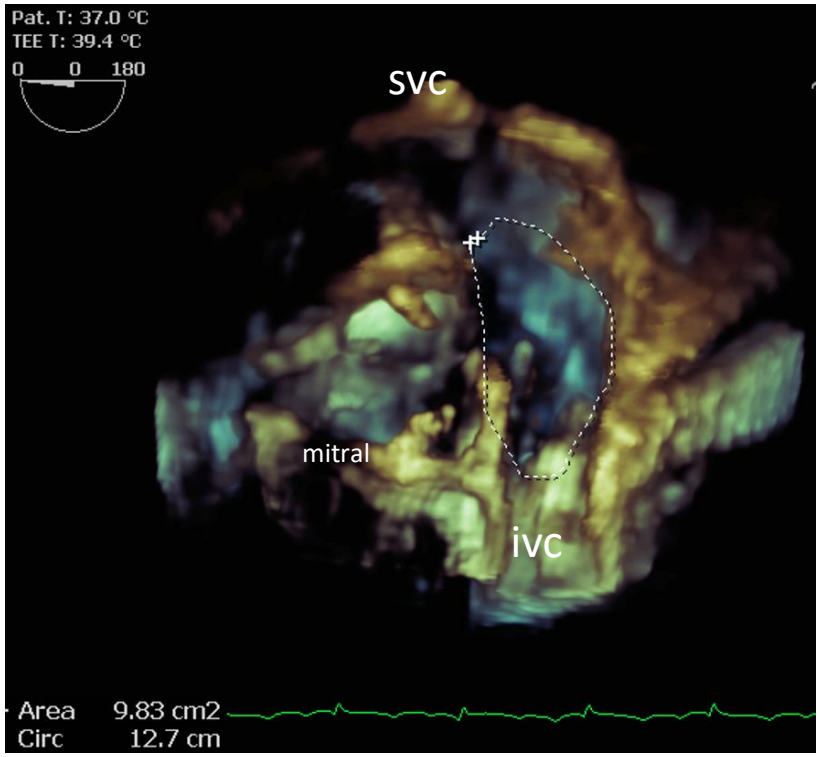
O'Neill WW, Wang DD, O'Neill BP et al. 2022

3D Surgeon's View impact of K-Clip

Baseline tricuspid annulus area: 14.5 sqcm

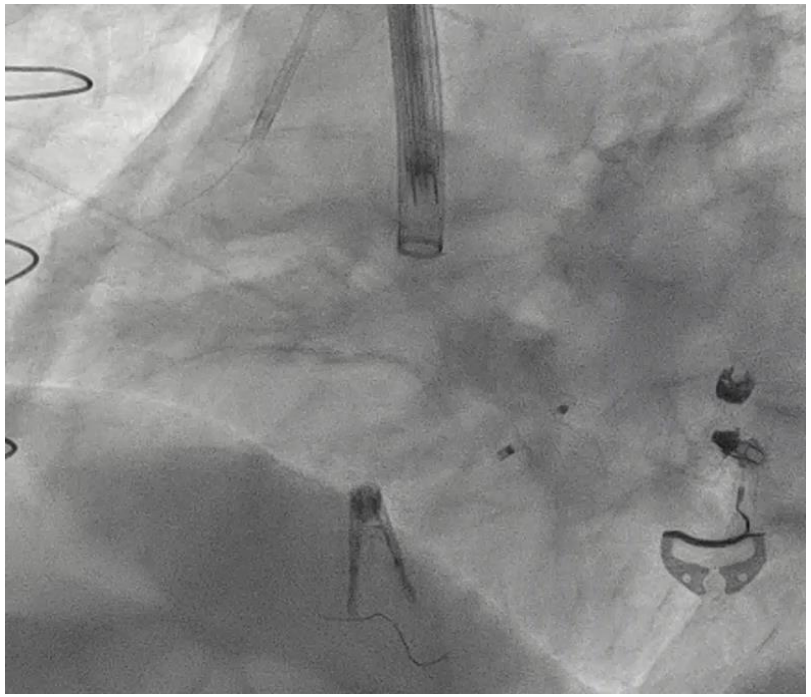


Post K-clip tricuspid annulus area: 9.83 sqcm



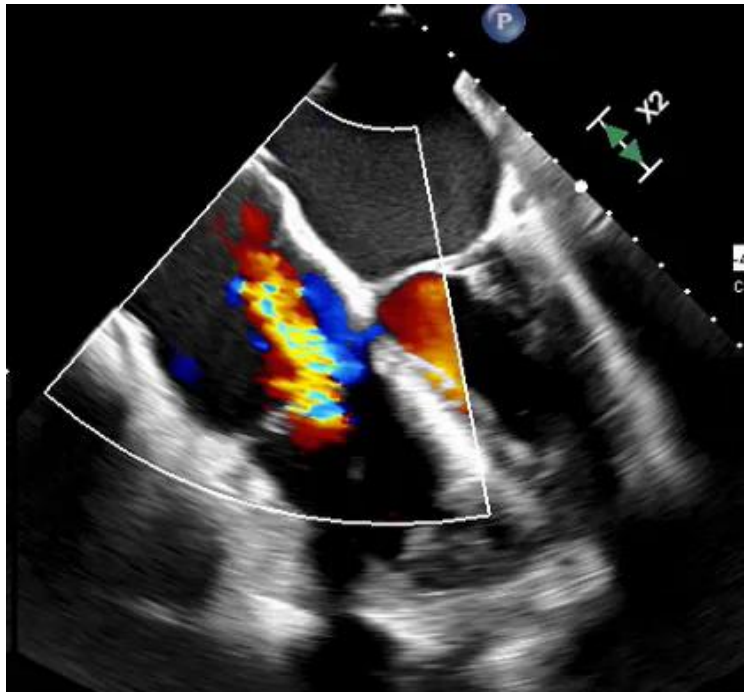
O'Neill WW, Wang DD, O'Neill BP et al. 2022

1st in human US: K-Clip at Henry Ford



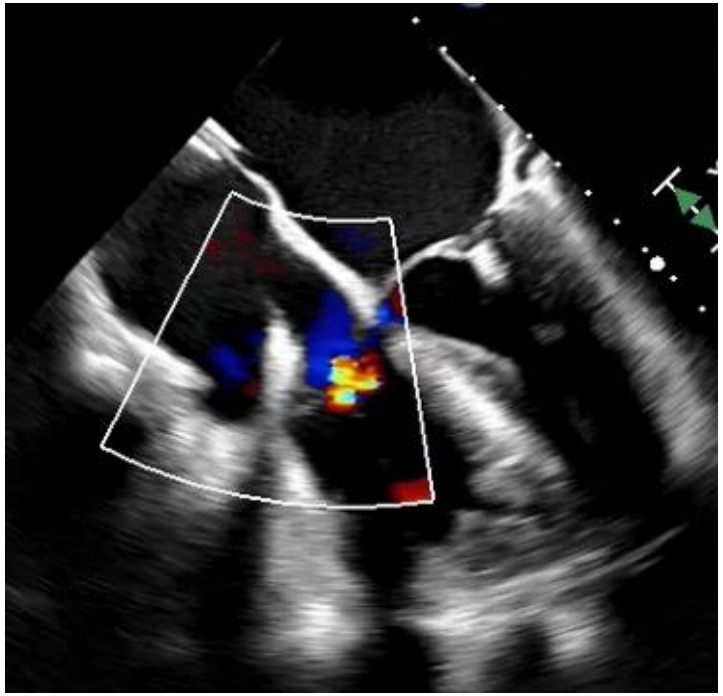
BASELINE:

severe tricuspid regurgitation



POST KCLIP:

trivial tricuspid regurgitation



Our K-Clip patient

Pre-discharge

30-day follow-up

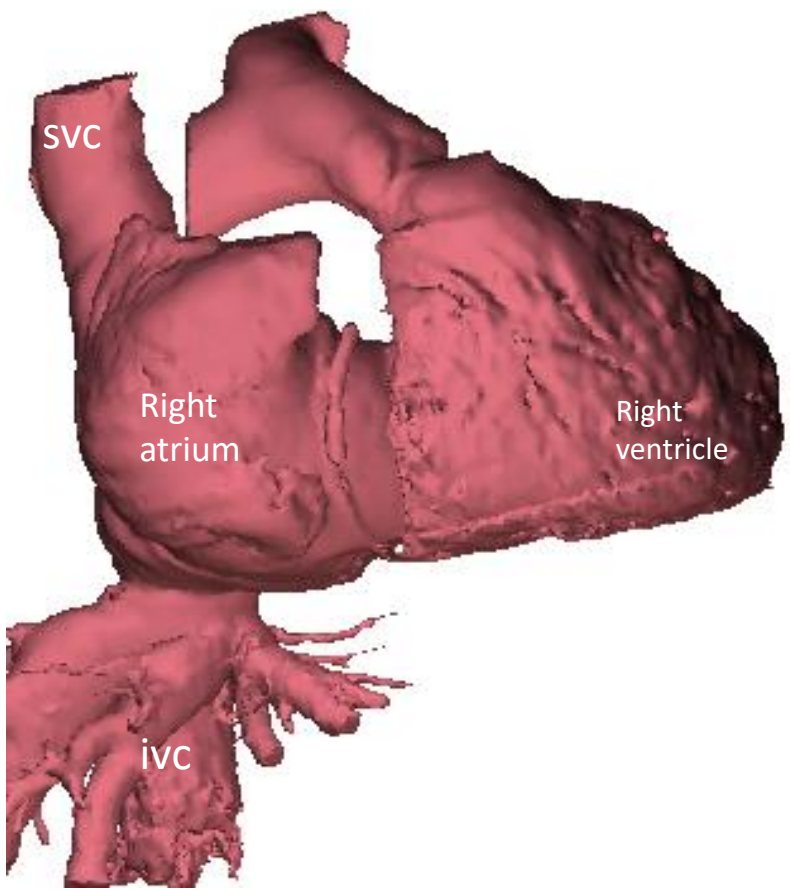
Goals

Discuss transcatheter strategies for tricuspid regurgitation

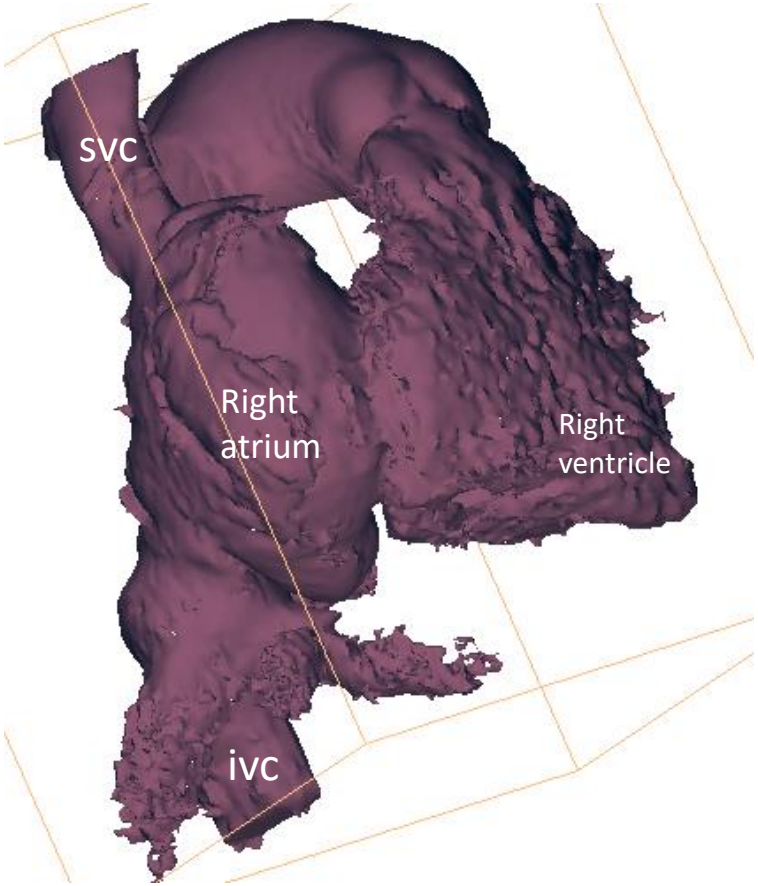
Identify future right heart technologies

Discuss our understanding of ‘right heart size’ and TR

3 patients with severe Tricuspid Regurgitation



A



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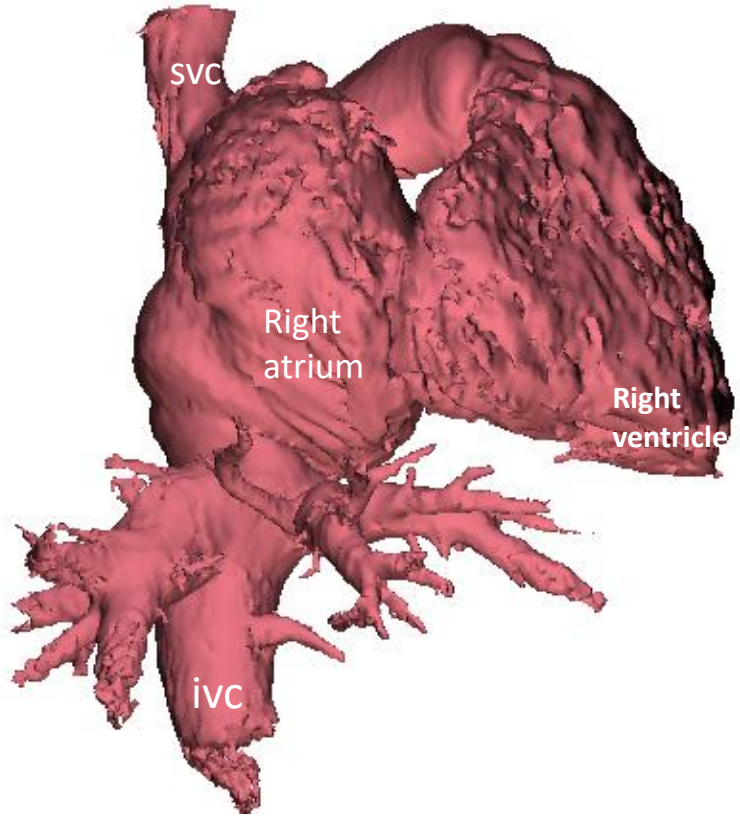
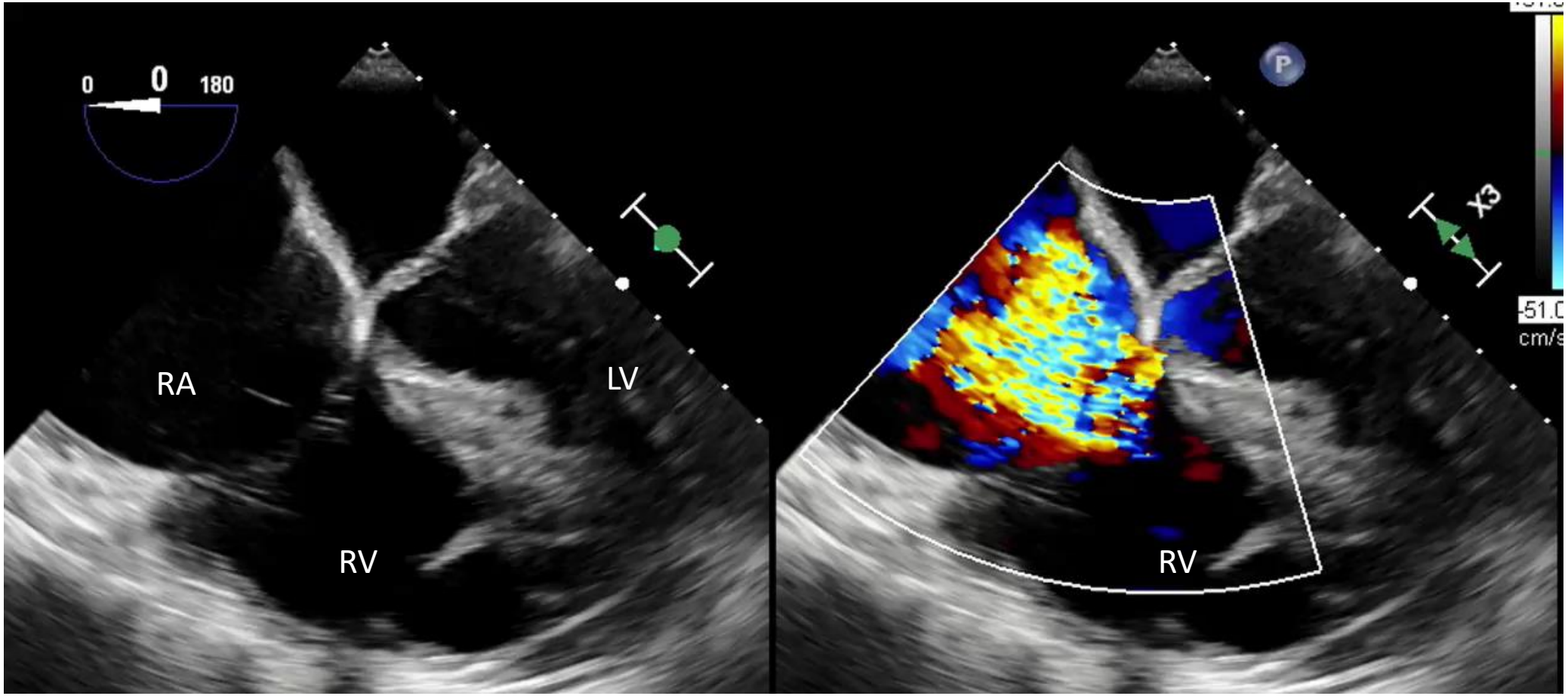


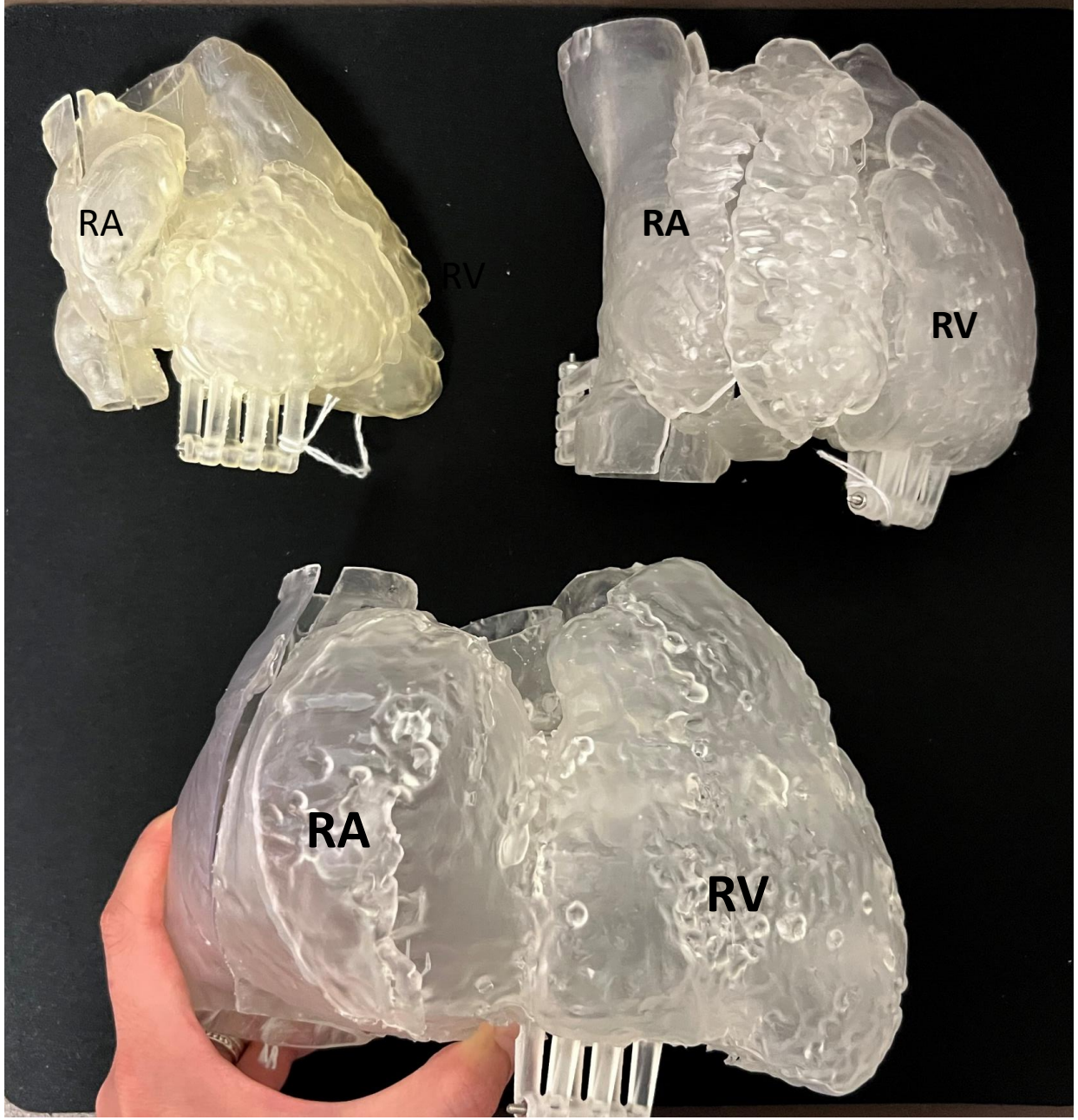
C

Blindspot of Imaging: absent context of “right heart size control”

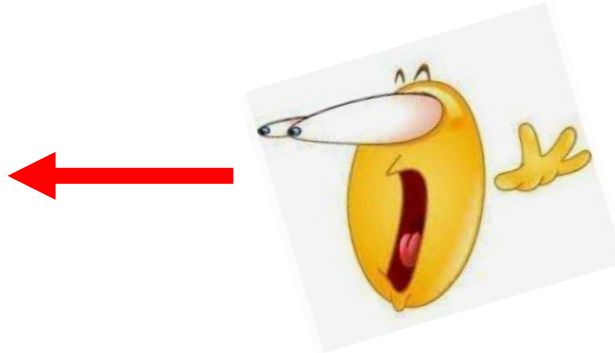


Do we have enough imaging information for TR trials?

Normal right heart

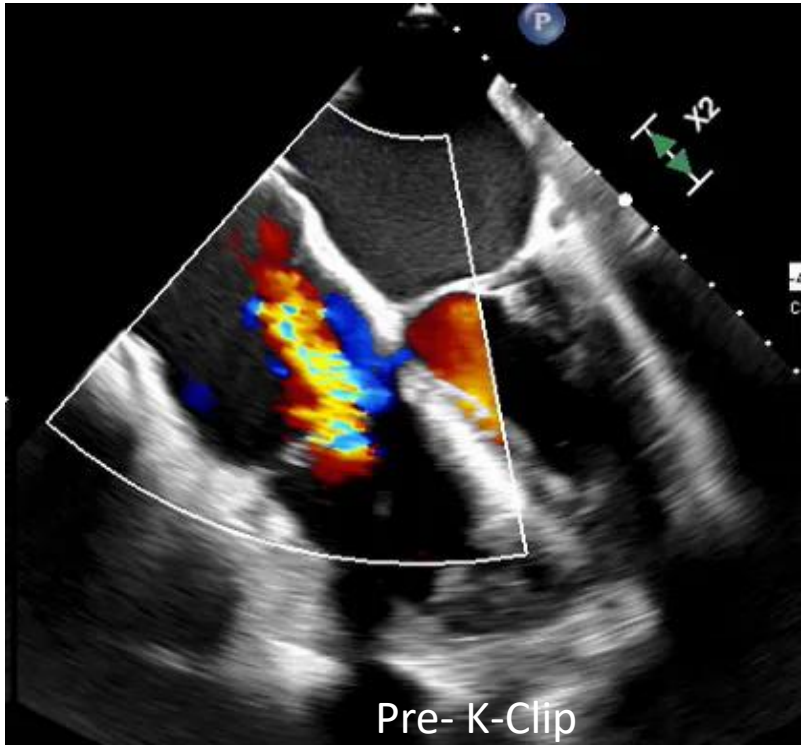


"Severe TR"



our patient…severe TR

right heart dilatation versus normal

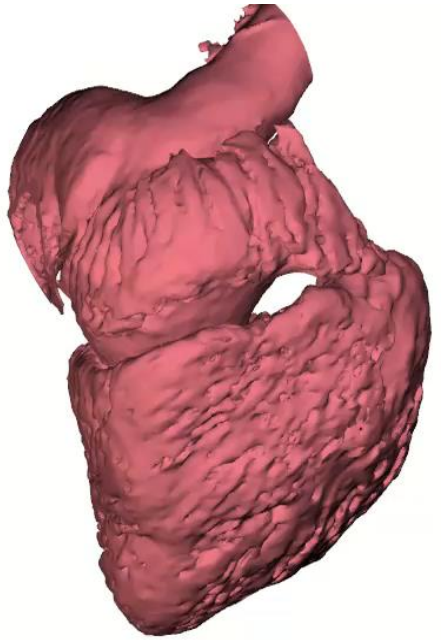


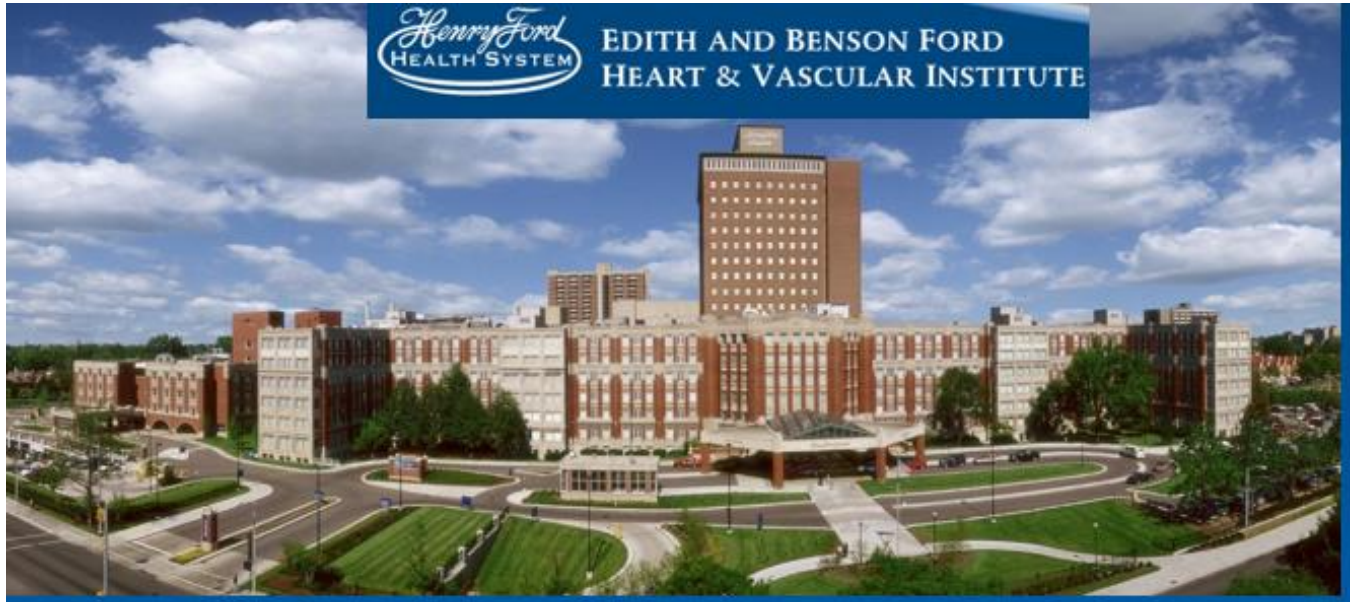
Take home points:

Many new right heart technologies to become available

Tricuspid imaging requires more understanding of right heart anatomy

Need more multi-modality imaging guidance for staging right heart disease





Thank you

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