ACC Roundtable ‘23

Percutaneous Management of Tricuspid Regurgitation

Paul Sorajja, MD

Roger L. and Lynn C. Headrick Family Chair

Valve Science Center, Minneapolis Heart Institute Foundation

Abbott Northwestern Hospital

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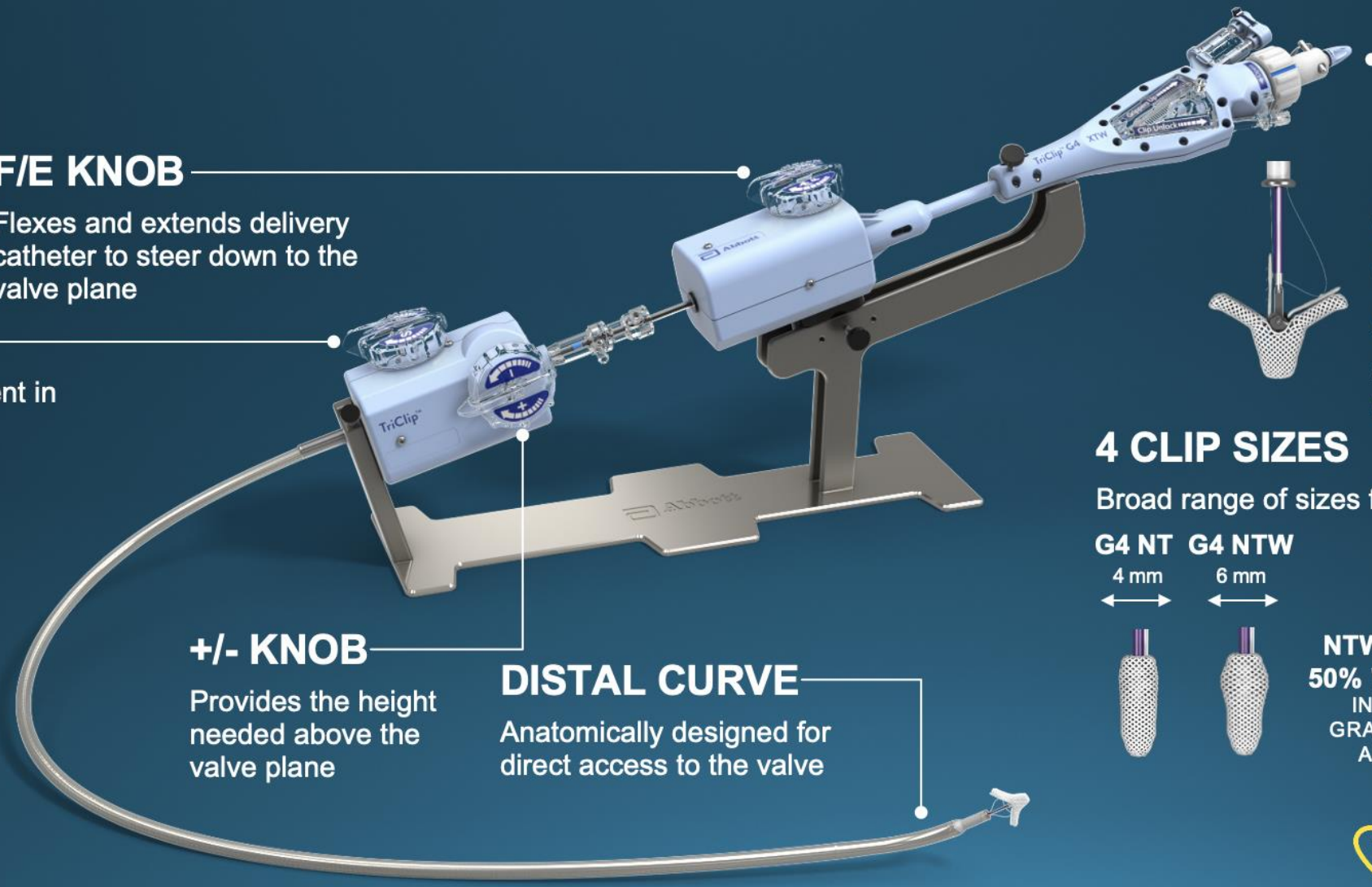
Disclosures

- Consulting or Advisory Board: 4C Medical, Abbott Structural, Anteris, Boston Scientific, Edwards Lifesciences, Foldax, GE Medical, Medtronic, Phillips, Siemens, TriFlo, xDot, VDyne, WL Gore
- Institutional Research: Abbott Structural, Boston Scientific, Edwards Lifesciences, Medtronic
- National P.I.: EXPAND II, HighLife (US), SOAR EFS, SUMMIT-MAC, TRILUMINATE Pivotal, VDyne

TriClip™ G4 Delivery System



F/E KNOB

Flexes and extends delivery catheter to steer down to the valve plane

S/L KNOB

Enables movement in septal or lateral direction

+/- KNOB

Provides the height needed above the valve plane

DISTAL CURVE

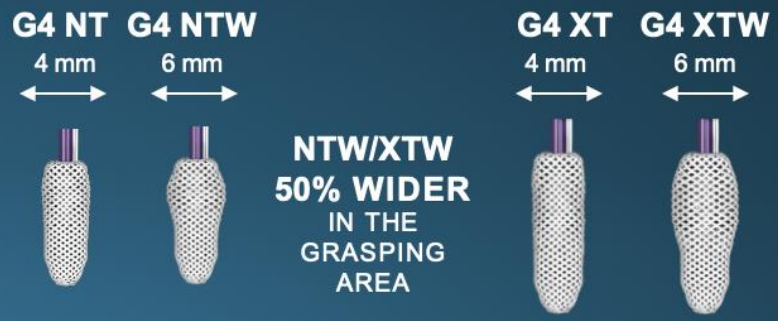
Anatomically designed for direct access to the valve

CONTROLLED GRIPPER ACTUATION

Ability to optimize leaflet grasping if needed

4 CLIP SIZES

Broad range of sizes for tailored treatment



TRILUMINATE™
PIVOTAL TRIAL

Study Enrollment Criteria

Key Inclusion Criteria

- Severe, symptomatic TR
- Stable GDMT and/or device therapy for heart failure for ≥ 30 days
- ≥ Intermediate risk of mortality/morbidity with tricuspid valve surgery

Key Exclusion Criteria

- Indication for other valve disease intervention
- Severe pulmonary HTN
- Left ventricular ejection fraction ≤20%
- Anatomy not suitable for TriClip therapy

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PIVOTAL TRIAL

Baseline Characteristics

	Device N=175 # (%)	Control N=175 # (%)
Age, Mean (years)	78.0 ± 7.4	77.8 ± 7.2
Sex (Female)	98 (56.0)	94 (53.7)
NYHA class III or IV	104 (59.4)	97 (55.4)
KCCQ Score, mean	56.0 ± 23.4	54.1 ± 24.2
Hypertension	142 (81.1)	141 (80.6)
Renal disease	62 (35.4)	62 (35.4)
Liver disease	11 (6.3)	16 (9.1)
Atrial fibrillation	153 (87.4)	162 (92.6)
Diabetes	28 (16.0)	27 (15.4)
COPD	19 (10.9)	24 (13.7)
CRT/CRT-D/ICD/PPM	28 (16.0)	24 (13.7)
Prior aortic intervention	27 (15.4)	27 (15.4)
Prior mitral intervention	45 (25.7)	42 (24.0)
Prior tricuspid intervention	1 (0.6)	0 (0.0)

	Device N=175 # (%)	Control N=175 # (%)
TR Severity		
Moderate	4 (2.3)	2 (1.2)
Severe	44 (25.4)	49 (29.7)
Massive	37 (21.4)	30 (18.2)
Torrential	88 (50.9)	84 (50.9)
Etiology (functional)	165 (94.8)	158 (92.9)
Coaptation Gap, Mean (mm)	5.5 ± 1.8	5.2 ± 1.7
Heart size/function, Mean		
RVEDD (base, cm)	5.0 ± 0.8	5.2 ± 0.8
TV annulus diameter (cm)	4.3 ± 0.7	4.5 ± 0.8
RV TAPSE (cm)	1.7 ± 0.4	1.6 ± 0.4
LVEF (%)	59.3 ± 9.3	58.7 ± 10.5
CO (L/min)	4.1 ± 1.2	4.2 ± 1.1

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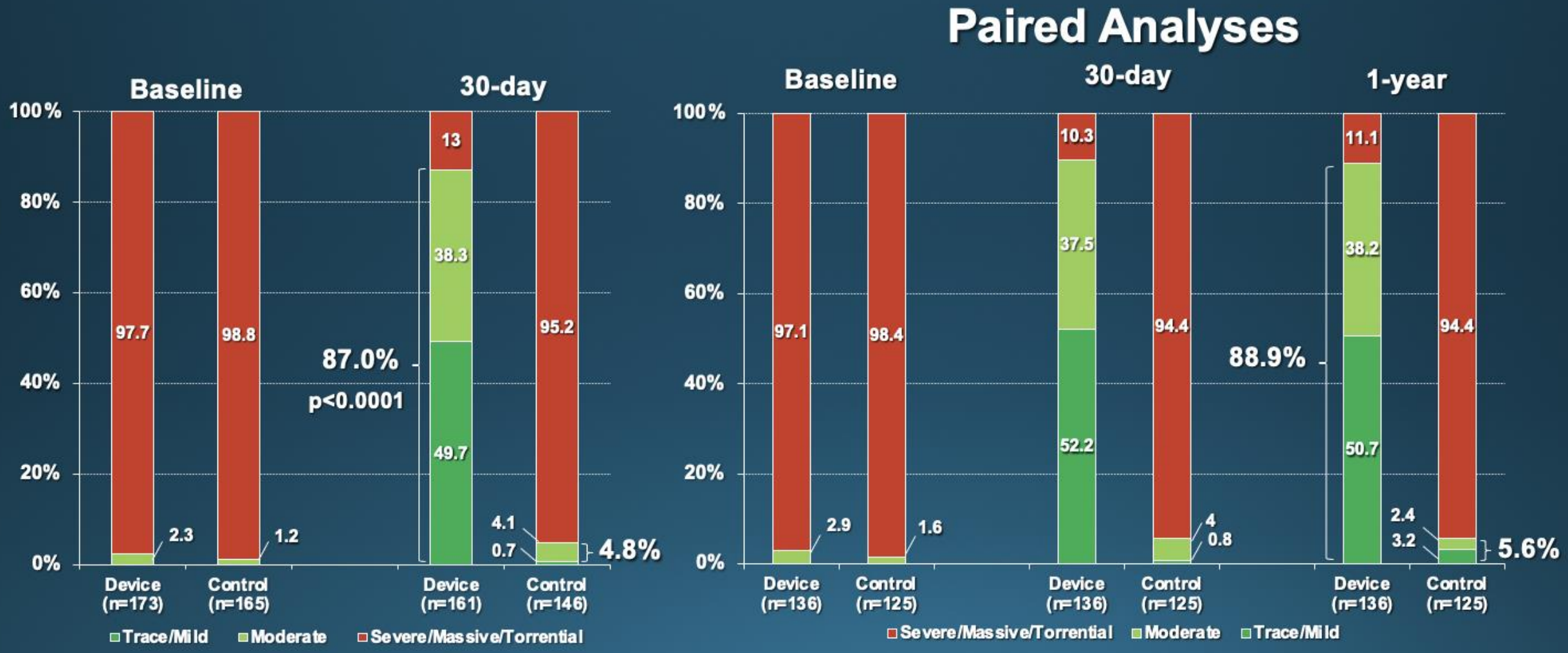
Reduction in TR Severity



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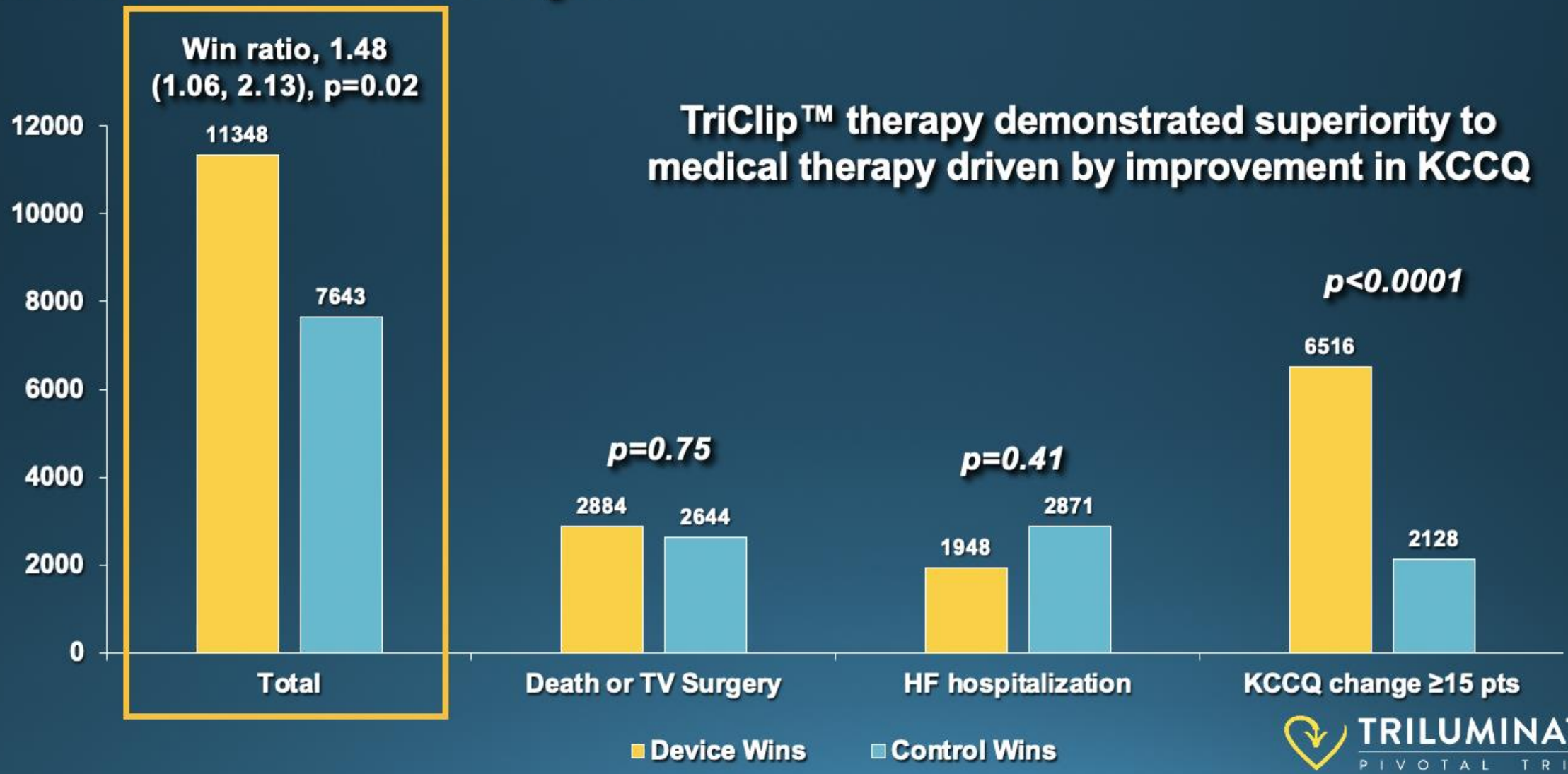
Primary Endpoint

Finkelstein-Schoenfeld Analysis



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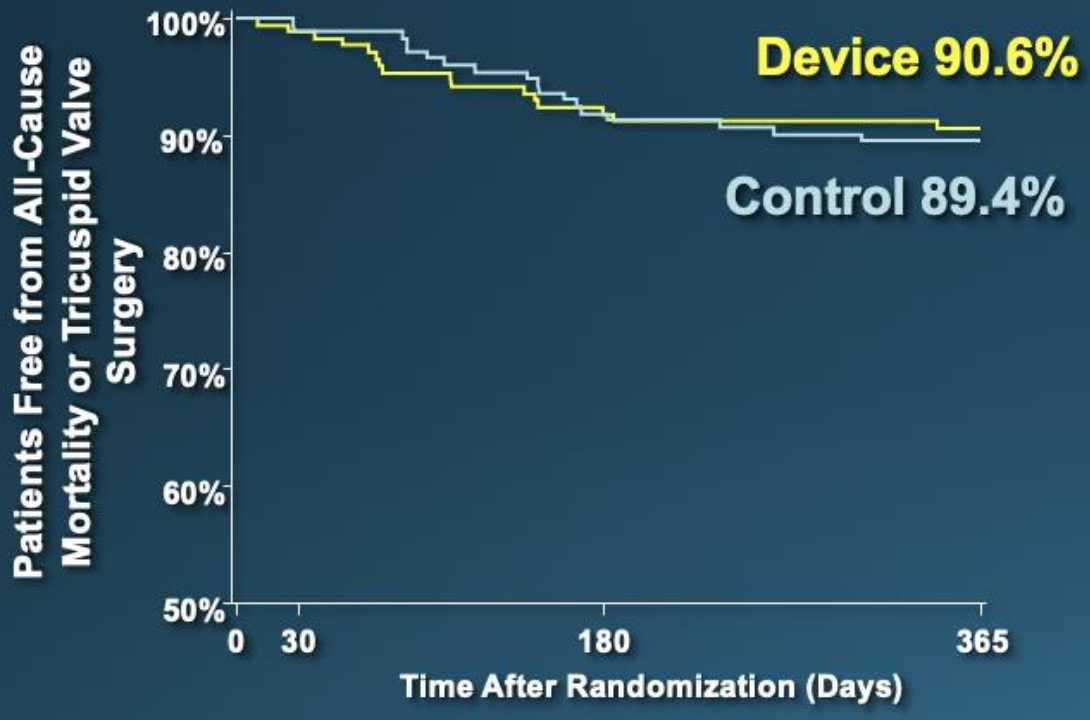
Individual Component Analysis

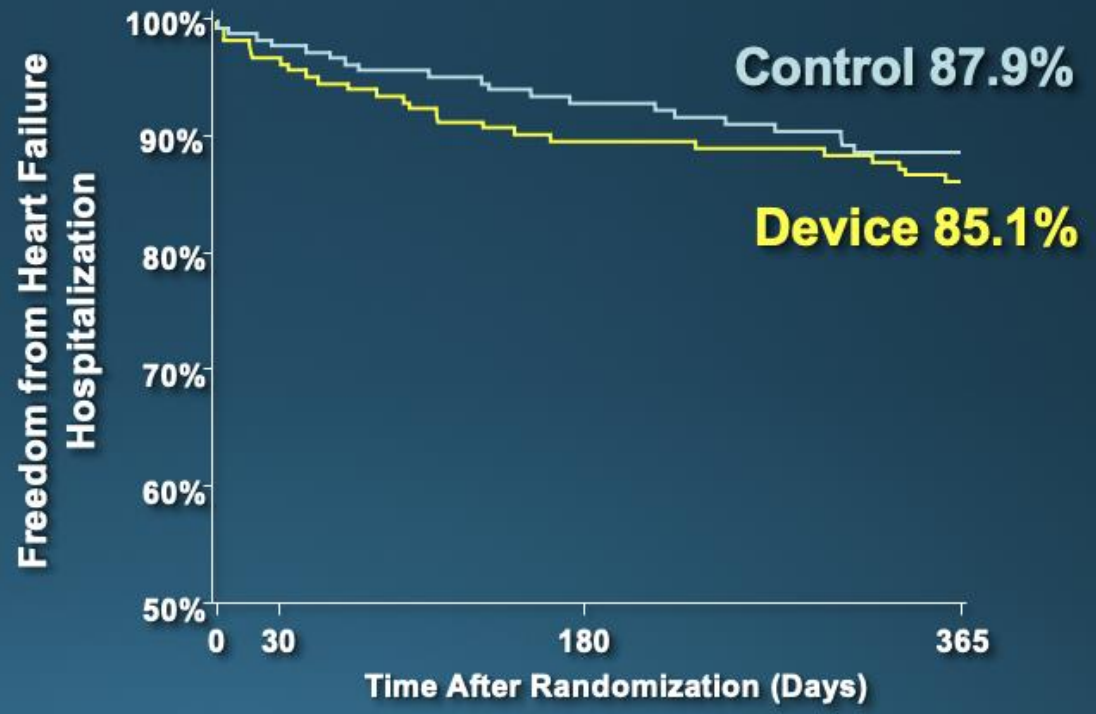
1st Component: Mortality or TV Surgery

p=0.75



2nd Component: Heart Failure Hospitalization

p=0.41



TRILUMINATE™ PIVOTAL TRIAL

Safety Profile

Major Adverse Event (MAE) Through 30 Days Post-Procedure – no.(%)	Device N=172†
Total	**3 (1.7%)**
Cardiovascular mortality	1 (0.6%)
Endocarditis requiring surgery	0 (0%)
New-onset renal failure	2 (1.2%)
Non-elective CV Surgery, TVRS for device-related AE	0 (0%)

Other Clinical Safety Endpoints Through 30 Days Post-Procedure– no.(%)	Device N=172†
Any-cause mortality	1 (0.6%)
Tricuspid valve surgery	1 (0.6%)
Tricuspid valve re-intervention	3 (1.7%)
Major bleeding#	8 (4.7%)
Tricuspid mean gradient ≥ 5mmHg	8 (4.7%)
Single leaflet device attachment (SLDA)*	12 (7.0%)
Stroke	1 (0.6%)
Myocardial Infarction	0 (0%)
Embolization*	0 (0%)
Thrombosis	0 (0%)
New CRT/CRT-D/ICD/perm. pacemaker^	1 (0.6%)

†Attempted procedure population (3 subjects randomized to Device withdrew consent prior to index procedure)
#Defined as bleeding ≥ Type 3 based on a modified Bleeding Academic Research Consortium (BARC) definition
*SLDA and embolization evaluated through 30-day follow-up
^Assessed through adverse event reporting

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Summary

- TR was reduced by TriClip therapy to moderate or less in 87%, vs. only 4.8% for the control group, and reduction was sustained to 1-year follow-up
- The primary endpoint was met (p=0.02) demonstrating device superiority, driven mainly by significant improvement in QOL
- Degree of TR reduction was related to degree of improvement in QOL
- The 30-day MAE rate was only 1.7%, and death and pacemaker implant each occurred in 0.6%
- Survival free of mortality and TV surgery was high at 1 year in both groups (~90%)

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PIVOTAL TRIAL

TRISCEND II Pivotal (n=820)

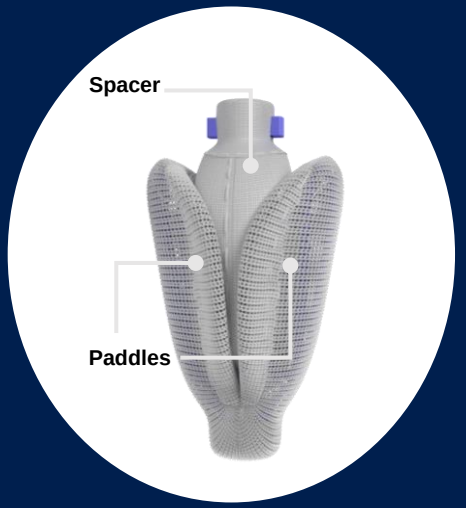
Randomization vs. medical therapy and single arm registry

6-mo outcome: TR reduction, NYHA, KCCQ, 6MWD

1-yr outcome: mortality, HF hospitalization, RVAD/tx, TV intervention, NYHA KCCQ, 6MWD

CLASP TR Pivotal (n=825)

Randomization vs. medical therapy



2-yr outcome: mortality, HF hospitalization, RVAD/tx, TV intervention, NYHA KCCQ, 6MWD

Intrepid Case

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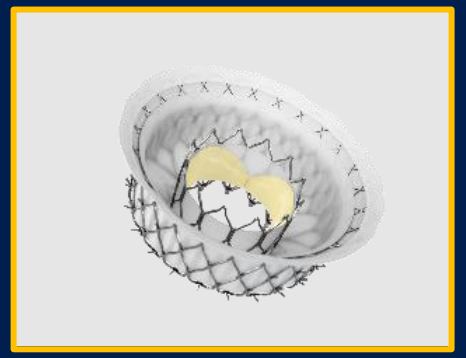
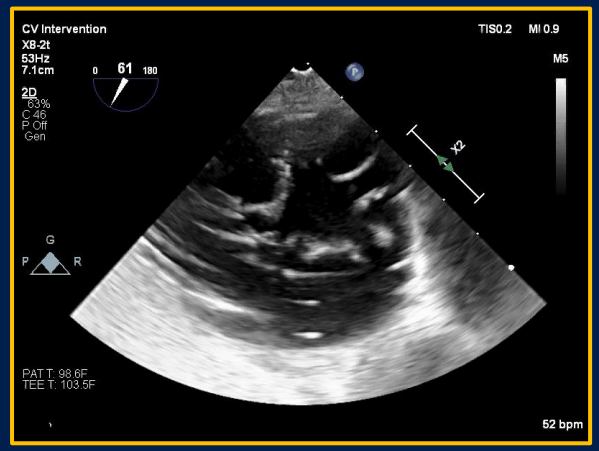
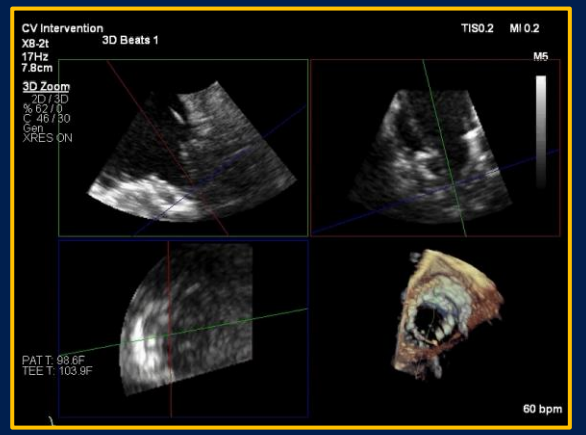






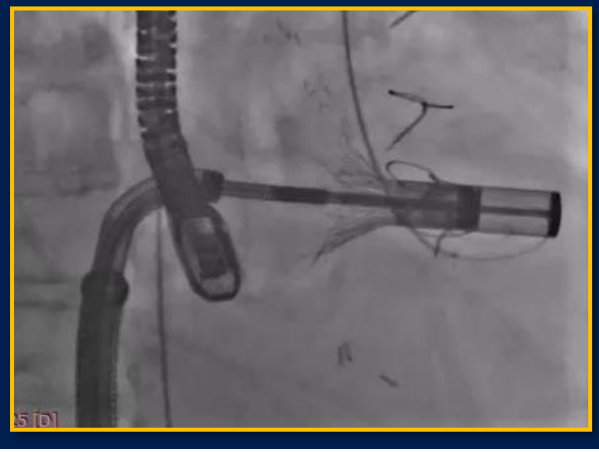
Conformable outer frame, 42-48 mm

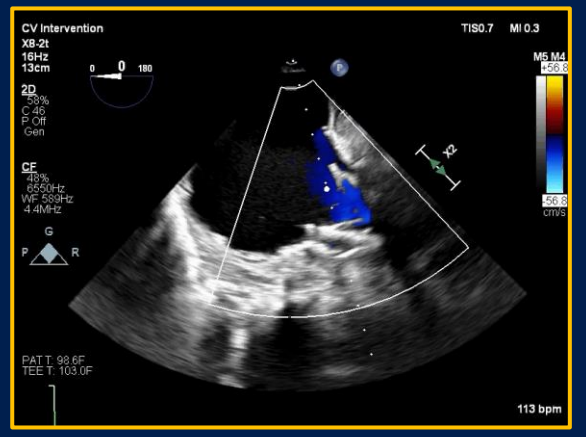
Houses 27 mm valve

35 Fr venous system

No need for rotational alignment

15 patients in EFS





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VDyne Case

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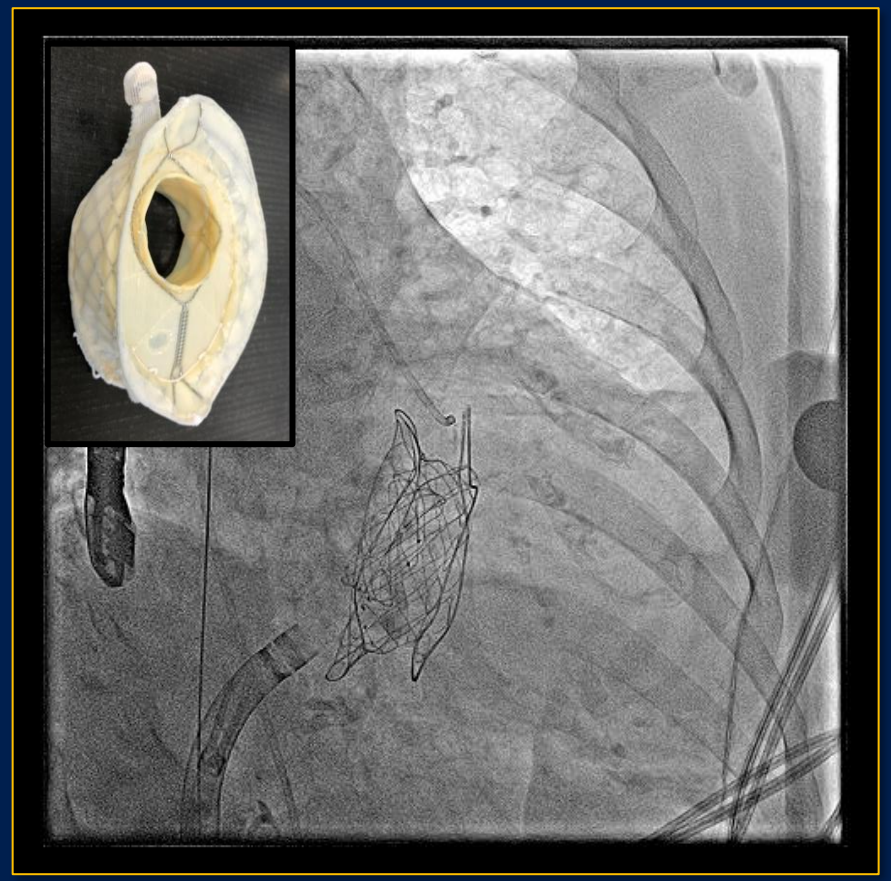

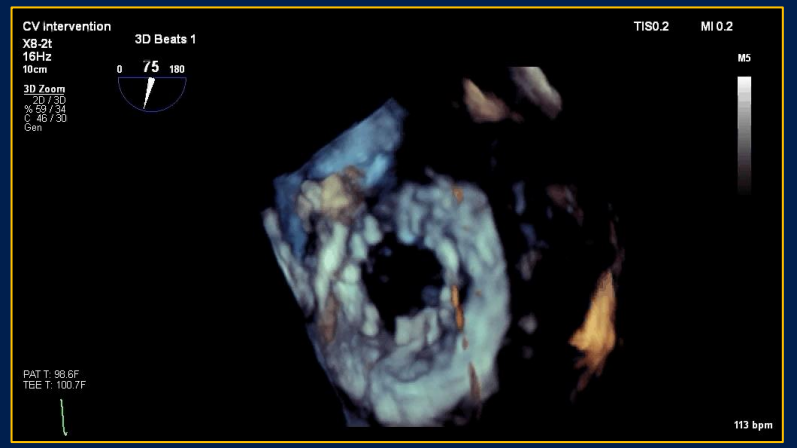

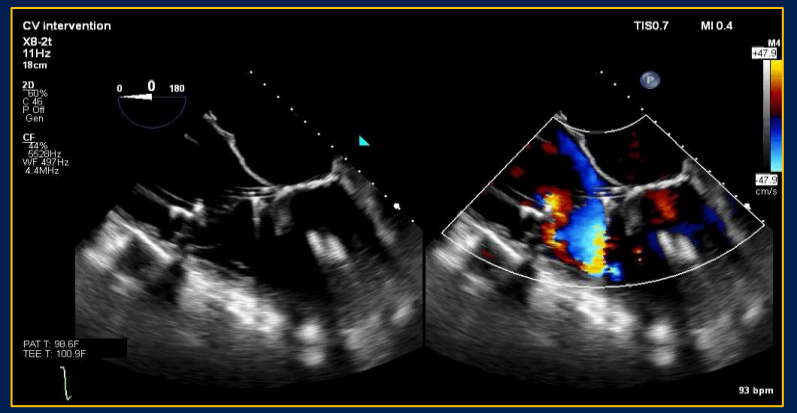

Fits non-circular shape of RV

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Some gaps or questions in percutaneous TR therapy

1) Diagnostic and therapeutic imaging expertise is limited, even in experienced centers
2) What is acceptable procedural risk threshold? Does it vary by procedure?
3) No standard definitions for GDMT, work-up needed
4) No consensus on anatomy for repair vs. replacement, single arm vs. RCT

Some gaps or questions in percutaneous TR therapy

5) Therapeutic goal remains undefined – is QOL enough? What about end-organ criteria?

6) How does one articulate a win ratio to a less informed person?

7) Is there logic in sequential therapy for VHD (e.g, MR + TR)?

8) Is there logic in sequential therapy for tools (e.g., ring + TEER)