

Severe Aortic Stenosis: Lifetime Management

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From inoperable patients to low-risk and asymptomatic disease — choosing the first valve with the next intervention in mind.



The question has changed

THEN

Can we replace the valve safely in a patient who cannot tolerate surgery?

NOW

Which intervention gives this patient the best outcomes over the next 10–25 years?

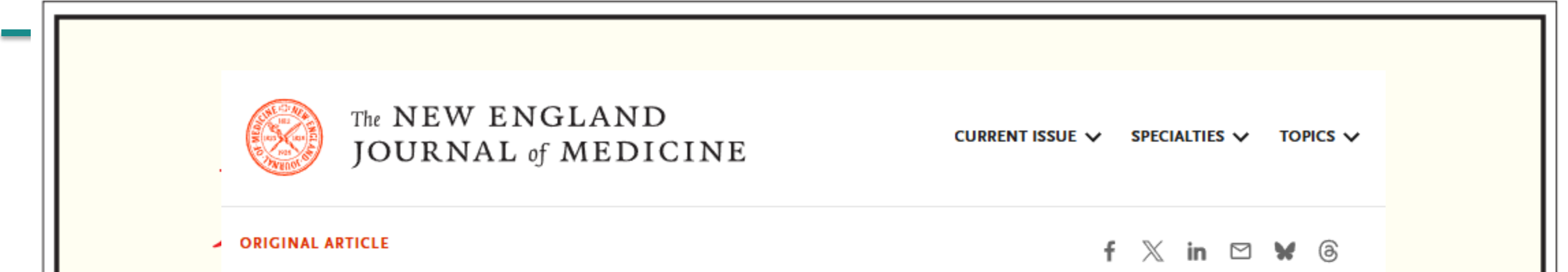
NEXT

Will today's choice preserve coronary access and feasible options for valve failure?

Core thesis: the index procedure is the first move in a lifetime treatment sequence—not the whole strategy.

Balance early procedural outcomes against durability, reintervention complexity, coronary access, and patient goals.

TAVR: from rescue therapy to a broad treatment option



CONCLUSIONS Transcatheter Aortic-Valve Replacement for

Among patients with Asymptomatic Severe Aortic Stenosis

the rate of

CONCLUSIONS

ntly

R 3

(Among patients with asymptomatic severe aortic stenosis, a strategy of early TAVR was superior to clinical surveillance in reducing the incidence of death, stroke, or unplanned hospitalization for cardiovascular causes. (Funded by Edwards Lifesciences; EARLY TAVR ClinicalTrials.gov number, [NCT03042104](#).)

Teaching point: the evidence base grew across risk strata; the lifetime evidence base remains shorter than a young patient's expected lifespan.

The Wall Street Journal Just Published a Warning About the Most Popular Heart Procedure in America

Cardiologists, heart surgeons sound alarm over widespread use of TAVR in low-risk patients

TAVR — transcatheter aortic valve replacement — has become the most popular heart procedure in America. But thousands of patients are now questioning the procedure's safety, and some are demanding honest answers to. H

[Michael Walter](#) | [October 03, 2025](#) | [Cardiovascular Business](#) | [TAVR](#)



Heart Health HQ

May 2, 2026 • 9 min r



find their new valves don't work as well or last as long as they hoped

The media critique: what should clinicians take seriously?

“A Breakthrough Heart Procedure Comes With Risky Tradeoffs”

The Wall Street Journal | April 2026 | reporting on TAVR failure, explant, and uncertainty in younger patients

VALID QUESTIONS

- No randomized 20–30-year TAVR follow-up
- TAVR explant can be complex and high risk
- Serial valve-in-valve can compromise future options
- Short recovery is not the only lifetime outcome

WHAT THE HEADLINE CANNOT PROVE

- A case report is not comparative effectiveness evidence
- Seven-year randomized data now exist; ten-year data exist in smaller cohorts
- SAVR also has failure modes and reintervention risk
- Selection should be patient-specific—not ideological

The question is not whether TAVR works; it is whether our first choice preserves the best next choices.



ORIGINAL ARTICLE



Transcatheter or Surgical Aortic-Valve Replacement in Low-Risk Patients at 7 Years

Authors: Martin B. Leon, M.D., Michael J. Mack, M.D., Philippe Pibarot, D.V.M., Ph.D., Rebecca T. Hahn, M.D. , Vinod H. Thourani, M.D., S.H. Kodali, M.D., Philippe G  n  reux, M.D., , for the PARTNER 3 Investigators* [Author Info & Affiliations](#)

Published October 27, 2025 | N Engl J Med 2026;394:773-783 | DOI: 10.1056/NEJMoa2509766 | [VOL. 394 NO. 8](#)

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CONCLUSIONS

Among low-risk patients with severe, symptomatic aortic stenosis, no significant differences with respect to two primary composite end points involving death, stroke, and rehospitalization were observed at 7 years between those who had undergone TAVR and those who had undergone surgery. (Funded by Edwards Lifesciences; PARTNER 3 ClinicalTrials.gov number, [NCT02675114](#).)

Low-risk trials: the trade-off is more than mortality

TAVR TENDS TO OFFER

- Faster early recovery
- Shorter hospital stay
- Less bleeding and new AF in many comparisons
- Avoids sternotomy

SAVR TENDS TO OFFER

- Lower paravalvular leak
- Lower pacemaker risk in many comparisons
- Established surgical options for concomitant disease
- Mechanical valve option

BOTH REQUIRE CONTEXT

- Anatomy and vascular access
- Coronary disease / CABG needs
- Bicuspid valve and aortopathy
- Expected longevity and future reintervention

PARTNER 3 at 7 years: low and similar rates of SVD, bioprosthetic valve failure, and reintervention in the trial analysis—reassuring mid-term evidence, not proof of 20-year equivalence.

Trial populations were selected; results should not be extrapolated uncritically to patients in their 50s or to every valve platform.

ACC/AHA: how to choose SAVR versus TAVR

For severe AS when AVR is indicated and a bioprosthesis is appropriate:

AGE <65 OR LIFE EXPECTANCY >20 Y

SAVR recommended (Class I, LOE A).
Durability and lifetime management carry greater weight.

AGE 65–80 Y

Symptomatic, transfemoral anatomy suitable: SAVR or TAVR after shared decision-making (Class I, LOE A).

AGE >80 OR LIFE EXPECTANCY <10 Y

Transfemoral TAVR preferred if anatomy suitable (Class I, LOE A).

HIGH / PROHIBITIVE SURGICAL RISK

TAVR favored for symptomatic patients if expected survival >12 months with acceptable quality of life.

IMPORTANT LIMITATION

Age cutoffs are decision aids, not substitutes for anatomy, comorbidity, patient goals, or Heart Team judgment.

Source: 2020 ACC/AHA VHD guideline.

Asymptomatic severe AS: the threshold is moving

Up to 40% of patients with severe AS do not report symptoms at the time of diagnosis.

In roughly one-third of these, exercise testing can uncover symptoms or reduced exercise capacity attributable to AS, and such patients should be treated as symptomatic.

Exercise testing is not always feasible because of frailty or impaired mobility.

For patients with severe high-gradient AS and no adverse prognostic features, close active clinical surveillance, so-called 'watchful waiting', has previously been the default management strategy.

four RCTs comparing early AV intervention with clinical surveillance suggest that early intervention should be considered as an alternative in patients at low procedural risk.

The early intervention approach is reinforced if additional adverse prognostic features (very high $V_{\max}$, elevated natriuretic peptides, severe valve calcification, rapid $V_{\max}$ progression, or LVEF of <55%) are present.

Asymptomatic severe AS: the threshold is moving

EARLY TAVR

randomized 901 patients to early TAVI or clinical surveillance and demonstrated a reduction of 50% in the primary composite endpoint of all-cause mortality, stroke, or unplanned hospitalization for cardiovascular causes associated with pre-emptive intervention

The result was driven by 26.2% of the patients in the clinical surveillance group who converted to TAVI within 6 months of randomization due to the development of symptoms or adverse prognostic factors.

There was no significant difference in strokes and all-cause mortality over 5-year follow-up.

Positive trials

RECOVERY TRIAL

AVATAR

Negative Trial

EVolveED

Metanalysis of 4

A meta-analysis of the four RCTs showed that early intervention is associated with a significant reduction in unplanned cardiovascular or HF hospitalization and stroke, but not all-cause or cardiovascular mortality.

Limitations of this analysis include the heterogeneity of the pooled trials and lack of granularity with respect to specific events owing to the study-level analysis

Asymptomatic severe AS: the threshold is moving

EARLY TAVR

Randomized evidence supports early TAVR over surveillance for selected asymptomatic severe AS; the primary composite was reduced.

ACC/AHA 2020

Routine TAVR for every asymptomatic patient is not the guideline message. If intervention is triggered by a Class IIa feature, SAVR is preferred in the 2020 framework.

CLINICAL DISCUSSION

Confirm severity; assess exercise response, LV function, velocity progression, BNP, CT calcium, procedural risk, and patient preferences.

Do not collapse these into one question:

1. WHEN to intervene?

Surveillance vs early AVR

2. HOW to intervene?

SAVR vs TAVR based on lifetime strategy

CMS finalized a revised national coverage policy in Sep 2026. The new Policy does not automatically establish routine clinical TAVR as the standard for asymptomatic AS.

Durability: what do we know—and what do we not know?

Valve Academic Research Consortium 3 (VARC-3)

Bioprosthetic valve Dysfunction (BVD): Broader dysfunction: SVD, thrombosis, endocarditis, or nonstructural dysfunction.

Structural Valve Deterioration (SVD): Intrinsic valve changes (calcification, leaflet tear, wear).

Non-Structural Valve Dysfunction (NSVD): Prothesis-related issues not caused by leaflet decay (e.g., patient-prosthesis mismatch, paravalvular leak, malposition).

Bioprosthetic Valve Failure (BVF): Clinically consequential failure, such as valve-related death, reintervention, or severe hemodynamic dysfunction.

Thrombosis (HALT / RLM): Hypo-attenuated leaflet thickening (HALT) and reduced leaflet motion (RLM) assessed via imaging alongside clinical sequelae.

Durability: what do we know—and what do we not know?

NOTION | 10 YEARS

Small randomized trial 280; corevalve 145, SAVR 135, mean age ~79. The primary composite outcome was the risk of all-cause mortality, stroke, or myocardial infarction.

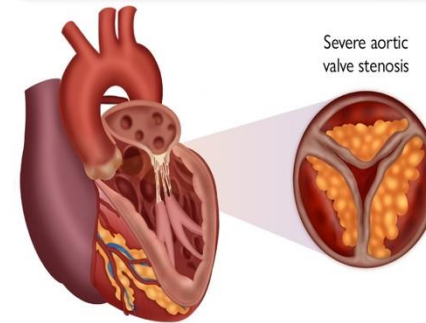
Severe SVD was defined as (i) a transprosthetic gradient of 30 mmHg or more and an increase in transprosthetic gradient of 20 mmHg or more or (ii) severe new intraprosthetic regurgitation.

Bioprosthetic valve failure (BVF) was defined as the composite rate of death from a valve-related cause or an unexplained death following the diagnosis of BVD, aortic valve re-intervention, or severe SVD.

Severe SVD was reported less often after **TAVR 1.5%** than **SAVR 10%**, while BVF did not differ significantly.

Early-generation valve and elderly cohort limit extrapolation.

Severe aortic valve stenosis:
mean age 79 years; 80% with low mortality risk



280 patients in nordic region

Randomized 1:1 in 2009-2013

145 TAVI

self-expanding
bioprosthesis



135 SAVR

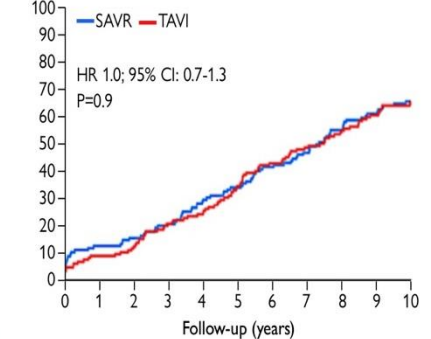
any type of
bioprosthesis



10-year follow-up

Primary composite outcome

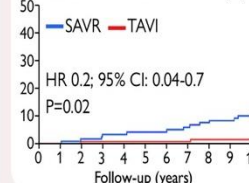
All-cause mortality, stroke or MI (%)



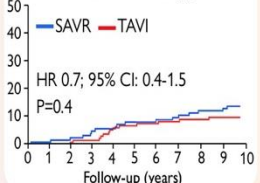
Severe structural valve
deterioration
(modified VARC-3 criteria)

Bioprosthetic valve failure
(modified VARC-3 criteria)

Severe SVD Cumulative Incidence (%)



BVF Cumulative incidence (%)

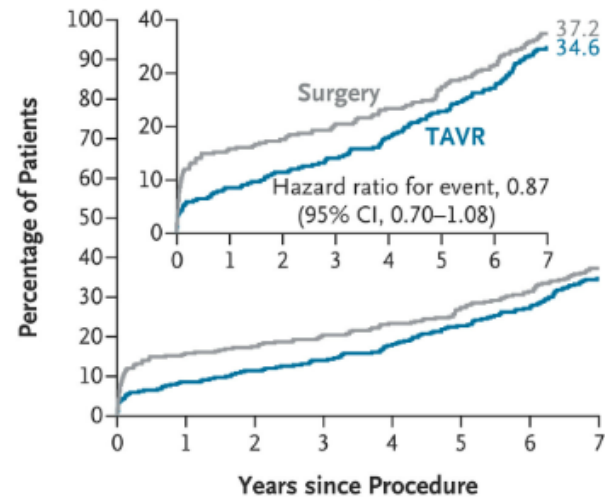


Durability: what do we know—and what do we not know?

PARTNER 3 | 7 YEARS

Low-risk randomized cohort; SVD, BVF, and reintervention rates were low and similar for SAPIEN 3 TAVR vs surgery at 7 years.

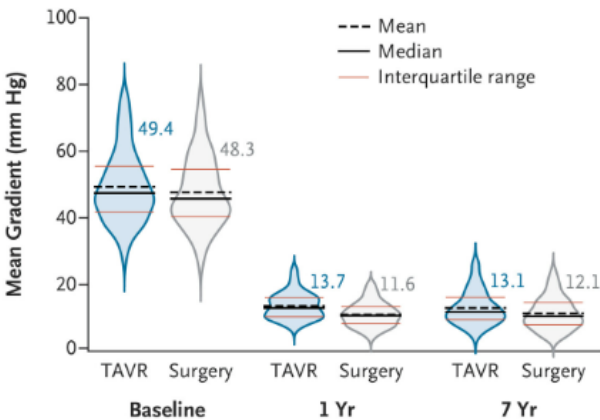
A Death from Any Cause, Stroke, or Rehospitalization



No. at Risk

TAVR	496	453	435	418	394	366	333	288
Surgery	454	371	349	328	310	288	265	229

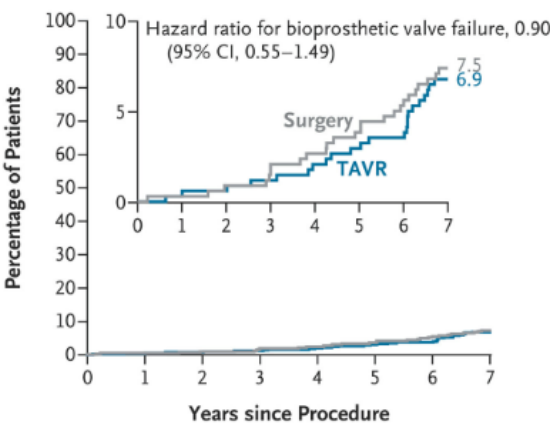
A Mean Aortic-Valve Gradient



No. of Echos

TAVR	483	473	287
Surgery	442	391	246

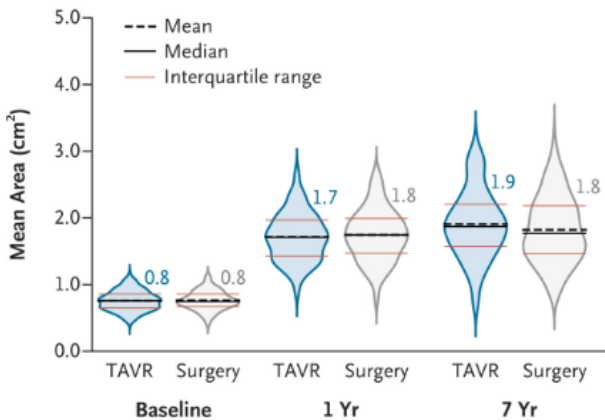
C Bioprosthetic Valve Failure



No. at Risk

TAVR	495	487	475	458	432	407	373	329
Surgery	453	426	407	390	372	348	327	288

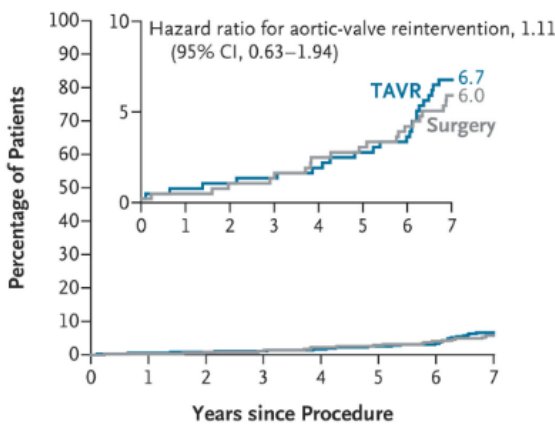
B Aortic-Valve Area



No. of Echos

TAVR	458	449	283
Surgery	424	371	241

D Aortic-Valve Reintervention



No. at Risk

TAVR	496	488	477	461	437	413	378	333
Surgery	454	426	407	391	373	352	332	294

The Index procedure is the first move not the final move, 4 questions before TAVI

1 | Valve longevity

What is the probability of structural deterioration over the patient's expected life span ?

2 | Coronary Access

Can we safely engage the coronaries after the proposed TAVI, including after a potential second valve?

3 | Reintervention feasibility

If the valve fails, is redo-TAVR anatomically feasible, or could it create severe PPM or coronary obstruction?

4 | Surgical option

Would SAVR now allow a mechanical valve, annular enlargement, treatment of concomitant disease or a better foundation for future interventions?

The first valve constrains the next intervention

DEVICE / IMPLANTATION

- Frame height and design
- Commissural alignment
- Implantation depth
- Leaflet position and neo-skirt

PATIENT ANATOMY

- Coronary heights and sinus dimensions
- STJ size and height
- Annulus / root dimensions
- Calcium distribution and access

FUTURE PROCEDURES

- Redo-TAVR feasibility
- Coronary obstruction / sinus sequestration
- Patient–prosthesis mismatch
- TAVR explant complexity

CT planning should answer: can the patient safely undergo the likely next procedure—and the one after that?

Do not optimize only for the first procedure; optimize the sequence.

Coronary access after TAVR is a lifetime issue

BEFORE TAVR

Assess coronary heights, sinus of Valsalva, STJ, annular dimensions, valve frame, commissural alignment, and likely future coronary engagement.

AFTER TAVR

Tall frames, displaced leaflets, commissural misalignment, and a narrow STJ can make selective coronary engagement more difficult—particularly after redo-TAVR.

PRACTICAL PLAN

Choose valve and implant strategy with future coronary access in mind; document commissural orientation and consider future PCI needs.

Coronary access is not a minor technical footnote: it can determine whether future PCI is straightforward, difficult, or occasionally impossible.

In patients with CAD, complex coronary anatomy, or long life expectancy, include anticipated future coronary intervention in the index Heart Team discussion.

When gradients rise: do not call every failure 'restenosis'

Thrombosis

Consider CT leaflet thickening / reduced motion; assess anticoagulation context.

Structural valve deterioration

Calcification, tear, permanent leaflet degeneration; serial echo and CT as indicated.

Endocarditis

Clinical suspicion, blood cultures, multimodality imaging; urgent specialist pathway.

Patient–prosthesis mismatch

High baseline gradients from the outset; indexed EOA and body size matter.

Nonstructural dysfunction

Paravalvular leak, malposition, frame underexpansion, pannus, or other mechanical issues.

Start with symptoms + serial TTE; escalate to TEE / gated CT / cultures as the suspected mechanism dictates.

Valve failure: choose the reintervention by mechanism and anatomy

REDO-TAVR

Potentially less invasive, but assess coronary obstruction, sinus sequestration, frame expansion, gradients, and PPM risk after a second valve.

SAVR / TAVR EXPLANT

May be necessary for endocarditis, unsuitable anatomy, severe PPM, or failed transcatheter strategies. Explant can be technically complex.

VALVE-IN-VALVE AFTER SAVR

Can be attractive for a failed surgical bioprosthesis, but small surgical valves can produce high residual gradients; initial valve size matters.

The best redo strategy is often determined by choices made during the index procedure.

an early referral to an experienced Heart Valve Centre for suspected prosthetic dysfunction; complex cases benefit from surgical and structural expertise together

A practical lifetime-management algorithm

1 | Confirm severe AS and indication for AVR

Symptoms, echo, flow state, exercise testing, CT calcium when needed

2 | Estimate longevity and procedural risk

Age, frailty, comorbidities, life expectancy, patient priorities

3 | Define anatomy and future constraints

CT: coronary access, root / STJ, annulus, bicuspid anatomy, access route

4 | Compare lifetime pathways

SAVR ± mechanical valve / enlargement / CABG vs TAVR ± redo feasibility

5 | Document the plan for the next intervention

Baseline echo, device / implant details, coronary strategy, follow-up plan

Three cases to test the lifetime strategy

CASE 1 | AGE 58

Symptomatic severe tricuspid AS; low STS risk; expected long survival.

Ask: What is gained by TAVR now—and what lifetime options might SAVR preserve?

CASE 2 | AGE 74

Asymptomatic severe AS; preserved EF; negative exercise test; anatomy suitable for transfemoral TAVR.

Ask: Should early intervention be considered? If yes, which modality and why?

CASE 3 | AGE 68

Low-risk severe AS; small annulus; low coronary heights; likely future PCI.

Ask: Which CT findings could change the decision? What is the plan for redo intervention?

The point is not one universal answer. The point is making the assumptions—and future constraints—explicit.

Choose the valve for the patient's lifetime—not just the hospital stay.

1. TAVR's expansion reflects strong evidence across risk strata; it does not erase the importance of patient selection.
2. Asymptomatic intervention is a separate question from TAVR-versus-SAVR selection.
3. Seven-year randomized and ten-year smaller-trial data are reassuring—but not a 20–30-year guarantee.
4. Plan for coronary access, valve failure, redo-TAVR, and explant before the index procedure.
5. For younger patients, the Heart Team should explicitly compare the full SAVR and TAVR sequences.

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- 2. Praz F, et al. 2025 ESC/EACTS Guidelines for the management of valvular heart disease. Eur Heart J. 2025;46:4635–4736. doi:10.1093/eurheartj/ehaf194.
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Links: ACC/AHA guideline: [jacc.org/doi/10.1016/j.jacc.2020.11.018](https://www.jacc.org/doi/10.1016/j.jacc.2020.11.018) | ESC/EACTS: academic.oup.com/eurheartj/article/46/44/4635/8234488

Tricuspid Valve Disease

Management and Latest Updates

Daniel Rothschild, MD, FACC, FSCAI

Structural and Interventional Cardiology

Norton Healthcare

Disclosures

- Edwards Lifesciences – Proctor
- Medtronic – Proctor

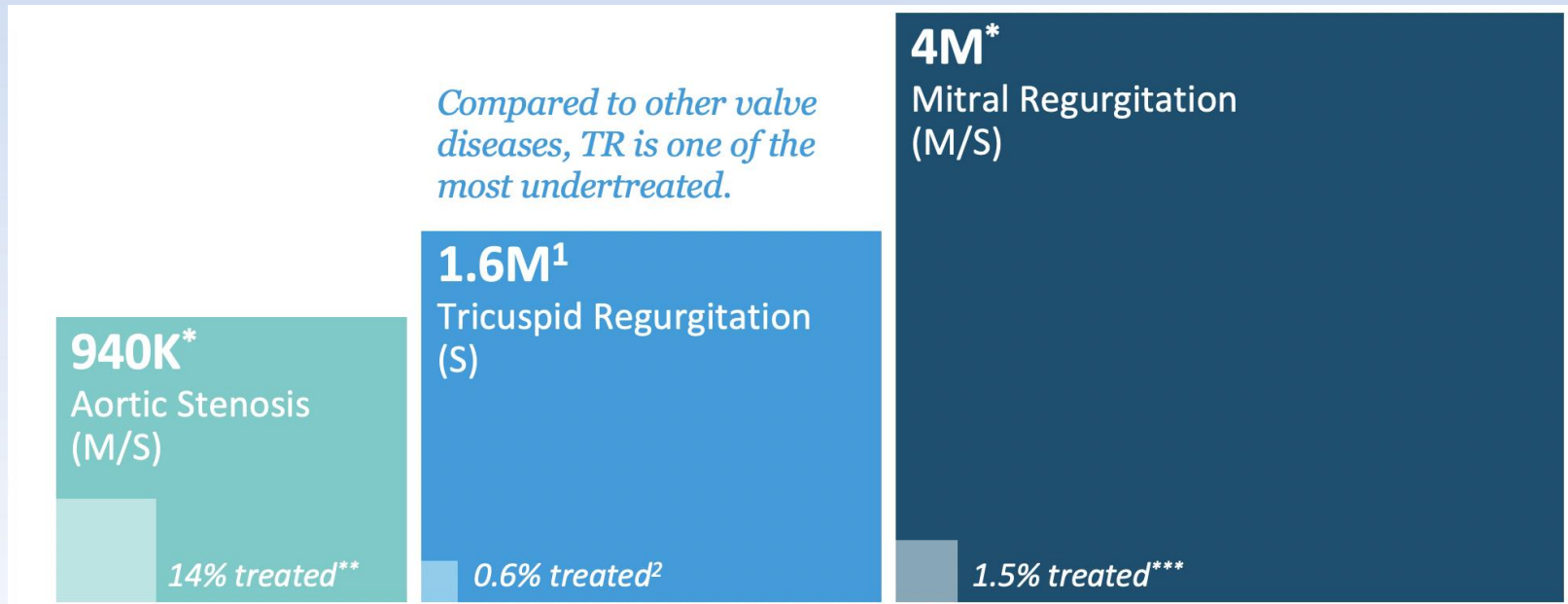
Summary

- Prevalence/Natural History
- Diagnostic Criteria
- Treatment strategies
 - Supporting evidence
- Case review

Prevalence/Natural History

Prevalence

- 1.6 million moderate or severe TR¹- 8000 surgeries performed annually (0.5%)²
 - ~1 million moderate or severe AS – 150,000 currently receive treatment (15%)



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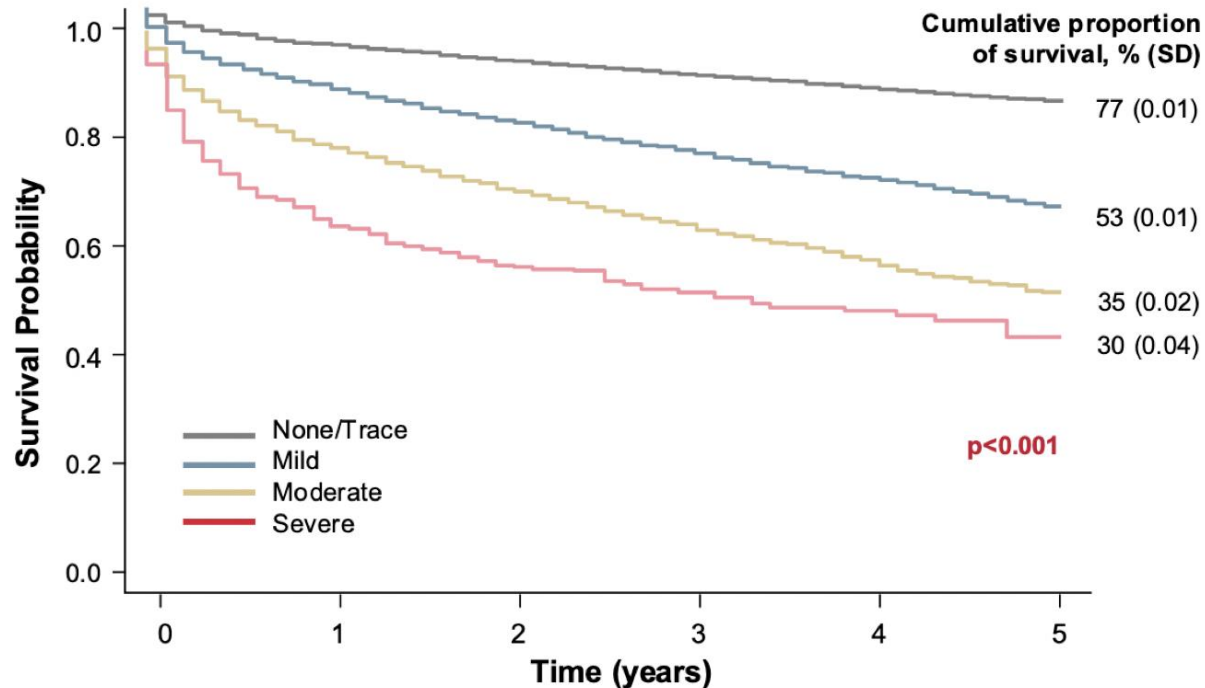
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3. J Am Coll Cardiol 2022 Mar 8;79(9):864-877

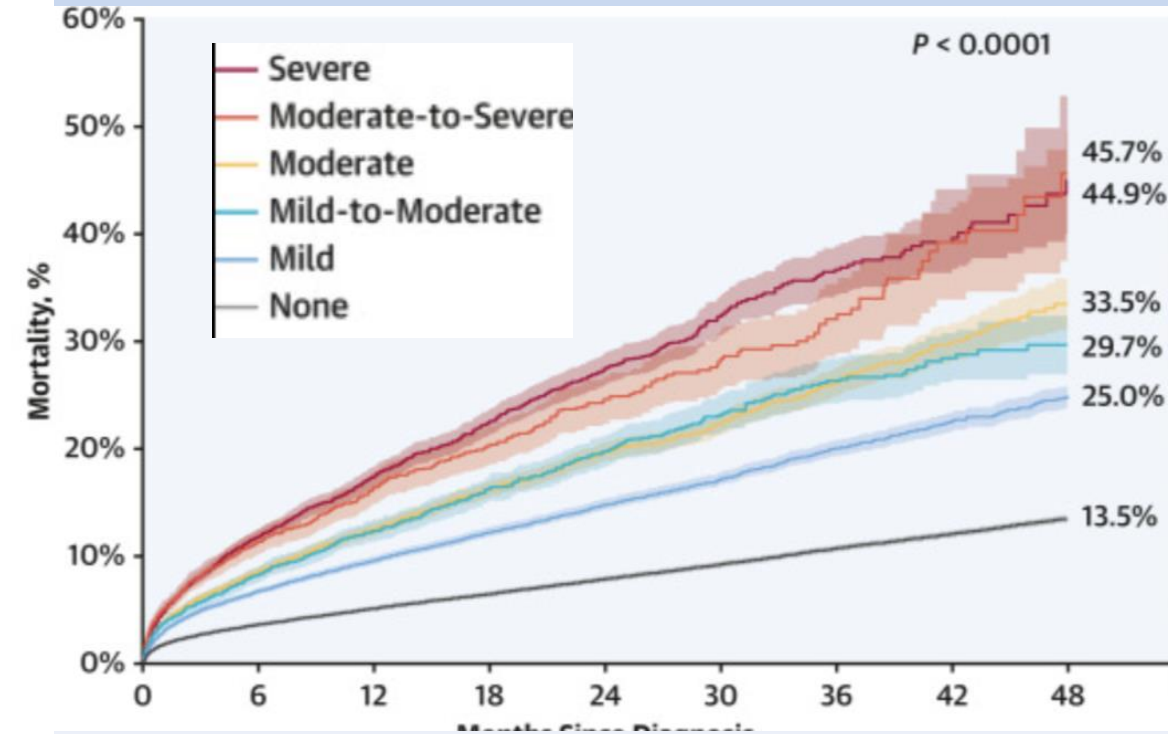
Natural History

Aortic stenosis mortality

Patients according to TR grade



Number at risk:	23045	20957	15985	11374	7138	2956
	7297	6000	4455	2970	1750	805
	2682	1867	1230	764	432	177
	281	52	101	65	42	14



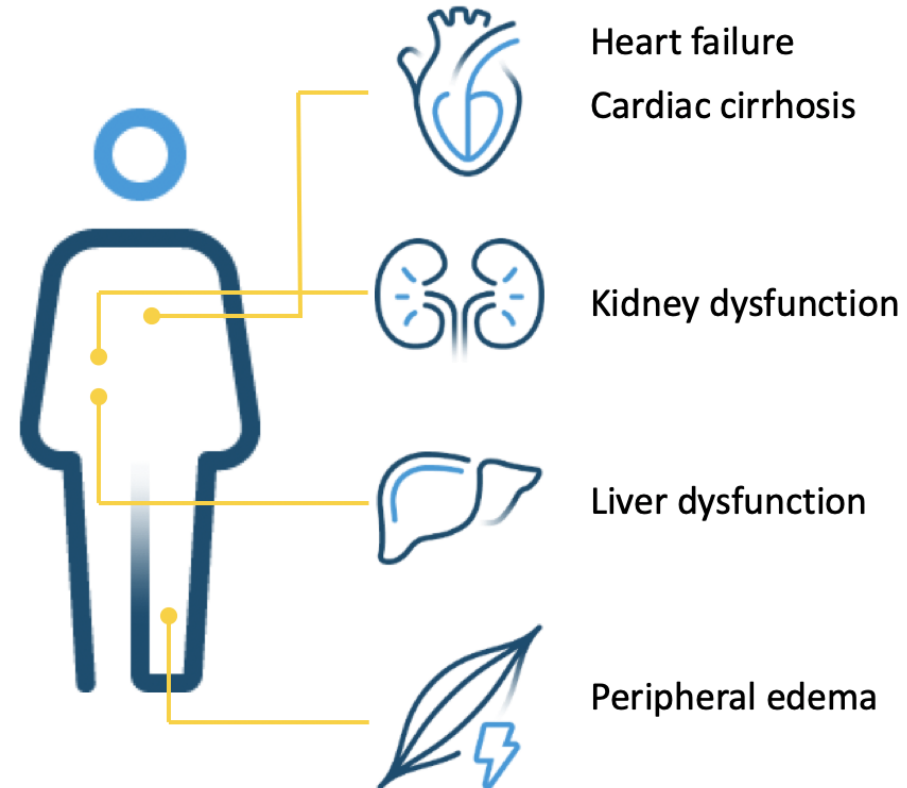
The Mortality Burden of Untreated Aortic Stenosis. J Am Coll Cardiol. November 28, 2023

Tricuspid Regurgitation Untreated

Symptoms of TR significantly impair quality of life (QoL)

SYMPTOMS INCLUDE:^{1,2}

- Shortness of breath
- Peripheral edema
- Ascites
- Fatigue
- Declining exercise capacity
- Discomfort after eating



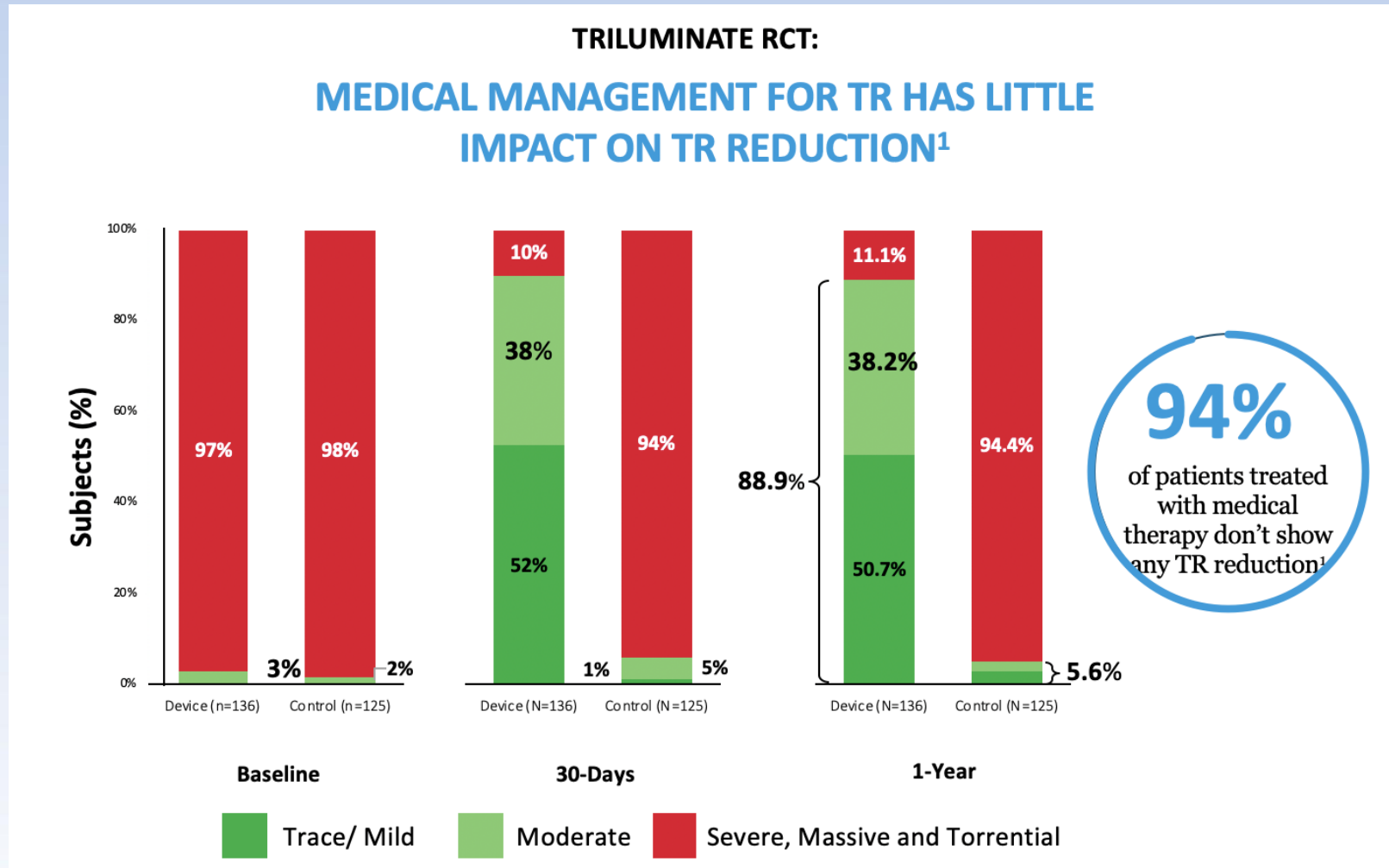
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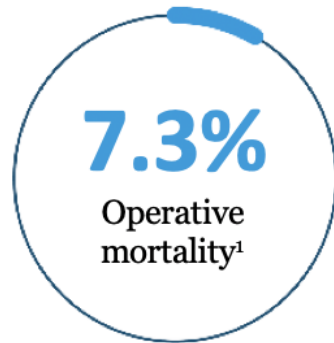
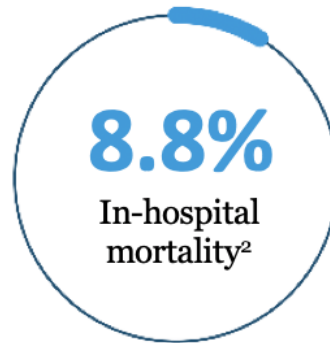
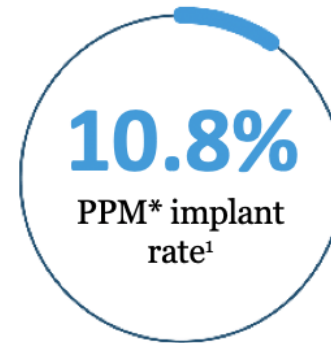
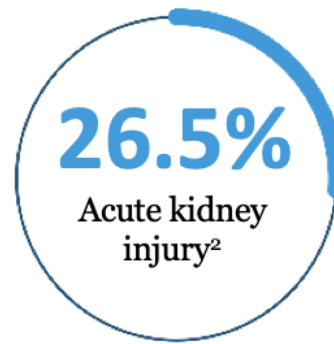
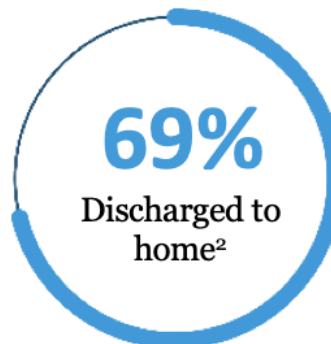
Medical Management



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Surgical Management

SURGERY FOR TR IS RARELY PERFORMED AND IS ASSOCIATED WITH HIGH IN-HOSPITAL AND OPERATIVE MORTALITY AND POST-PROCEDURE ADVERSE EVENTS^{1,2}



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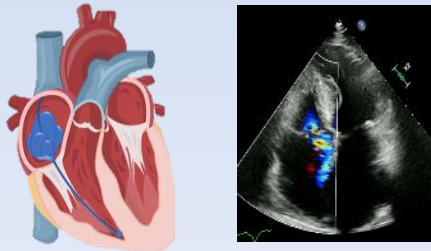
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Diagnostic Approach/Criteria

Complex condition with many causes^{1,2}

PRIMARY — ~5-10%

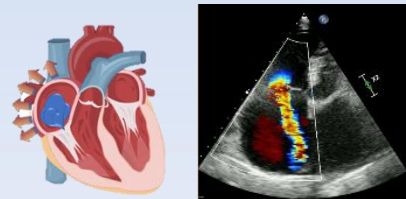
Lack of leaflet coaptation due to intrinsic changes leading to restricted or excessive leaflet mobility or leaflet perforation.



SECONDARY — ~80%

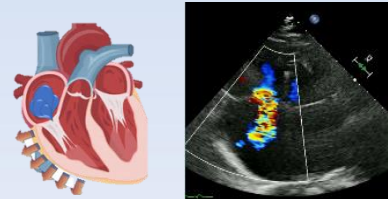
Atrial

Right Atrium (RA) enlargement and dysfunction leading to significant isolated annular dilation; RV often normal.



Ventricular

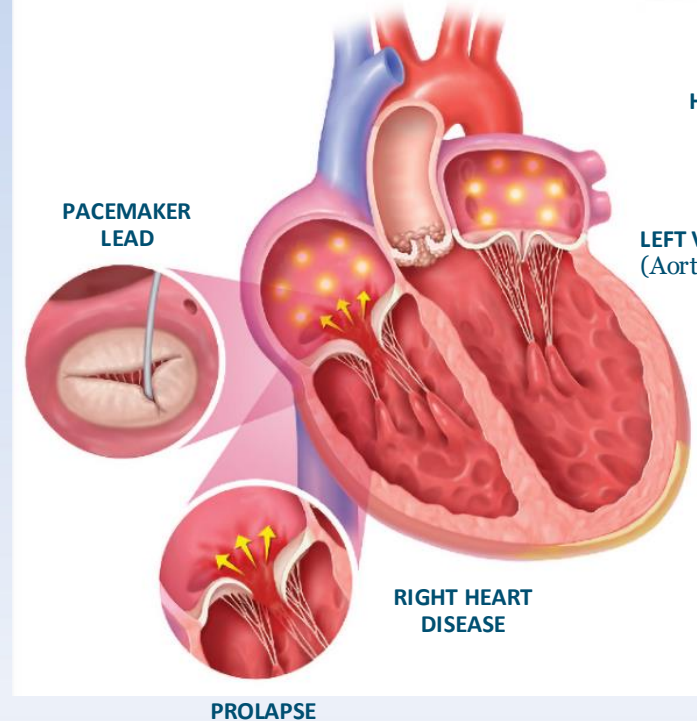
Right Ventricle (RV) enlargement and dysfunction leading to significant leaflet tethering and annular dilation.



CARDIAC IMPLANTABLE ELECTRONIC DEVICE (CIED) RELATED — ~10-15%

- **Causative:** Leaflet impingement, perforation, valvular/subvalvular adhesion restriction due to Pacemaker Implantable cardiac defibrillator (ICD) Cardiac resynchronization therapy (CRT) devices
- **Incidental:** Cardiac implantable electronic devices (CIED) present without tricuspid valve apparatus interference

PRIMARY



SECONDARY

Functional

PULMONARY HYPERTENSION

ATRIAL FIBRILLATION

LEFT VALVE DISEASE (Aortic and Mitral)

LEFT HEART DISEASE

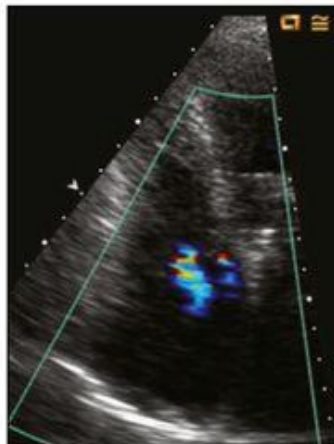
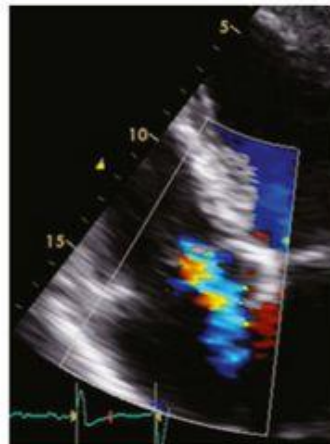
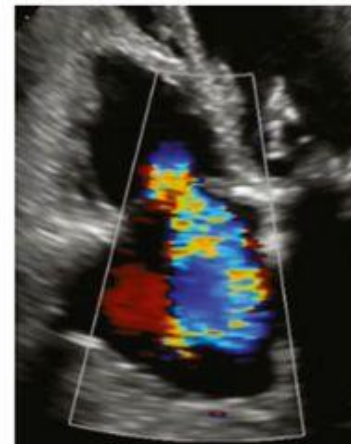
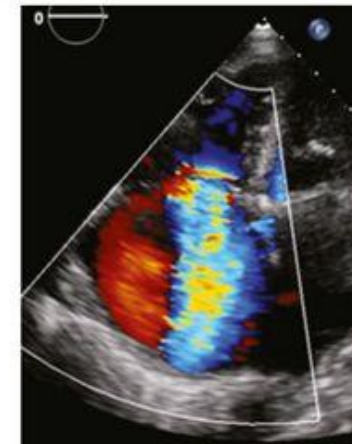
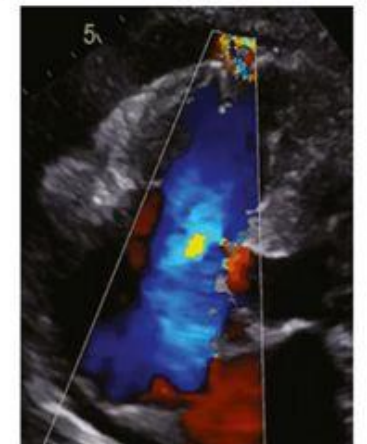
1. Hahn RT, Lawlor MK, Davidson CJ, et al. Tricuspid valve academic research consortium definitions for tricuspid regurgitation and trial endpoints. *Eur Heart J*. 2023;44(43):4508-4532. doi:10.1093/eurheartj/ehad653

2. Praz F, Muraru D, Kreidel F, et al. Transcatheter treatment for tricuspid valve disease. *EuroIntervention*. 2021;17(10):791-808. doi:10.4244/EIJ-D-21-00695

Grading of TR: Extended Grading Scheme to 5+

Parameters	MILD	MODERATE	SEVERE	MASSIVE	TORRENTIAL
Vena Contracta width (biplane average)	<3 mm	3-6.9 mm	7 mm - 13 mm	14-20 mm	≥21 mm
EROA by PISA	<20 mm ²	20-39 mm ²	40-59 mm ²	60-79 mm ²	≥80 mm ²
3D Vena Contracta Area or Quantitative Doppler EROA	-	-	75-94 mm ²	95-114 mm ²	≥115 mm ²

Example:



Which Patient



- Symptomatic severe Tricuspid regurgitation (TR) (3+ or greater)
- Anatomically suitable functional or primary TR
- Normal or mild RV dysfunction
- Mild to moderate pulmonary hypertension/pulmonary vascular disease
- Treated or controlled left-sided heart disease (valvular/coronary/ myocardial)
- On appropriate guideline directed medical therapy



- Asymptomatic, or mild or moderate TR
- Anatomically not suitable (e.g. rheumatic, complex anatomy)
- Severe RV dysfunction
- Severe pulmonary hypertension/pulmonary vascular disease
- Untreated left-sided heart disease.
- Not on appropriate guideline directed medical therapy

Pulmonary Hemodynamics

Precautions for Tricuspid valve intervention:

- Systolic PA pressure > 70 mm Hg
 - Fixed pulmonary vascular resistance ≥ 5 wood units ($[\text{PA mean} - \text{PCW}]/\text{CO}$)
- Deferred
 - PCW ≥ 25 mm Hg, Pt needs to be further optimized with GDMT and diuretics
- Other considerations for procedural selection:
 - TAPSE <10
 - TASPE/PASP ratio (“RV-PA coupling”)

Treatment Modalities

T-TEER - Triclip

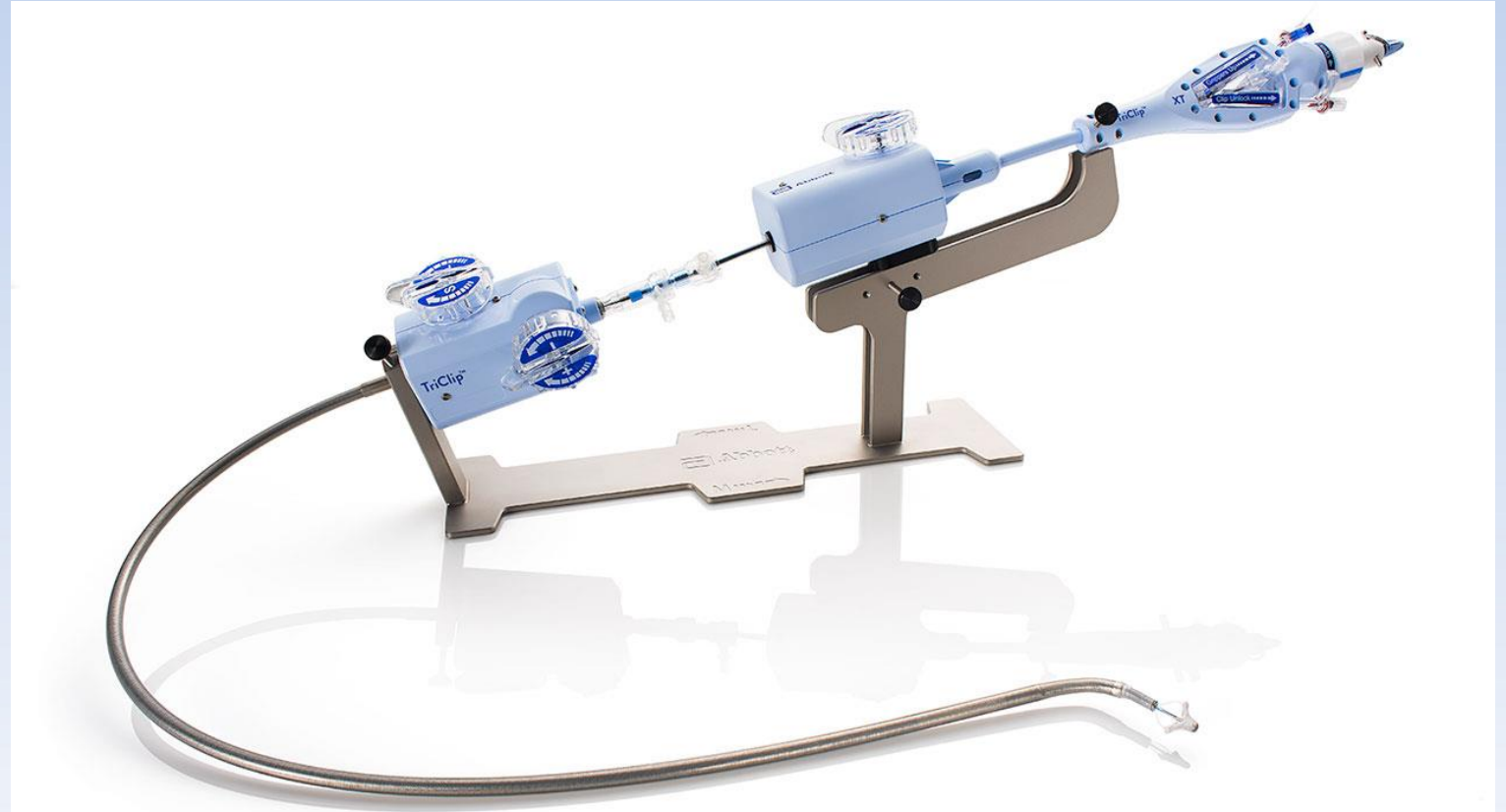
TTVR - EVOQUE

- DESIGNED SPECIFICALLY FOR THE TRICUSPID VALVE

TriClip™ TEER System

Designed for the tricuspid valve¹ – compared to Mitraclip system

- Shorter curved tip 1.5 vs 2.5cm
- Septal/lateral deflection of steerable guide catheter



1. Abbott. Data on file. TriClip G4 System Instructions for Use.

2. Lurz P, Stephan von Bardeleben R, Weber M, et al. Transcatheter edge-to-edge repair for treatment of tricuspid regurgitation. *J Am Coll Cardiol*. 2021;77(3):229-239. doi:10.1016/j.jacc.2020.11.038

3. Sorajja P, Whisenant B, Hamid N, et al. Transcatheter repair for patients with tricuspid regurgitation. *N Engl J Med*. 2023;388(20):1833-1842. doi:10.1056/NEJMoa2300525.

4. Lurz P, Besler C, Schmitz T, et al. Short-term outcomes of tricuspid edge-to-edge repair in clinical practice. *J Am Coll Cardiol*. 2023;82(4):281-291. doi:10.1016/j.jacc.2023.05.008

5. Adams D, Sorajja P, et al. TRILUMINATE Pivotal: Outcomes of All Randomized and Single-arm Subjects with Transcatheter Tricuspid Valve Edge-to-Edge Repair for Tricuspid Regurgitation. Presented at TCT on October 24, 2023; San Francisco, CA; USA.

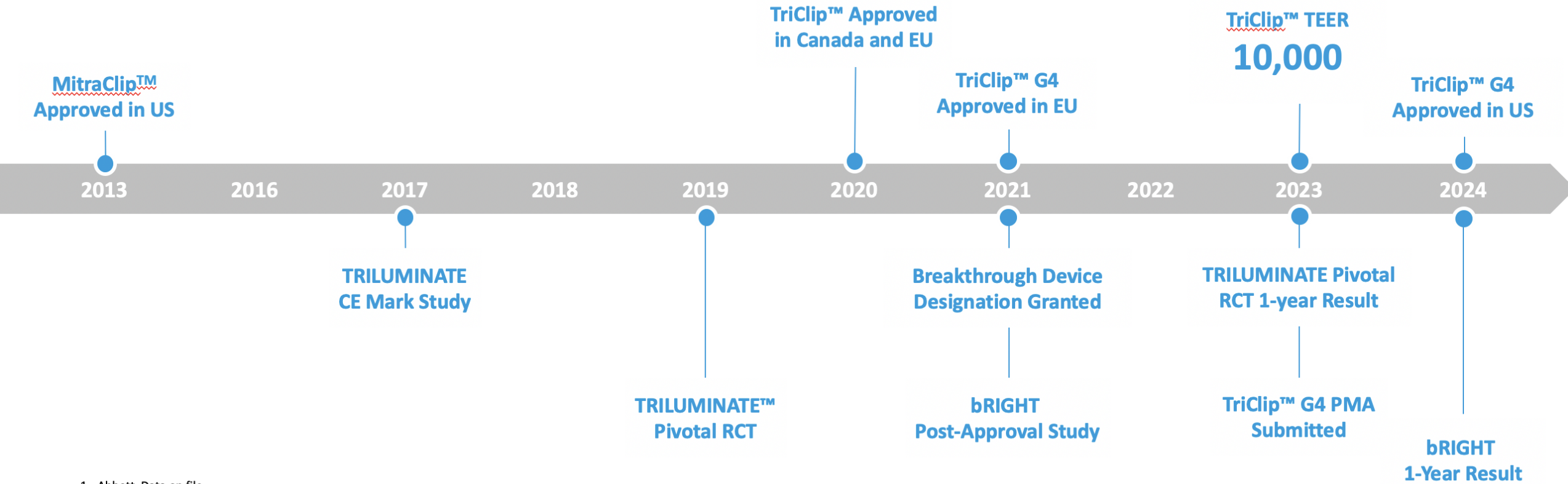
6. Donal E, Shueler R, Goebel B, et al. Real-world outcomes for tricuspid edge-to-edge repair: initial echocardiographic results from the TriClip bRIGHT study, *European Heart Journal - Cardiovascular Imaging*, Volume 23, Issue Supplement_1, February 2022, jeab289.203, <https://doi.org/10.1093/ehjci/jeab289.203>.

7. Estevez-Loureiro, R., Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 2-year Outcomes from the bRIGHT trial. Presented at PCR London Valves; November 19, 2023; London, England.

For U.S. audience, see Important Safety Information referenced within.

For audiences outside of the U.S., always check the regulatory status of the device in your region.

Device Evolution



1. Abbott. Data on file.

Triclip Safety

	 TRILUMINATE™³ <small>TRIAL</small> Author: Prof. Nickenig N: 85	 bRIGHT™⁴ <small>STUDY</small> Author: Prof. Lurz N: 511	 TRILUMINATE™² <small>PIVOTAL TRIAL</small> Author: Dr. Sorajja N: 175
At 30-Days			
MAEs	1.2%*	2.5%**	1.7%***
Survival	100%	99%	99%^{††}
Conversion to surgery	0%	0.2%	0%
Embolization	0%	0%	0%
Major bleeding	7%	7.2%	4.7%
New pacemaker	N/A[†]	0%	0.6%

*MAE as defined in the Triluminate Clinical trial includes cardiovascular mortality, myocardial infarction, stroke, new onset renal failure, endocarditis requiring surgery, and non-elective cardiovascular surgery for tricuspid valve repair system-related adverse events post-procedure. **MAE as defined in the bRIGHT Real-world Study includes cardiovascular mortality, myocardial infarction, stroke, new onset renal failure, endocarditis requiring surgery, and nonelective cardiovascular surgery for TriClip™ device-related adverse events occurring after the index procedure. ***MAE as defined in the Triluminate Pivotal study includes death from cardiovascular causes, new-onset kidney failure, endocarditis treated with surgery, and nonelective cardiovascular surgery for a TriClip™ device-related adverse events occurring after the index procedure. †Not reported. ††One patient (0.6%) in the TEER group died within 30 days after the procedure; the death was adjudicated as not related to the device or procedure.

1. Adams D, Sorajja P, et al. TRILUMINATE Pivotal: Outcomes of All Randomized and Single-arm Subjects with Transcatheter Tricuspid Valve Edge-to-Edge Repair for Tricuspid Regurgitation. Presented at TCT on October 24, 2023; San Francisco, CA; USA.
2. Sorajja P, Whisenant B, Hamid N, et al. Transcatheter repair for patients with tricuspid regurgitation. *N Engl J Med*. 2023;388(20):1833-1842. doi:10.1056/NEJMoa2300525.
3. Lurz P, Stephan von Bardeleben R, Weber M, et al. Transcatheter edge-to-edge repair for treatment of tricuspid regurgitation. *J Am Coll Cardiol*. 2021;77(3):229-239. doi:10.1016/j.jacc.2020.11.038
4. Lurz P, Besler C, Schmitz T, et al. Short-term outcomes of tricuspid edge-to-edge repair in clinical practice. *J Am Coll Cardiol*. 2023;82(4):281-291. doi:10.1016/j.jacc.2023.05.008

Triclip Outcomes



Author: Prof. Nickenig
N: 85



Author: Prof. Lurz
N: 200



Author: Dr. Sorajja
N: 175

Implant Success

100%^{1,2}

98%⁶

99%¹⁰

TR Reduction to ≤ Moderate

79%³

at 3-years vs 5% at baseline

73%⁷

at 2-years vs 2% at baseline

89%¹⁰

at 1-year vs 3% at baseline

NYHA Class I/II

82%³

at 3-years vs 24% at baseline

69%⁷

at 2-years vs 19% at baseline

82%¹⁰

at 1-year vs 24% at baseline

Δ KCCQ-OS* (points) at 1-year

20⁴

21 ± 27⁸

15 ± 22¹⁰

RVEDD Reduction

6.5%²

at 6 months

8%⁹

at 1 year

N/A**

*5-point improvement in KCCQ overall summary score (KCCQ-OS) is considered clinically meaningful

**Not reported

1. Lurz P, Stephan von Bardeleben R, Weber M, et al. Transcatheter edge-to-edge repair for treatment of tricuspid regurgitation. *J Am Coll Cardiol*. 2021;77(3):229-239. doi:10.1016/j.jacc.2020.11.038
2. Nickenig G, Weber M, Lurz P, et al. Transcatheter edge-to-edge repair for reduction of tricuspid regurgitation: 6-month outcomes of the TRILUMINATE single-arm study [published correction appears in *Lancet*. 2020 Mar 14;395(10227):870]. *Lancet*. 2019;394(10213):2002-2011. doi:10.1016/S0140-6736(19)32600-5.
3. Nickenig, G., Percutaneous edge-to-edge repair for tricuspid regurgitation: 3-year outcomes from the TRILUMINATE trial. Presented at PCR London Valves; November 19, 2023; London, England.
4. Abbott. Data on file. RPT2139672.
5. Lurz P, Besler C, Schmitz T, et al. Short-term outcomes of tricuspid edge-to-edge repair in clinical practice. *J Am Coll Cardiol*. 2023;82(4):281-291. doi:10.1016/j.jacc.2023.05.008
6. Lurz P, Schueler R, et al. Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 30-Day Results from the TriClip™ bRIGHT Study. Presented at PCR London Valves 2021; November 21, 2021; London, England.
7. Adams D, Sorajja P, et al. TRILUMINATE Pivotal: Outcomes of All Randomized and Single-arm Subjects with Transcatheter Tricuspid Valve Edge-to-Edge Repair for Tricuspid Regurgitation. Presented at TCT on October 24, 2023; San Francisco, CA; USA.
8. Lurz P, Schmitz T, Bekeredjian R, et al. Real-world Outcomes for Tricuspid Edge-to-Edge Repair: Initial 1 Year Outcomes from the bRIGHT trial. Presented at PCR London Valves; November 27-29, 2022; London, England.
9. Donal E, Shueler R, Goebel B, et al. Real-world outcomes for tricuspid edge-to-edge repair: initial echocardiographic results from the TriClip bRIGHT study, *European Heart Journal - Cardiovascular Imaging*, Volume 23, Issue Supplement_1, February 2022, jeab289.203, <https://doi.org/10.1093/ehjci/jeab289.203>.
10. Sorajja P, Whisenant B, Hamid N, et al. Transcatheter repair for patients with tricuspid regurgitation. *N Engl J Med*. 2023;388(20):1833-1842. doi:10.1056/NEJMoa2300525.

TRIC I-HF

DESIGN – 2022-2025

--n=360 – 237 T-TEER vs 123 OMT

POPULATION

--51% severe/34% massive/10%
torrential TR

--median age 80yo

--56% women, 75% NYHA III/IV

--82% cardiorenal/46%
cardiohepatic

PRIMARY OUTCOME –

--Death from any cause

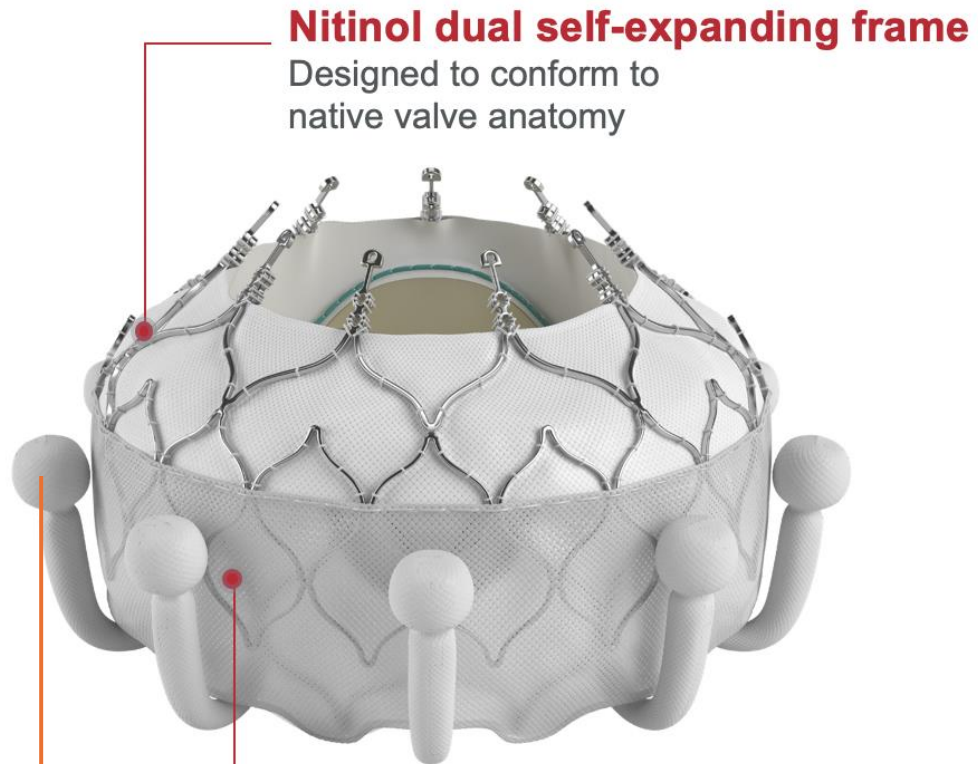
--hospitalization for HF

3yr combined endpoint

--52.4% vs 21%

EVOQUE - TTVR

44mm, 48mm, 52mm, 56mm



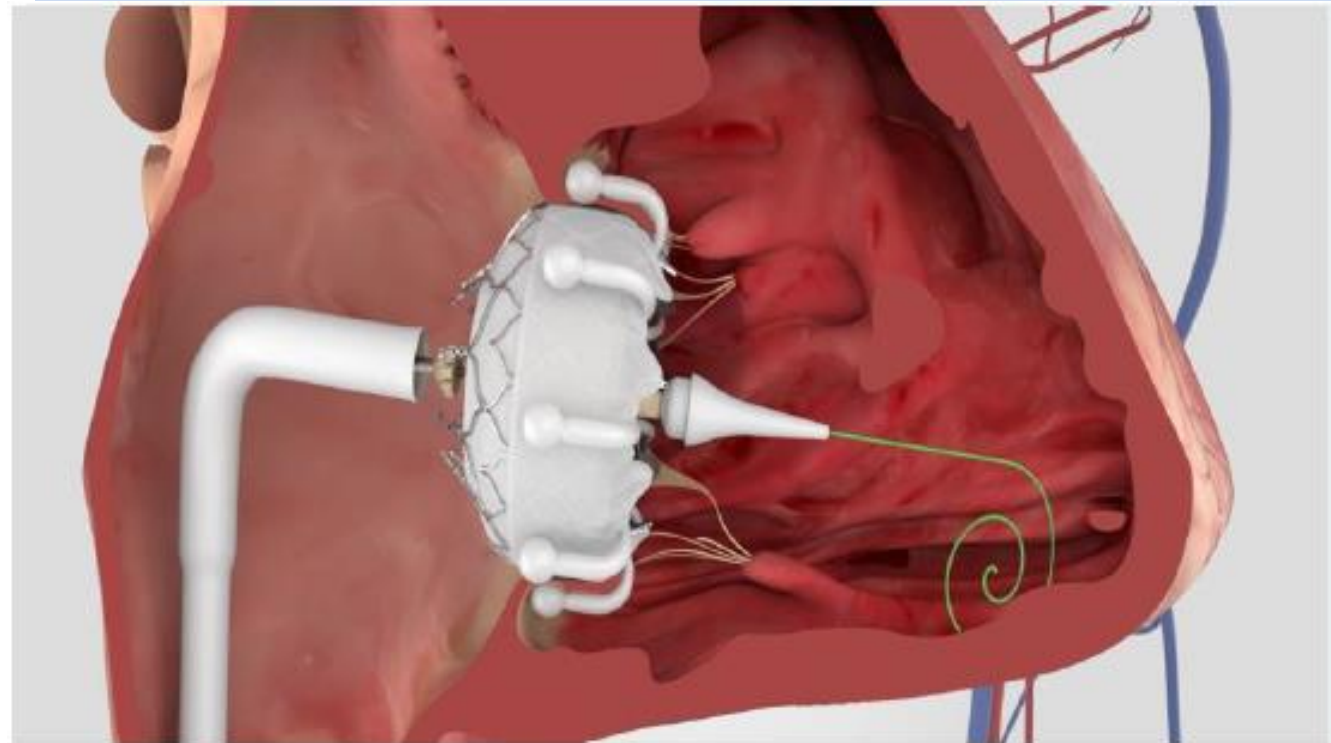
Nitinol dual self-expanding frame

Designed to conform to native valve anatomy

Intra-annular sealing skirt and frame

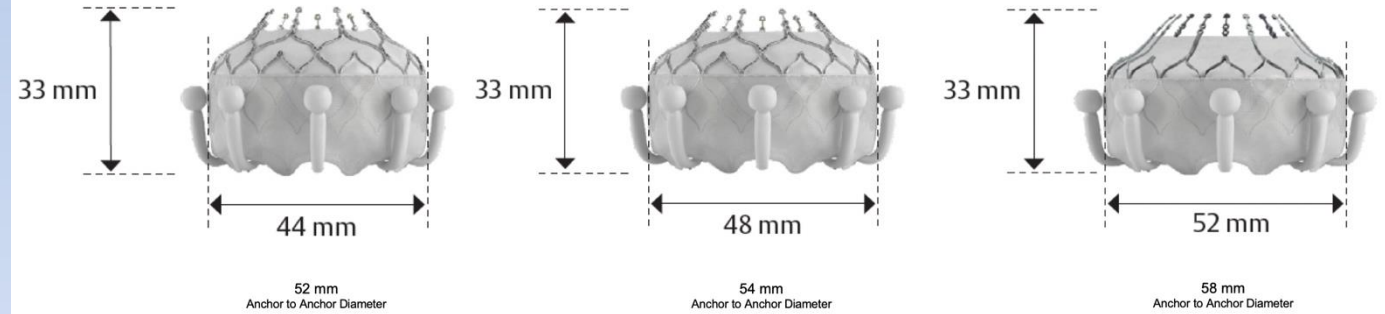
Designed to seal within the native tricuspid annulus

9 ventricular anchors
Engage leaflets, subvalvular anatomy, and the annulus

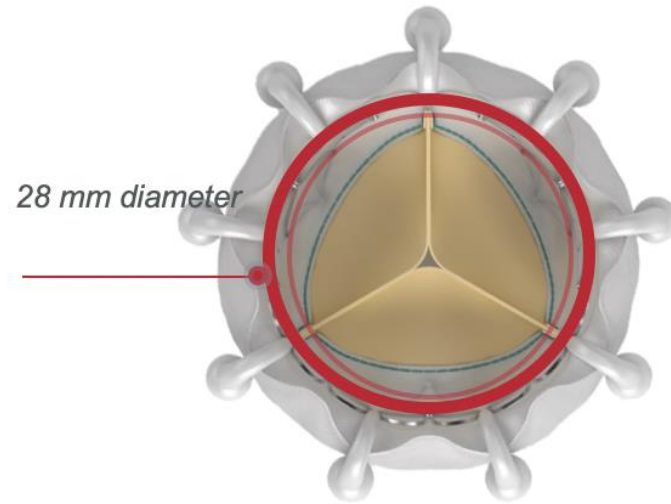
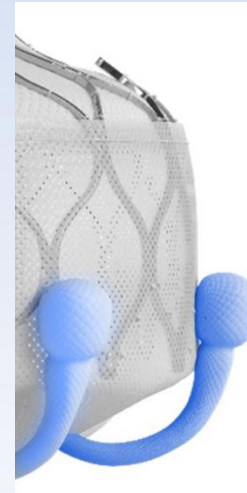
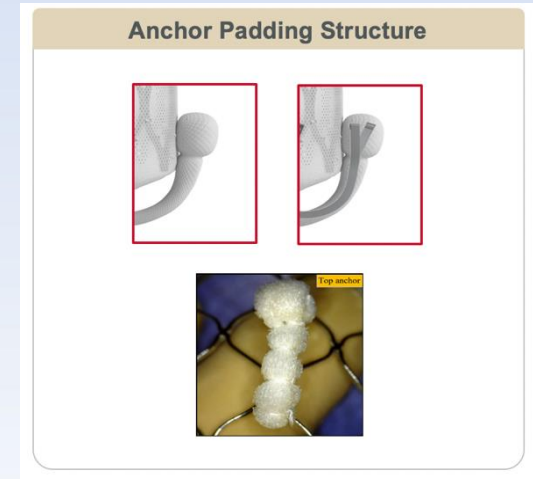


Transcatheter Tricuspid Valve Replacement Procedural Animation

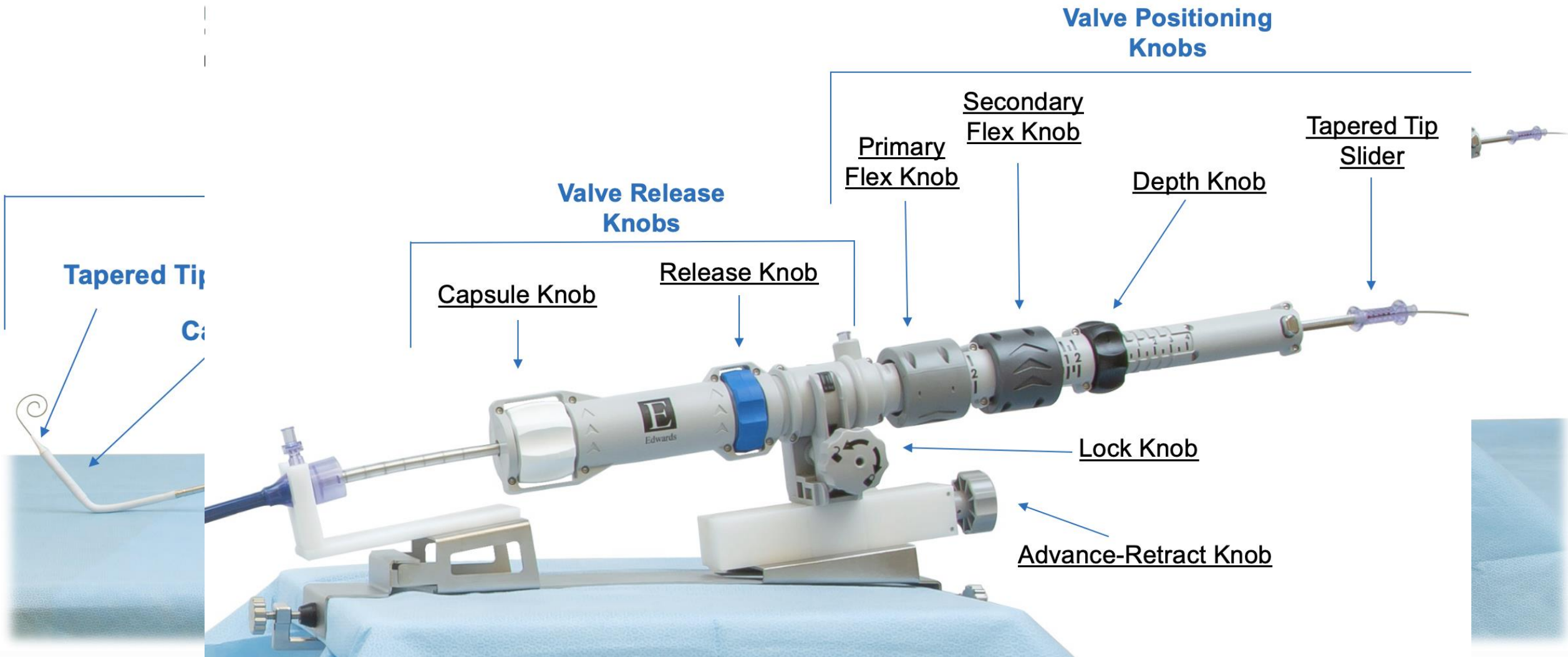
EVOQUE - TTVR



28mm Bovine Pericardial Tissue Valve



Delivery System



TRISCEND II

DESIGN

--n=400 – 267 EVOQUE vs 133 OMT

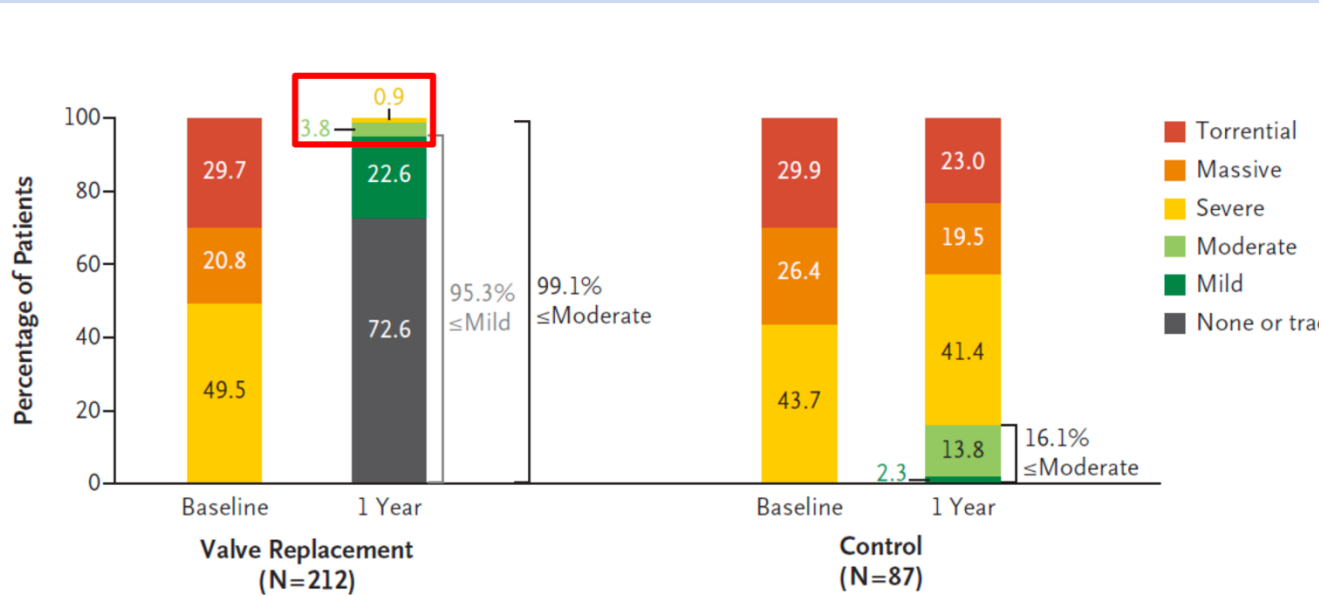
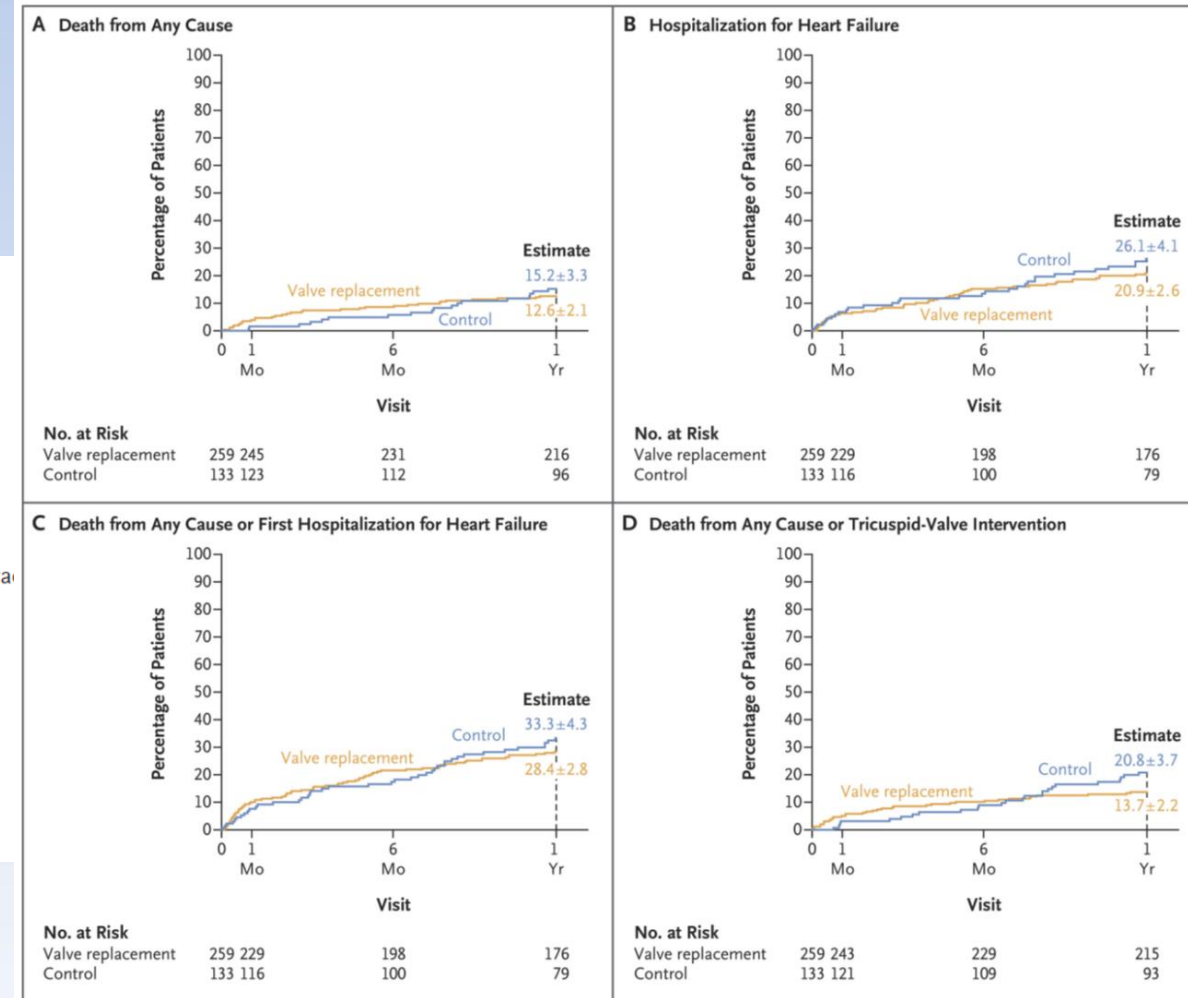
POPULATION

--symptomatic severe TR
--median age 79yo
--75% women, 95% afib
--STS mortality for MVR 9.7%

PRIMARY OUTCOME - hierarchical

--Death from any cause
--RVAD or heart tx
--TV surgery or intervention
--annualized hospitalization HF
--KCCQ improvement 10pt
--NHYA functional class
improvement – >1
--6 min walk improvement 30m

TRICEND II OUTCOMES



1 year Win ratio favored TTVR 2.02 (95% CI 1.56 - 2.62)

TRISCEND Safety Outcomes

- 1yr death from any cause
 - 11.6 vs 10.5
- 1yr Severe Bleeding
 - 5.3 vs 15.4 (3.1 access site)
- PPM
 - 2.3 vs 17.4

Hahn et al., NEJM 2025;392(2):115

Table 2. Safety Outcomes.*

Safety Event	Early Events (≤30 Days)†		Late Events (31 to 365 Days)‡		Cumulative Events (0 to 365 Days)†		P Value§
	Valve Replacement (N=259)	Control (N=133)	Valve Replacement (N=247)	Control (N=128)	Valve Replacement (N=259)	Control (N=133)	
	number of patients (percent)						
Death from any cause¶	9 (3.5)	0	21 (8.5)	14 (10.9)	30 (11.6)	14 (10.5)	0.87
Death from cardiovascular cause	8 (3.1)	0	14 (5.7)	10 (7.8)	22 (8.5)	10 (7.5)	0.85
Myocardial infarction	2 (0.8)	0	3 (1.2)	1 (0.8)	5 (1.9)	1 (0.8)	0.67
Stroke	1 (0.4)	0	3 (1.2)	0	4 (1.5)	0	0.30
New renal-replacement therapy	4 (1.5)	NA	4 (1.6)	NA	8 (3.1)	NA	NA
Severe bleeding**	27 (10.4)	2 (1.5)	13 (5.3)	6 (4.7)	40 (15.4)	7 (5.3)	0.003
Nonelective tricuspid-valve reintervention††	2 (0.8)	1 (0.8)	0	3 (2.3)	2 (0.8)	4 (3.0)	0.19
Major access-site and vascular complication	8 (3.1)	NA	0	NA	8 (3.1)	NA	NA
Major cardiac structural complication	3 (1.2)	NA	0	NA	3 (1.2)	NA	NA
Device-related pulmonary embolism	2 (0.8)	NA	1 (0.4)	NA	2 (0.8)	NA	NA
Arrhythmia and conduction disorder resulting in permanent pacing	41 (15.8)	0	5 (2.0)	3 (2.3)	46 (17.8)	3 (2.3)	<0.001
New pacemaker or cardiac implantable electronic device‡‡							
In all patients	40 (15.4)	0	5 (2.0)	3 (2.3)	45 (17.4)	3 (2.3)	<0.001
In patients without pre- existing pacemaker§§	40/162 (24.7)	0/80	5/118 (4.2)¶¶	3/76 (3.9)¶¶	45/162 (27.8)	3/80 (3.8)	<0.001

TRISCEND – 2 year data

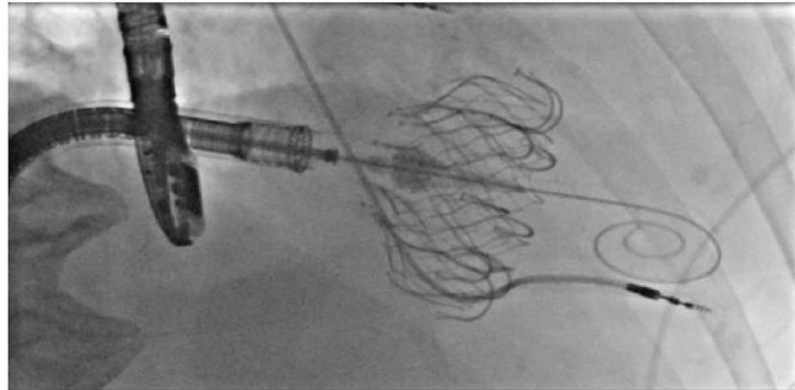
- Complete data on 200/267 TTVR; 86/133 control group
 - 58 control group pt crossed over for treatment; 28 remained OMT only
- Intention to Treat analysis – no difference in all cause mortality 19.1% vs 25.3%
- Crossover 1 year landmark – all cause mortality 19.1% vs 44.9%; $P < 0.001$

TTVR w PPM

- 38.2% TRISCEND patients had CIED – did not provide info re: lead function
- 32 consec

ng TTVR

Device-lead abnormalities and function after transcatheter tricuspid valve replacement



Cohort and results

- 32 patients underwent TTVR with CIED in place
- 10 patients had lead changes
 - R-wave sensing loss - 55 %
 - Insulation breach (noise $\pm$ impedance drop) - 13%

Key message

Early after TTVR, nearly one-third of patients with jailed CIED leads exhibit electrical abnormalities; R-wave sensing loss predominates, but a clinically important 13 % show insulation breach.

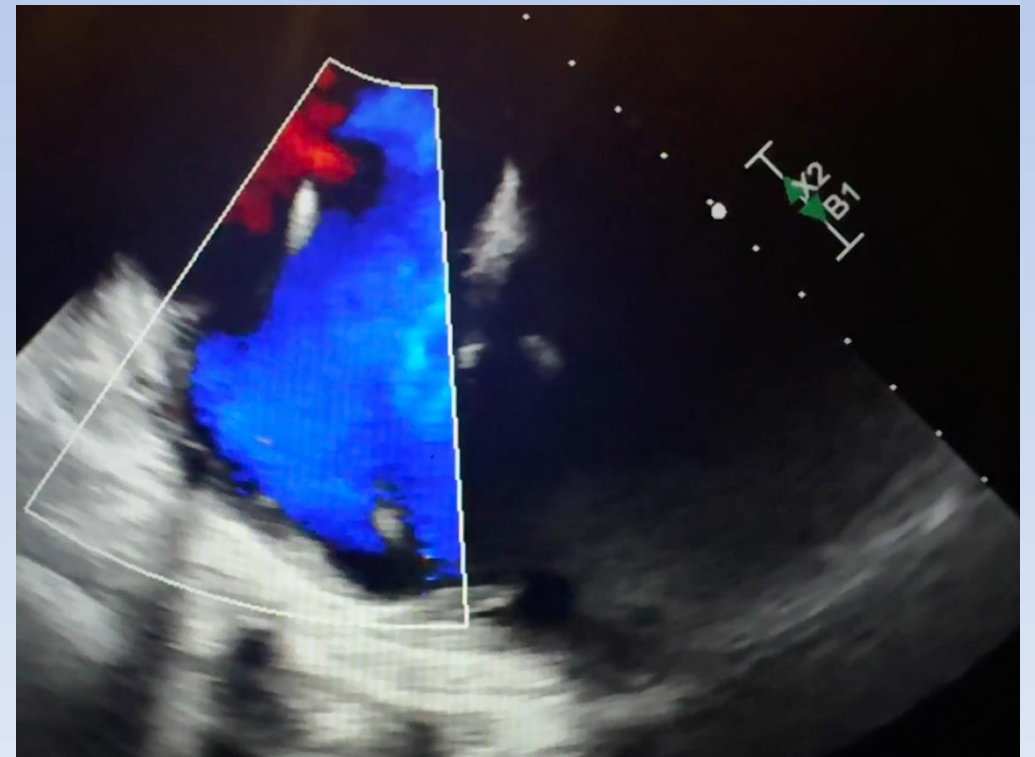
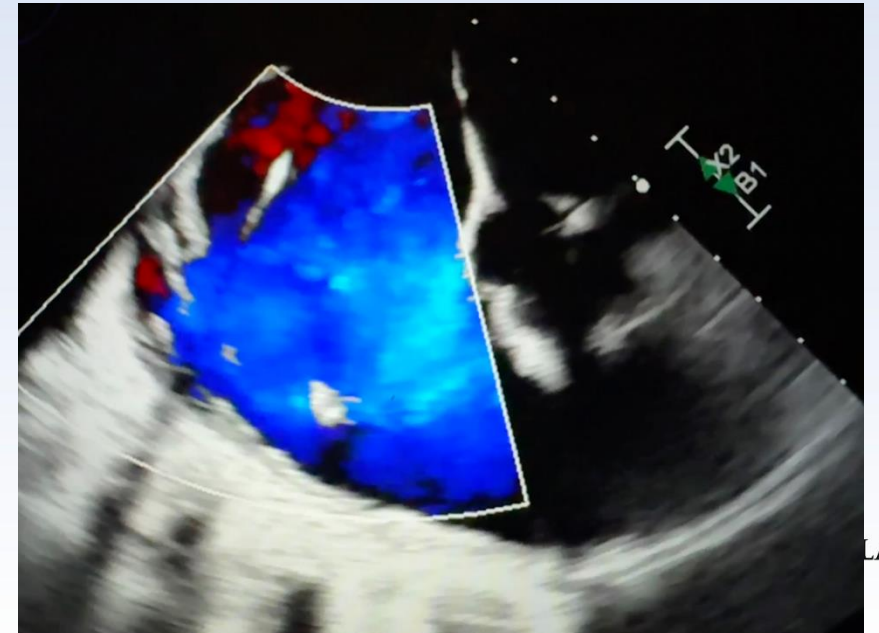
Case Review

HPI

- 82yoF with a history of mitral valve repair 2002 and permanent pacemaker for sick sinus syndrome
 - NYHA III Shortness of breath and lower extremity edema on diuretics
 - Normal kidney/liver function
 - Atrial fibrillation – tolerating AC

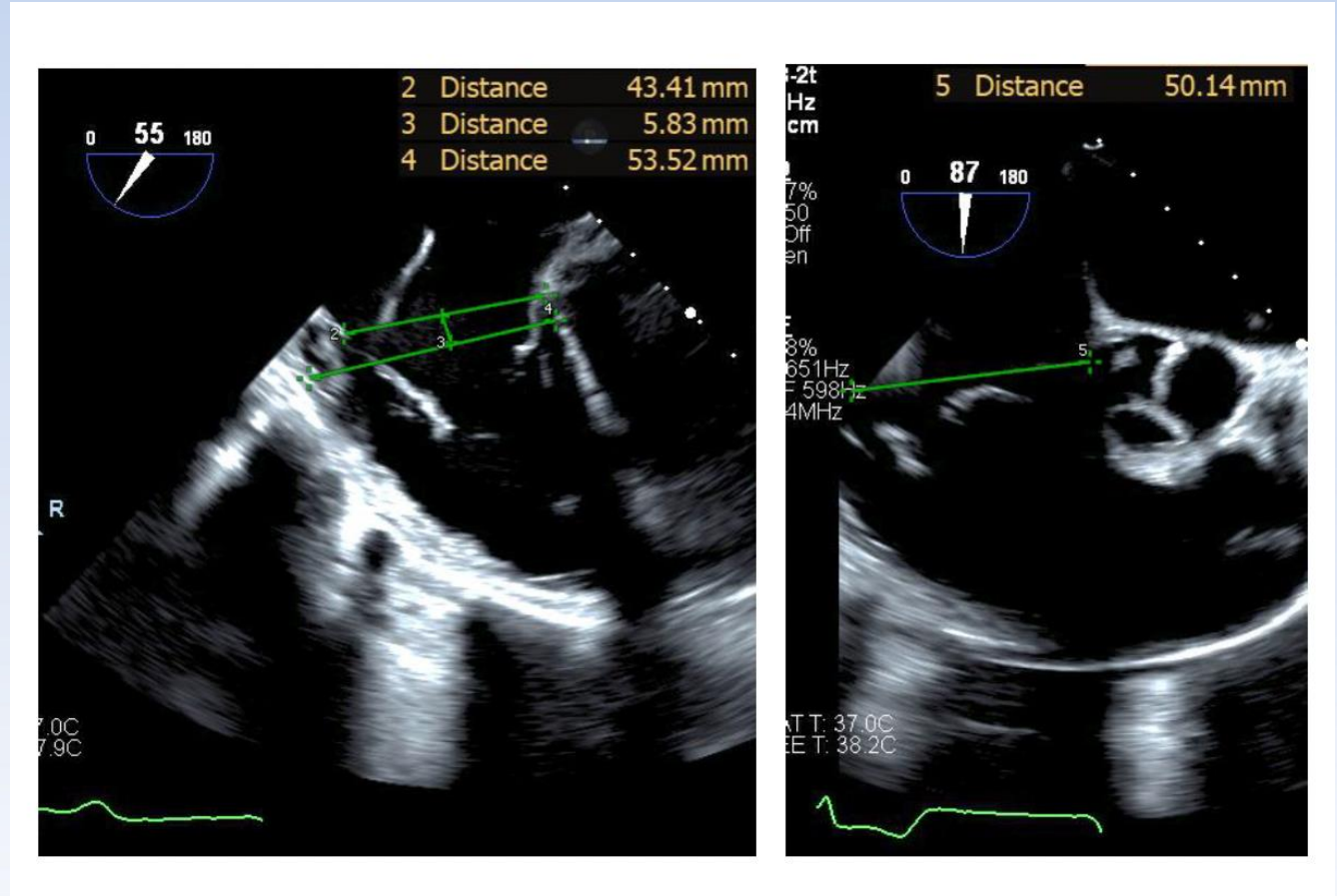
EVOQUE IFU 6mo AC -1yr f/u of initial 27 cases, 25 remained on AC¹

1. Webb, et al JACC, 2022, 15:5



ECHO/CT Assessment

- RA – moderately dilated
- RV – moderately dilated, mild dysfunction
- RVSP 55-60mmHg
- Annulus: 50mm
- Basal: 53mm
- Septal leaflet length 9mm
- Leaflet gap 6mm



ECHO/CT Assessment - TTVR Workup

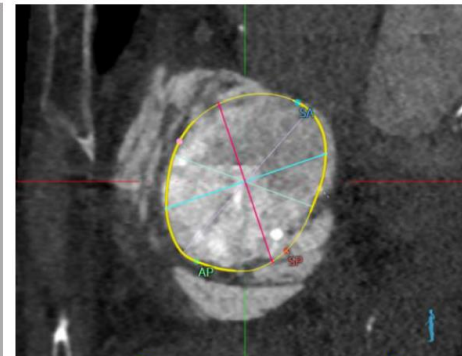
Patient ID:	31904462	Hospital:	Norton Hospital	Report Date:	2026/05/26	Created by:	MH
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CT Screening Results:		Within Parameters		
Optimal Valve Size:	52mm	CT Anatomical Sizing	Diastole 90%	Systole 30%
Additional Sizing Considerations:	None	TV Annulus Oversizing	13.4%	14.5%
RA Height - Systole:	62.6mm	Basal RV Oversizing	1.1%	16.1%
TEE PDD Diastole:	N/A	Paps overall favorable	Not Required	

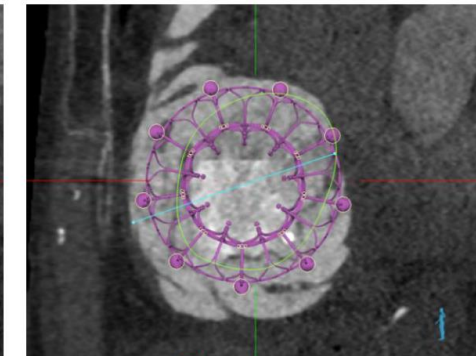
Patient Initials: H;M	CT Study Date: 2026/05/15	PT Wt (kg): 47.5
Female	TEE Study Date: 2026/04/24	PT Wt (kg): 49.4

- RV pacing lead(s) present – ensure backup pacing plan in place
- RV lead w/ minimal slack, crossing TVA in SP comm, inserting into apex.

TVA Diastole: 90%



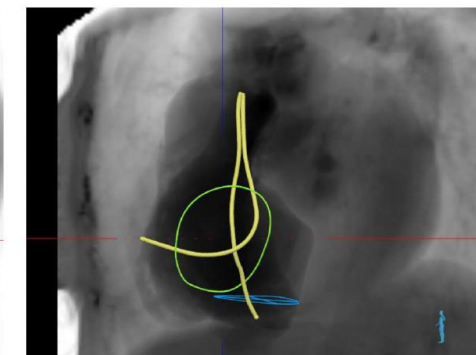
Basal RV Diastole: 90%



Implant: 90%
RAO: 18° CRAN: 0°



En face: 90%
LAO: 72° CAUD: 14°



ECHO/CT Assessment - TTVR Workup

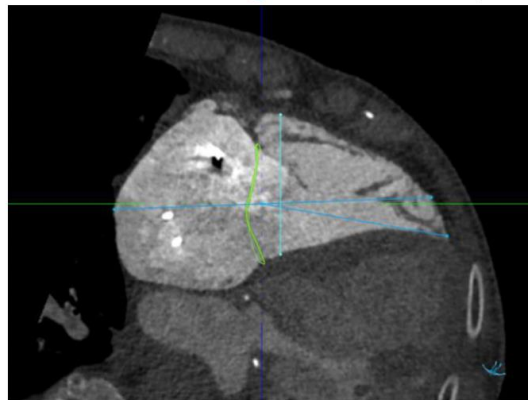
Anatomical "Working Room" - Delivery System

Patient ID: 31904462

RA + RV Room
(CG height consideration)

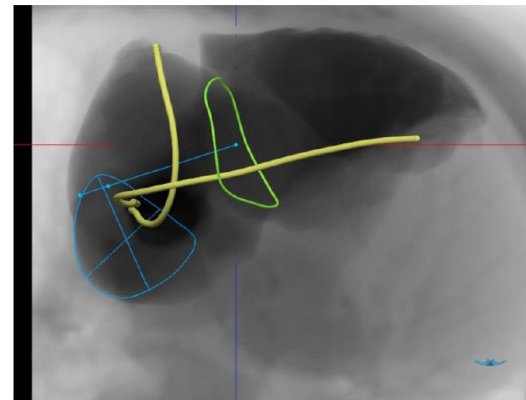
IVC:TV Annulus Overlap
(Secondary flex consideration)

Anatomical Working Room - Diastole (90%)



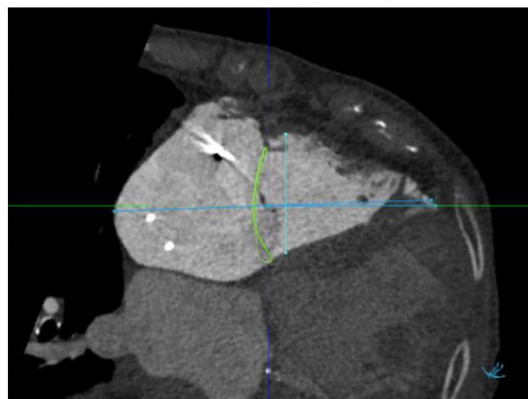
SL at 10mm: 55.2mm RV Depth (coaxial): 67.0mm
RA Height: 58.3mm RV Depth (apex): 74.3mm

IVC to TVA Offset - Diastole (90%)

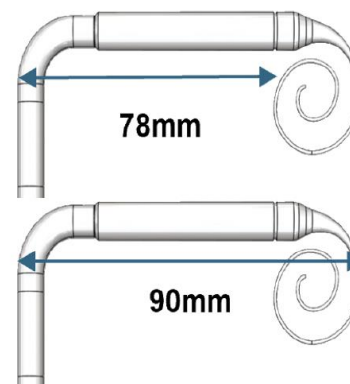


IVC to TVA distance: 51.2mm IVC to TVA Offset: 0.0mm

Anatomical Working Room - Systole (30%):



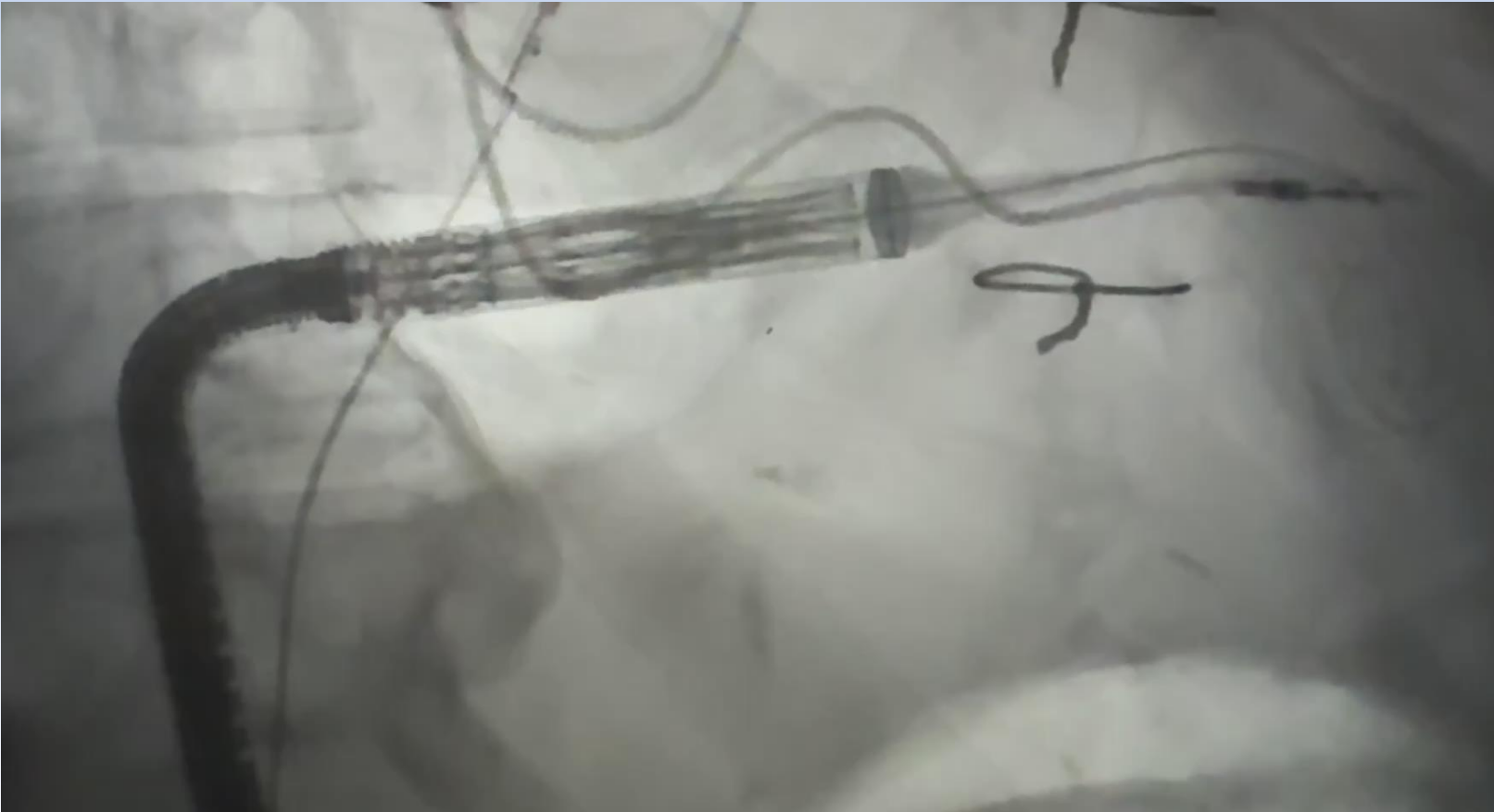
SL at 10mm: 48.1mm RV Depth (coaxial): 65.9mm
RA Height: 62.6mm RV Depth (apex): 67.7mm



Anatomical Measurements	Diastole(90%):	Systole(30%):
IVC to TVA Offset Distance (bottoms up view)	Overlap	
IVC to TVA distance (Implant AP view)	51.2mm	51.7mm
RA Height	58.3mm	62.6mm
RV Depth (co-axial)	67.0mm	65.9mm
RV Depth (apex)	74.3mm	67.7mm
Total RA+RV (apex) Working Room	132.6mm	130.3mm

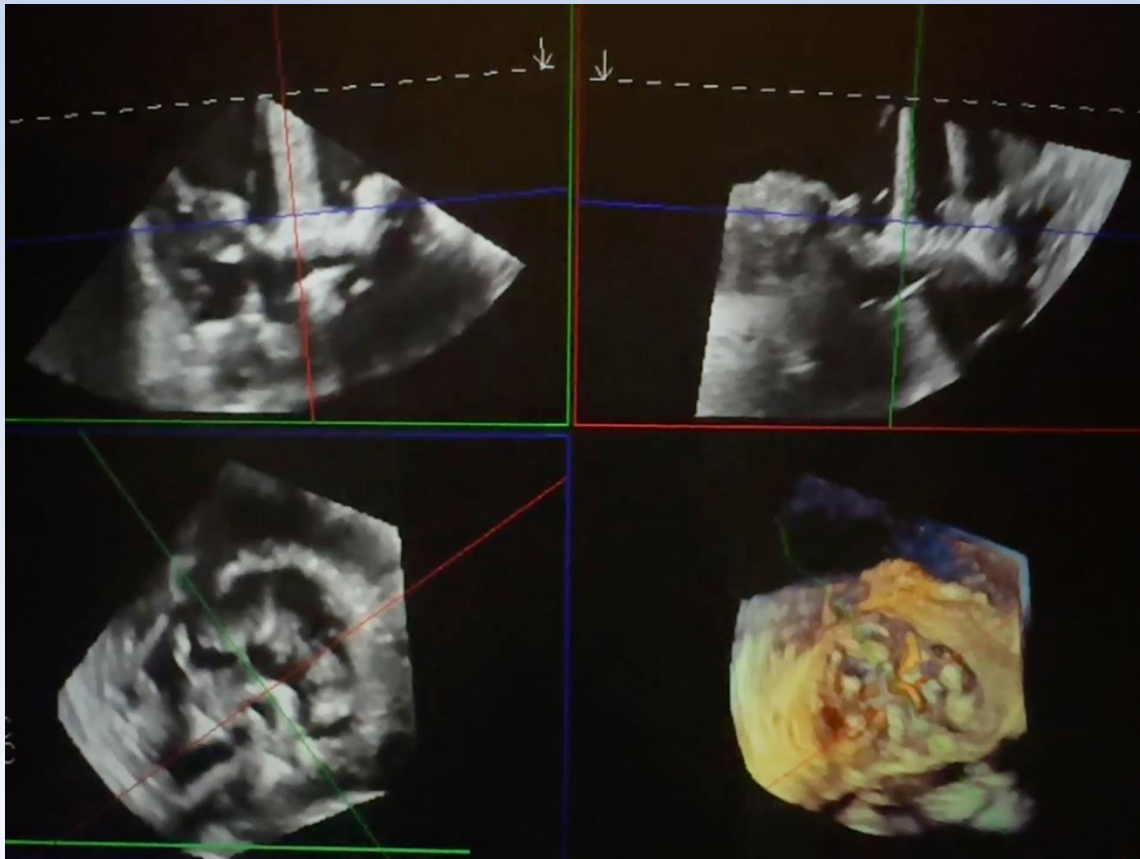
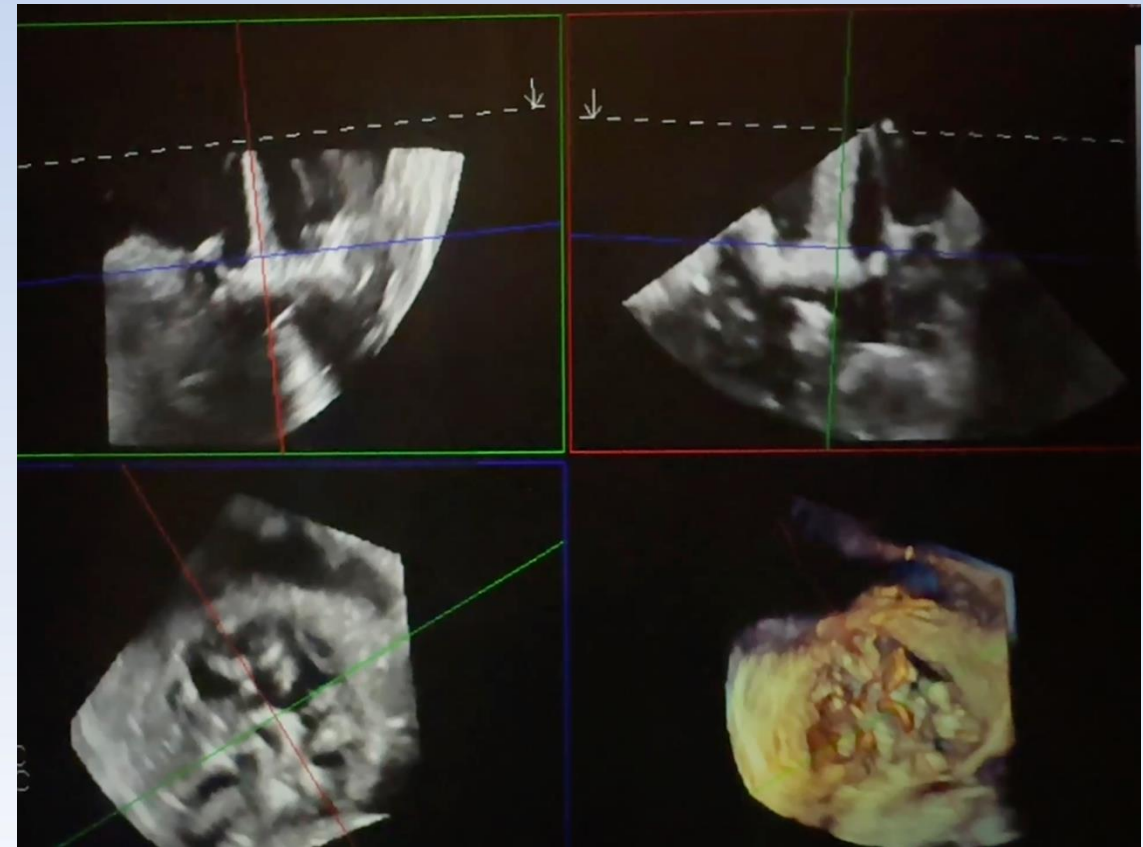
SUMMARY
Working room within parameters

Implant

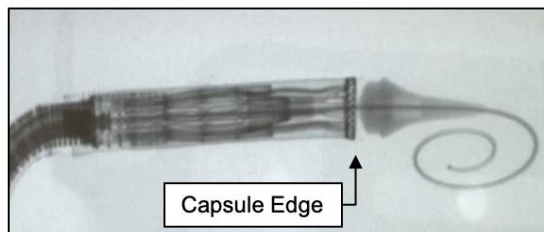
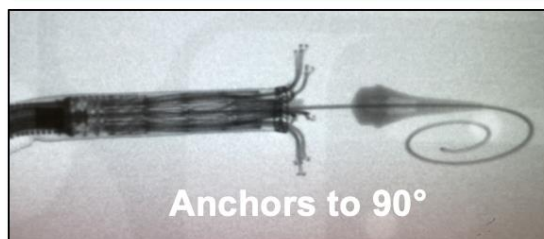
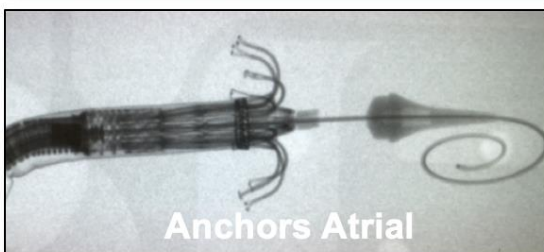


- 28F R or L femoral vein or IJ approach
- Safari wire placed in RV apex via Agilis deflectable catheter
- 4D ICE adjunctive imaging commonly used

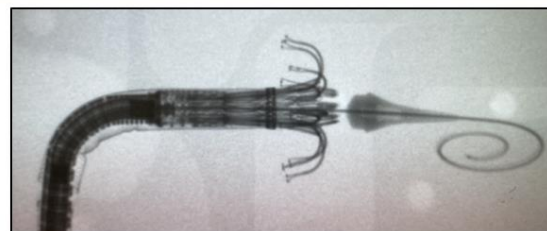
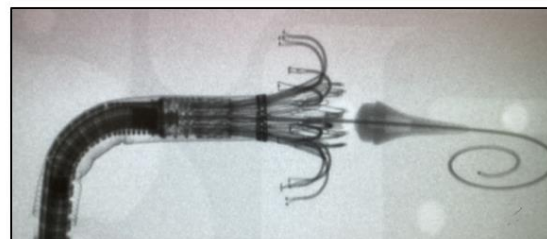
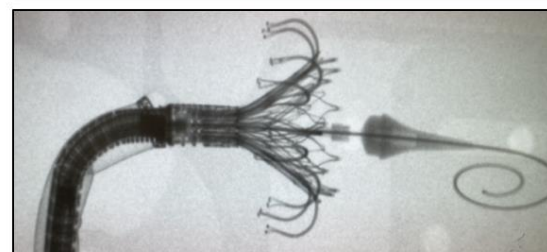
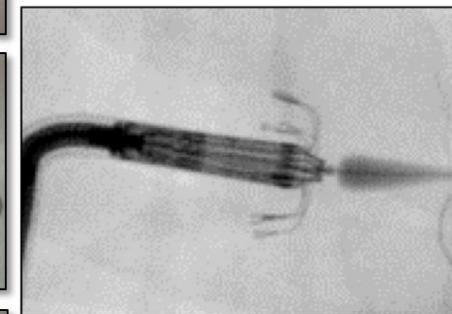
Implant



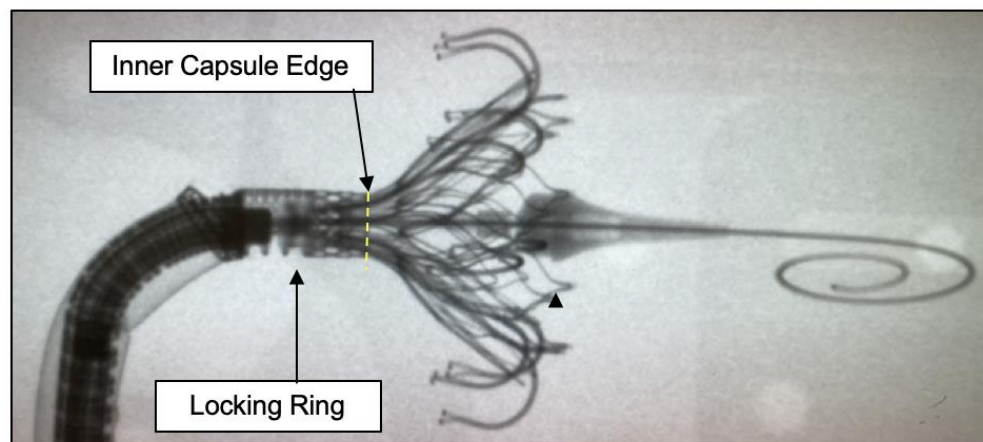
Anchor Release



Ventricular Expansion



Atrial Expansion



Post Images



Thank you!