

Valvular Heart Disease Landscape: Evolution in the Revolution

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The Society of Thoracic Surgeons Adult Cardiac Surgery Database: 2024 Update on National Trends and Outcomes



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TABLE 1 Volume of Major Adult Cardiac Surgery and Transcatheter Valve Procedures From 2015 to 2023^{1,3}

Variable	2015	2016	2017	2018	2019	2020	2021	2022	2023
Total surgical procedure count^a	303,216	310,714	307,836	305,487	301,773	256,421	282,550	287,734	299,679
Isolated CABG	154,772	160,801	161,886	161,675	163,682	138,112	154,682	157,275	161,907
Isolated AVR	30,148	28,643	26,320	25,779	21,092	15,590	17,052	17,664	18,900
Isolated MVR	10,411	11,069	10,576	10,951	10,880	9,528	10,573	10,981	11,293
Isolated MVr	12,924	12,523	12,622	12,730	12,687	10,868	11,784	12,200	12,756
AVR + CABG	18,106	17,731	16,169	16,139	14,382	11,198	12,676	12,923	13,230
TVr	9060	9377	9072	8981	8952	8055	8495	8366	8403
TVR	1551	1808	2077	2246	2224	2214	2266	2117	1967
Total transcatheter procedure count^c									
TAVR	24,647	37,819	50,946	59,815	73,396	77,149	87,586	92,250	10,0501
TEER	2556	4226	5667	6976	10,576	10,866	12,625	13,182	14,631
TMVR	224	358	641	889	1125	1061	1250	1431	1598
Transcatheter TVr							367	389	438
Transcatheter TVR							142	132	174

TABLE 2 Selected Outcomes of Commonly Performed Surgical Operations in 2023

Variable	AVR (n = 18,900)	MVR (n = 11,293)	MVr (n = 12,756)	TVr (n = 8403)	TVR (n = 1967)
Mortality					
In-hospital	1.6	4.4	0.8	6.0	8.0
Operative	2.1	4.9	1.0	6.6	8.7
Major morbidity	10.6	21.6	7.3	26.8	31.0
Reoperation	3.8	6.0	2.8	7.2	8.8
DSWI or mediastinitis	0.3	0.4	0.2	0.6	0.7
Permanent stroke	1.3	2.4	1.0	2.2	1.3
Prolonged ventilation >24 hours	6.3	15.4	4.0	21.2	24.0
Renal failure	2.0	4.8	1.1	7.1	9.1
New-onset atrial fibrillation	28.0	33.2	28.9	27.5	14.5
30-day readmission	8.9	14.4	7.9	13.0	15.7
Postoperative length of stay, d	7.19	10.73	6.34	12.51	14.9

Give Years Back to Life, Give Life Back to Years

Life-Long Management of Valvular Heart Disease

Shared Decision-Making Process, Heart-Team Approach

Staged or Destination Therapy and Exit strategy
Futility, Risk and Benefit

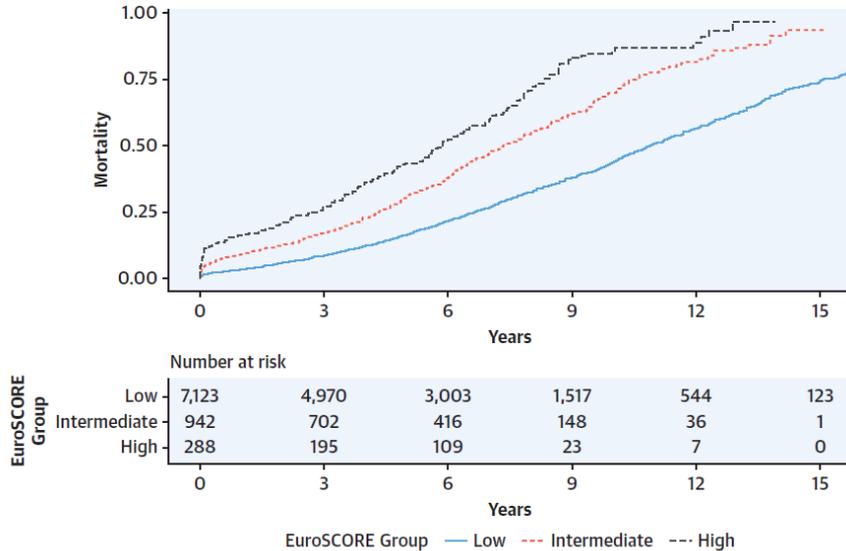
Phenotype and Clustering Analysis

Availability, Ability and Accountability (AAA)

Health Care Economics, Access and Economy

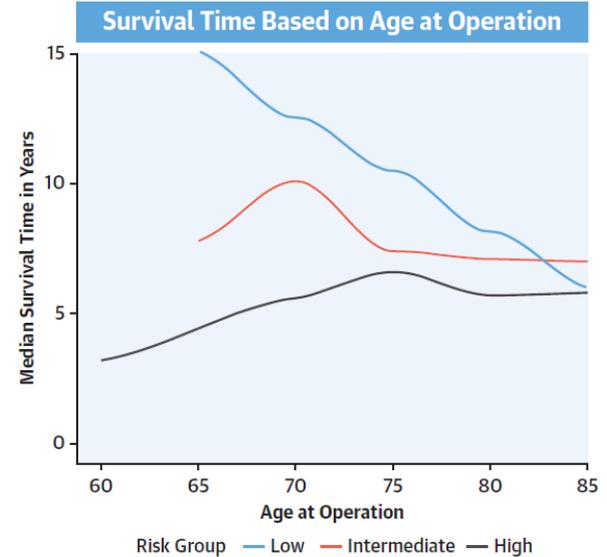
Life Expectancy After Surgical Aortic Valve Replacement

CENTRAL ILLUSTRATION Cumulative Mortality After Surgical Aortic Valve Replacement With a Bioprosthesis for Aortic Stenosis



Martinsson, A. et al. J Am Coll Cardiol. 2021;78(22):2147-2157.

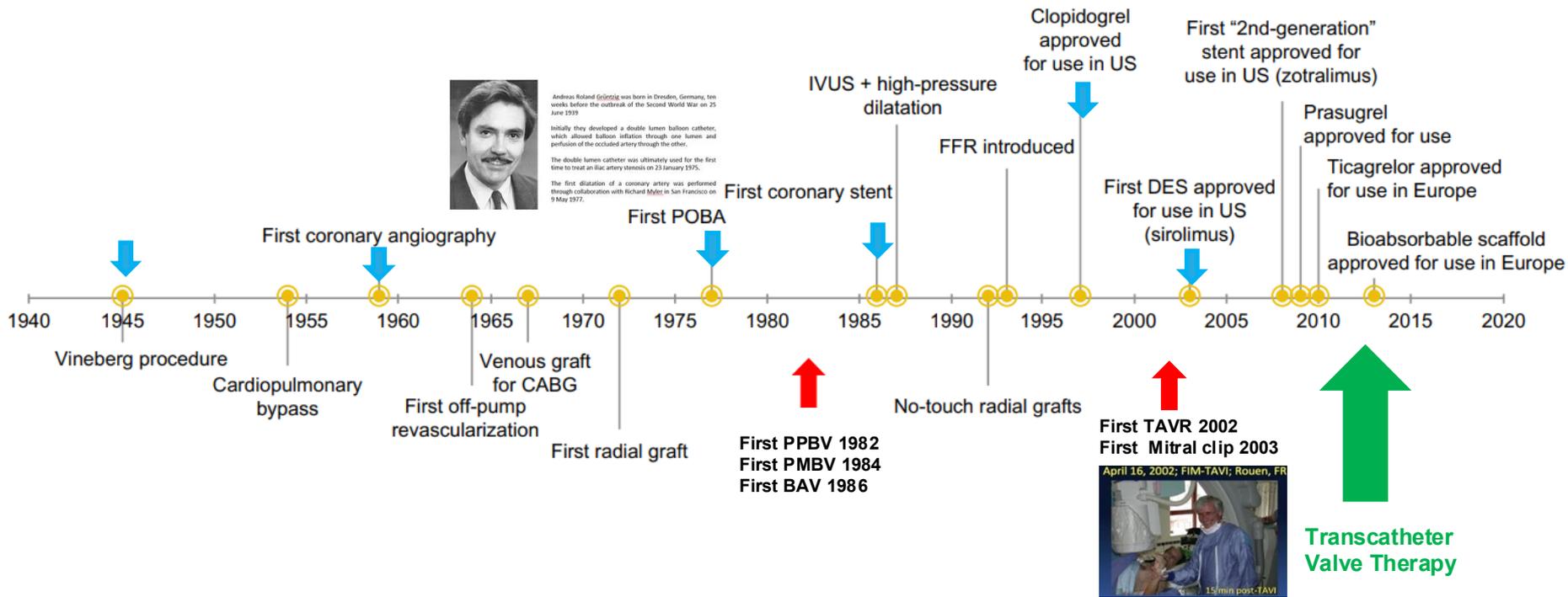
FIGURE 2 Smoothed Line Plot of Survival Time Based on Age at Operation



The median survival time as a function of age for low-, intermediate-, and high-risk patients. As is illustrated, older age had a substantial impact on median survival for patients in the low-risk group but the impact was attenuated for intermediate- and high-risk patients.

OBJECTIVES

1. Update on transcatheter aortic valve intervention
2. Update on transcatheter mitral valve intervention
3. Update on transcatheter tricuspid valve intervention
4. Updates on clinical trial and post market data



CASE 01

Demographics (age 78 yrs old, F)

HPI:

She reports shortness of breath at distances of <1 block w/ intermittent chest pain, symptoms alleviated by rest. Symptoms developed over the last 6-12 months. The patient denies orthopnea, PND, or peripheral edema.

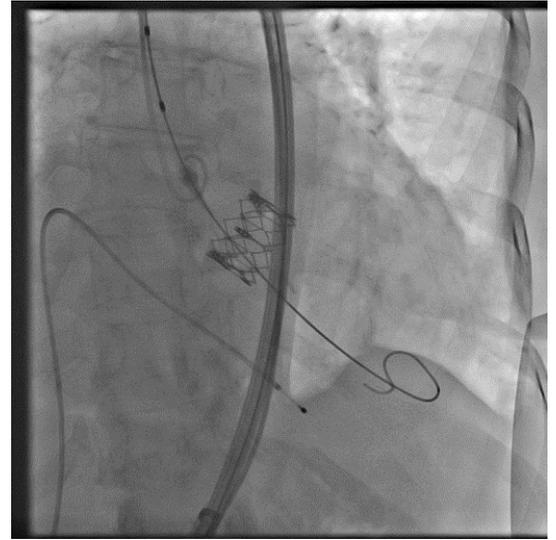
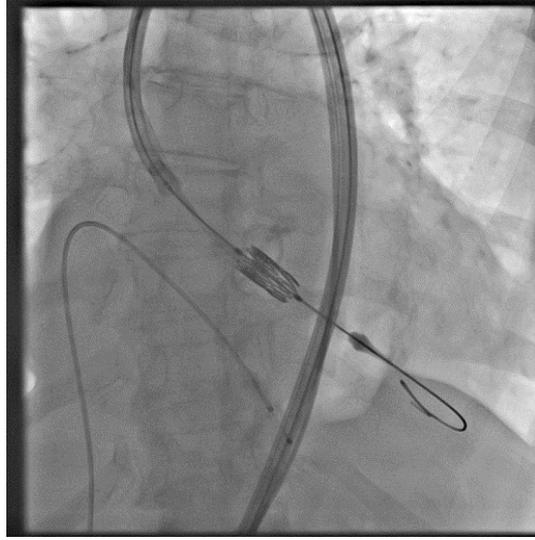
PMH:

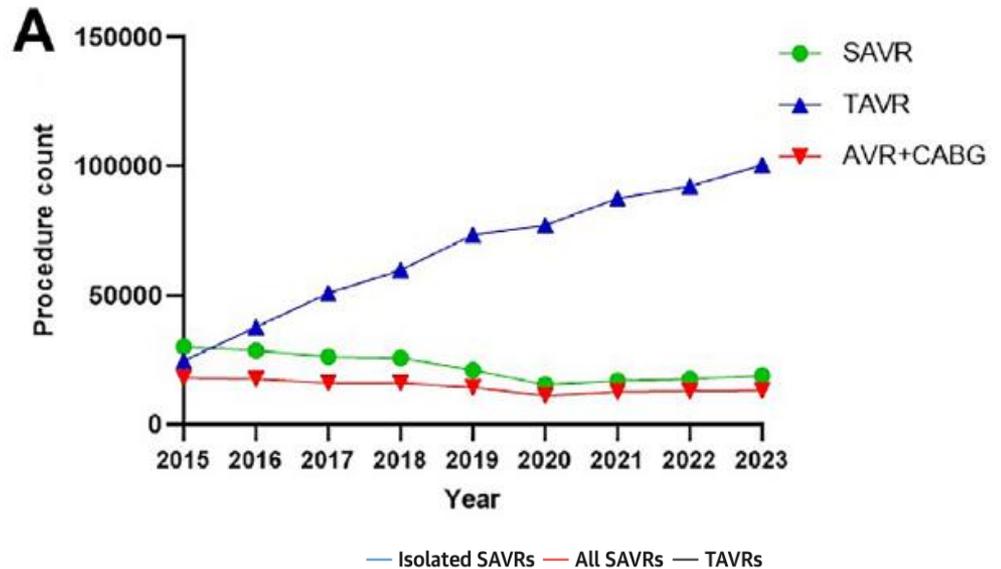
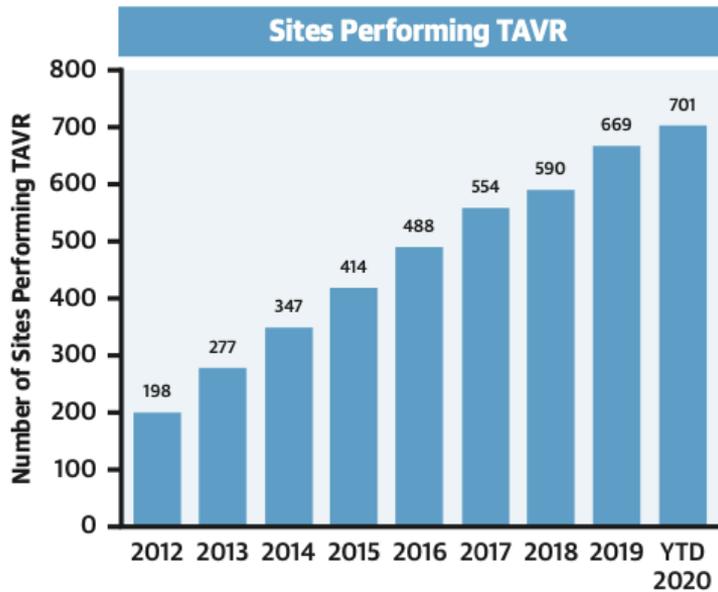
Aortic valve stenosis
Aortic insufficiency
HFpEF
HTN
HLD
T2DM
Obesity
OSA on CPAP
Osteoporosis
GERD
Gallbladder removed 1985
Appendectomy
Rotator cuff repair 2003

Diagnostic Tests:

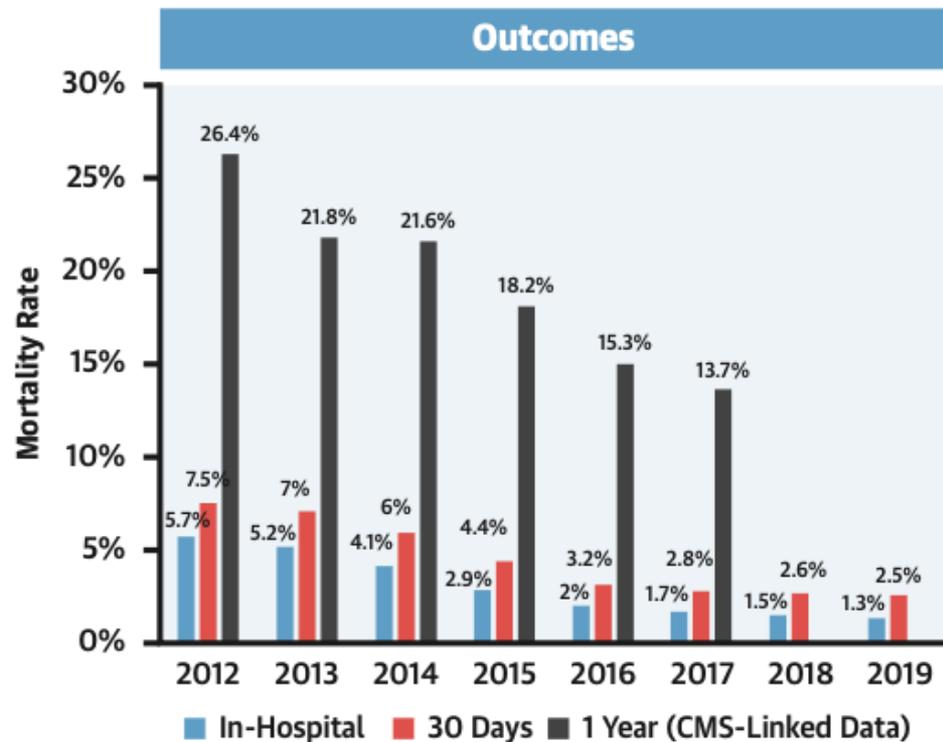
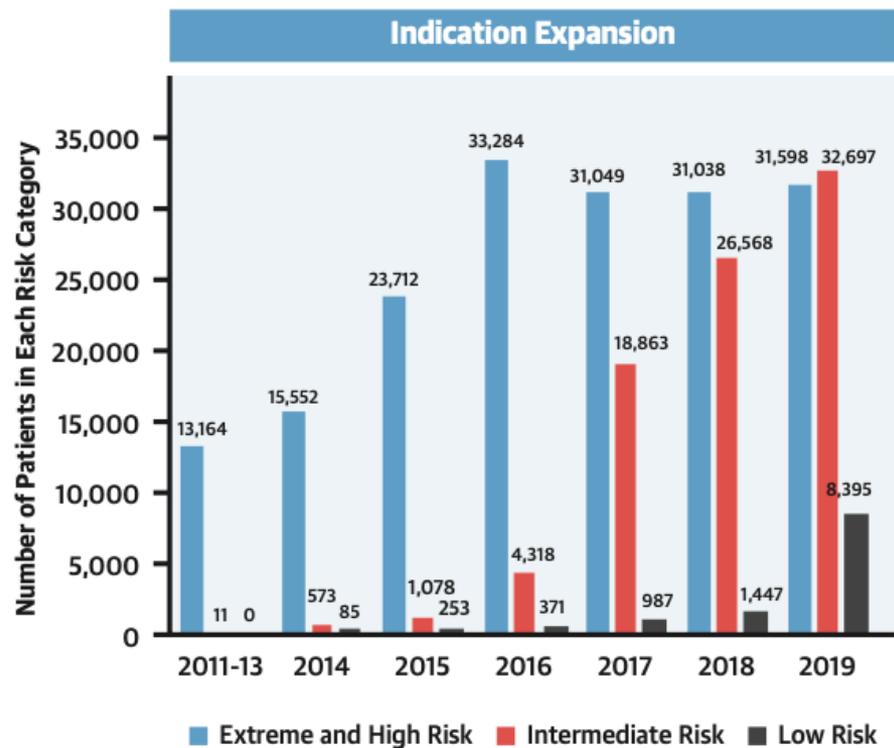
11/14/23 TTE:

- LVEF normal w/ evidence of DD
- Mild MR + TR
- Severe AS (pV 4.1, mG 40, AVA 0.8), mod AI





Ann Thorac Surg 2025;119:1139-50



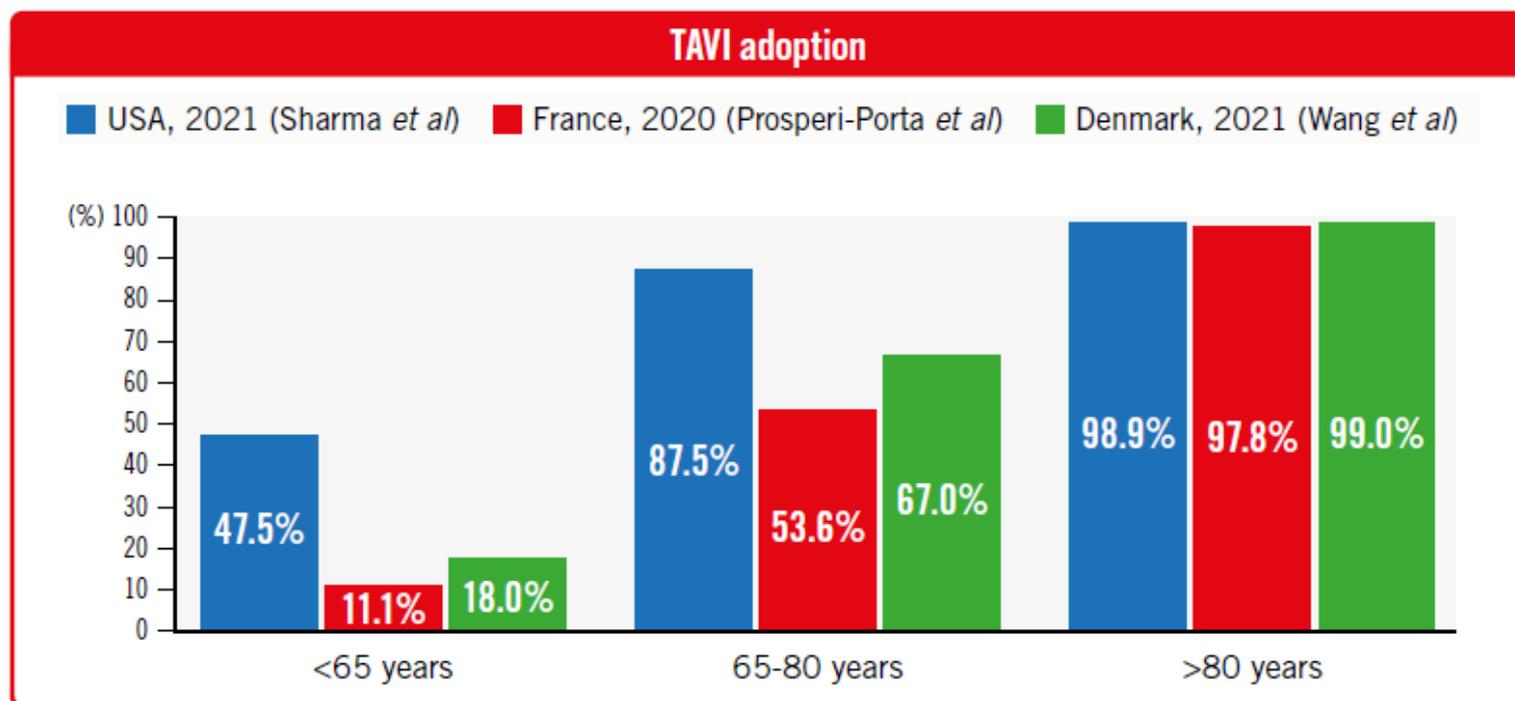
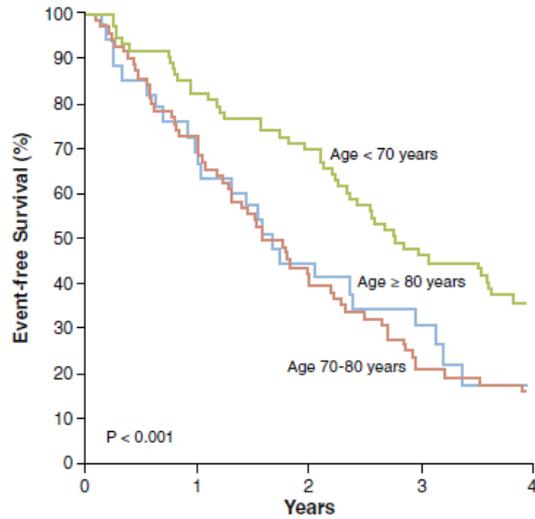


Figure 1. The modern Heart Team approach and contemporary TAVI adoption rates. CT: computed tomography; TAVI: transcatheter aortic valve implantation

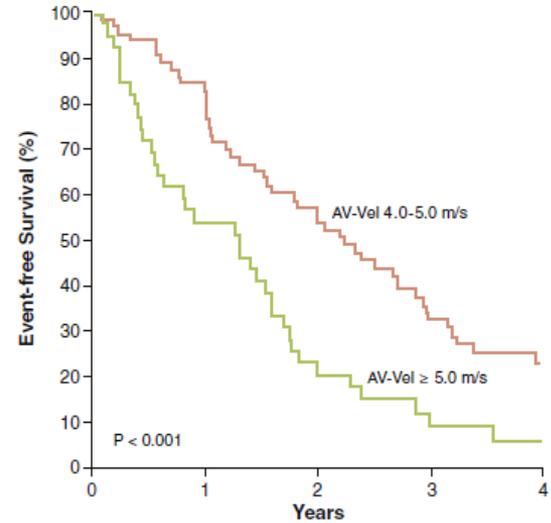
Asymptomatic Severe Aortic Stenosis in the Elderly



Patients at Risk:

— Age < 70 years	83	63	53	34	24
— Age 70-80 years	69	51	30	16	11
— Age ≥ 80 years	34	24	15	09	04

Kaplan-Meier event-free survival for patients 70 to 80 years of age (pink line), patients ≥80 years (blue line), and patients <70 years (green line).



Patients at Risk:

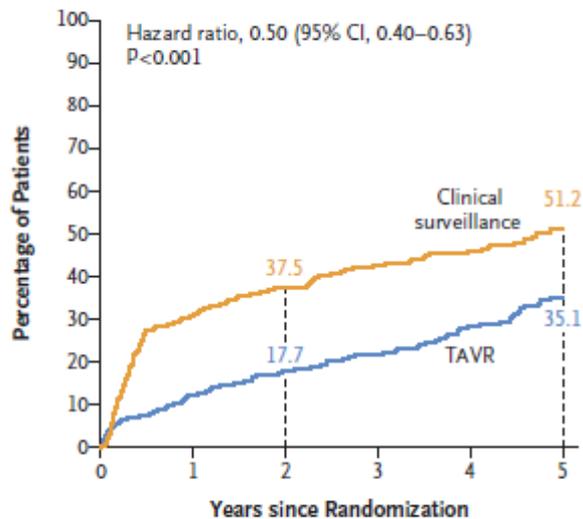
— AV-Vel 4.0-5.0 m/s	64	53	36	20	12
— AV-Vel ≥ 5.0 m/s	39	22	09	04	03

Kaplan-Meier event-free survival for patients with an AV-Vel of 4.0 to 5.0 m/s (pink line) and patients with an AV-Vel ≥5 m/s (green line). AV-Vel = peak aortic jet velocity.

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

EARLY TAVR ClinicalTrials.gov number, NCT03042104

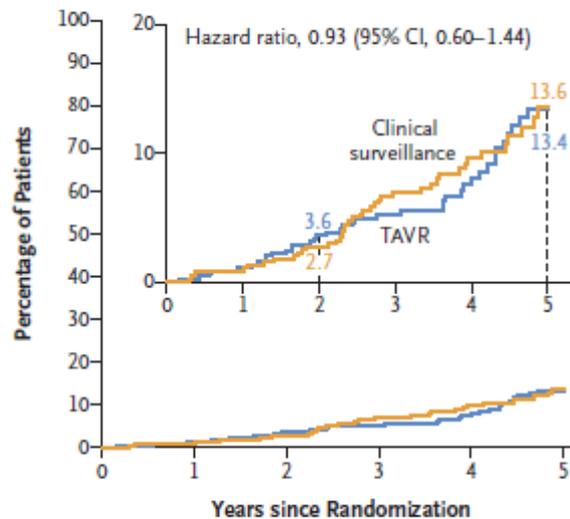
A Death, Stroke, or Unplanned Hospitalization for Cardiovascular Causes (%)



No. at Risk

TAVR	455	390	363	285	142	103
Clinical surveillance	446	305	266	187	117	46

B Death from Any Cause



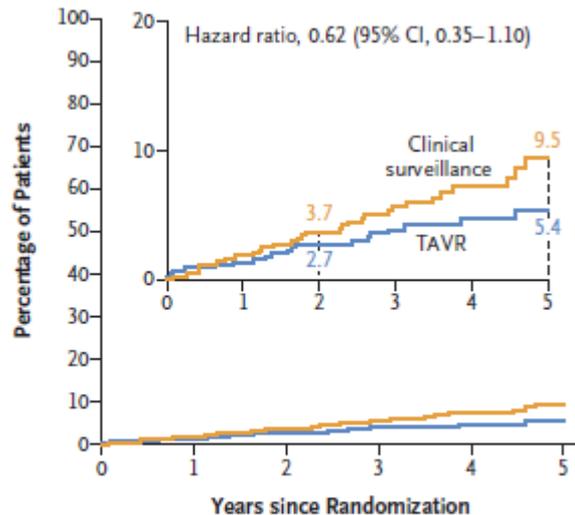
No. at Risk

TAVR	455	439	425	346	187	136
Clinical surveillance	446	436	418	310	199	95

Transcatheter Aortic-Valve Replacement for Asymptomatic Severe Aortic Stenosis

EARLY TAVR ClinicalTrials.gov number, NCT03042104

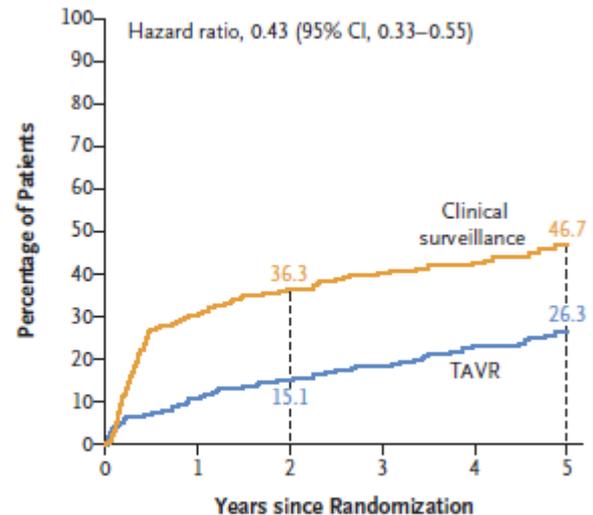
C Stroke



No. at Risk

TAVR	455	433	415	335	180	130
Clinical surveillance	446	429	406	295	185	87

D Unplanned Hospitalization for Cardiovascular Causes



No. at Risk

TAVR	455	392	365	287	142	103
Clinical surveillance	446	306	267	189	118	46

5-Year Follow-Up From the PARTNER 2 Aortic Valve-in-Valve Registry for Degenerated Aortic Surgical Bioprostheses

TABLE 4 Kaplan-Meier Estimate of Clinical Outcomes

	30 Days	1 Year	5 Years
Death (all-cause)	2.7 (10, 10)	11.8 (43, 43)	50.6 (171, 171)
Stroke (all)	2.5 (9, 9)	4.5 (17, 16)	10.5 (34, 30)
All neurologic events (all strokes and TIA)	2.5 (9, 9)	5.1 (20, 18)	13.8 (51, 38)
Myocardial infarction	1.1 (5, 4)	1.7 (7, 6)	12.0 (36, 31)
Repeat hospitalization ^a	2.5 (9, 9)	4.6 (16, 16)	15.7 (52, 43)
Bleeding (need for transfusion)	11.8 (43, 43)	16.8 (64, 60)	28.5 (106, 89)
New permanent pacemaker	2.2 (8, 8)	4.3 (15, 15)	9.5 (28, 27)
Atrial fibrillation	7.1 (28, 26)	12.8 (49, 45)	24.1 (93, 71)

TABLE 3 Echocardiographic Characteristics: Baseline to 5 Years

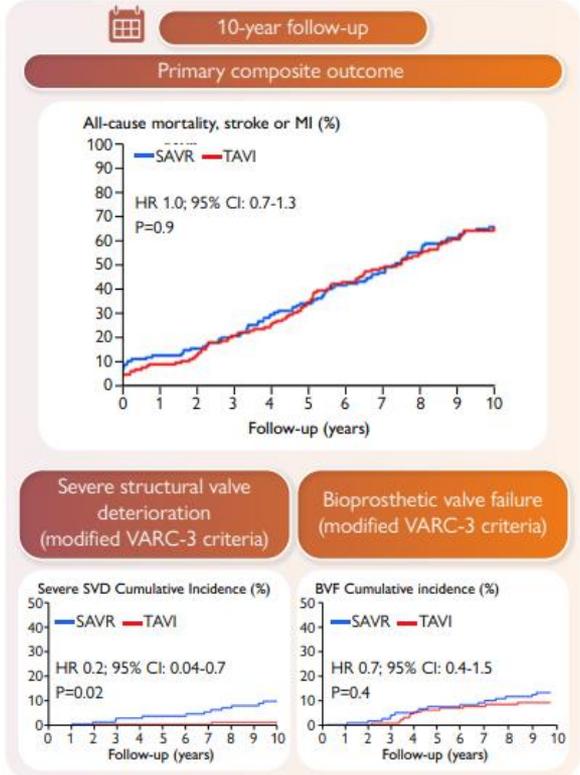
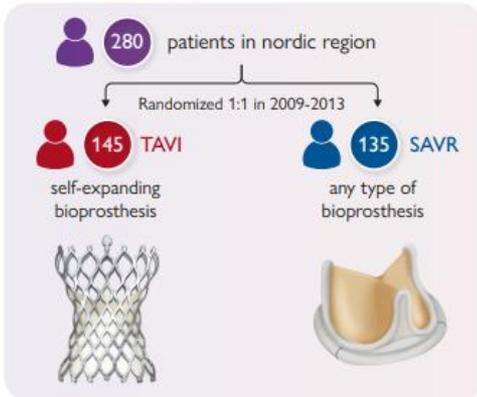
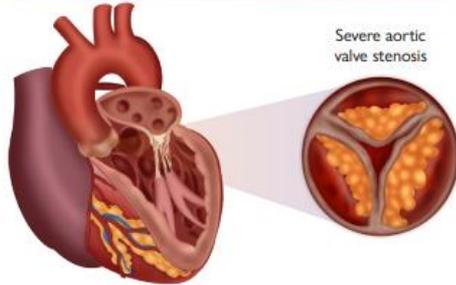
	Baseline (N = 330)	30 Days	1 Year	5 Years	Difference 5 Years vs Baseline (95% CI)	P Value	Difference 5 Years vs 30 Days (95% CI)	P Value
EOA, cm ²	0.90 ± 0.43	1.1 ± 0.37	1.1 ± 0.41	1.1 ± 0.42	0.14 (0.03-0.25)	0.014	0.02 (−0.05 to 0.08)	0.63
EOA index, cm ² /m ²	0.5 ± 0.22	0.6 ± 0.19	0.6 ± 0.21	0.6 ± 0.21	0.07 (0.02-0.13)	0.005	0.01 (−0.02 to 0.04)	0.58
Doppler velocity index	0.3 ± 0.11	0.4 ± 0.09	0.4 ± 0.09	0.4 ± 0.10	0.08 (0.05-0.1)	<0.0001	0.003 (−0.02 to 0.02)	0.79
Mean gradient, mm Hg	35.1 ± 15.81	17.8 ± 7.99	17.8 ± 7.85	16.8 ± 7.90	−18.35 (−21.68 to −15.01)	<0.0001	−1.84 (−3.22 to −0.46)	0.01
LVEF, %	50.7 ± 13.11	50.0 ± 13.12	53.8 ± 11.33	53.9 ± 11.69	2.57 (−1.17 to 6.30)	0.17	2.05 (−1.29 to 5.39)	0.22
LV mass, g	263.2 ± 82.51	241.8 ± 78.16	228.2 ± 77.31	218.8 ± 74.59	−57.19 (−74.75 to −39.63)	0.023	−34.87 (−46.37 to −23.36)	<0.0001
LV mass index, g/m ²	136.4 ± 37.36	125.0 ± 33.97	118.0 ± 33.26	110.6 ± 29.84	−30.24 (−39.23 to −21.26)	<0.0001	−18.00 (−23.64 to −12.34)	<0.0001
Total AR								
None to mild	55.8 (184/330)	97.5 (311/319)	98.1 (257/262)	97.0 (96/99)	NA	NA	NA	NA
Moderate	28.2 (93/330)	2.2 (7/319)	1.9 (5/262)	3.0 (3/99)	NA	NA	NA	NA
Severe	16.1 (53/330)	0.3 (1/319)	0.0 (0/262)	0.0 (0/99)	NA	NA	NA	NA
Moderate or severe	44.2 (146/330)	2.5 (8/319)	1.9 (5/262)	3.0 (3/99)	NA	NA	NA	NA
Mitral and tricuspid regurgitation								
Moderate or severe MR	34.7 (111/320)	15.3 (49/321)	11.2 (28/251)	4.0 (4/99)	NA	NA	NA	NA
Moderate or severe TR	29.7 (94/316)	20.3 (64/316)	16.7 (41/245)	10.2 (10/98)	NA	NA	NA	NA

Values are mean ± SD or % (n/N), unless otherwise noted.

AR = aortic regurgitation; EOA = effective orifice area; LV = left ventricular; LVEF = left ventricular ejection fraction; MR = mitral regurgitation; TR = tricuspid regurgitation.

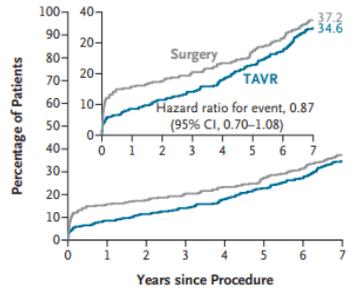
Transcatheter or surgical aortic valve implantation: 10-year outcomes of the NOTION trial

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



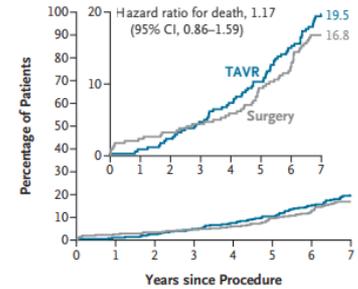
Transcatheter or Surgical Aortic-Valve Replacement in Low-Risk Patients at 7 Years

A Death from Any Cause, Stroke, or Rehospitalization



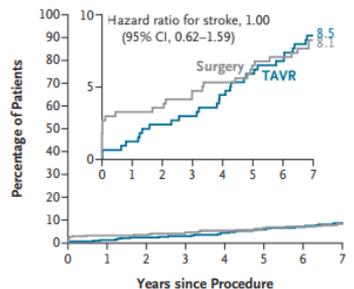
No. at Risk	0	1	2	3	4	5	6	7
TAVR	496	453	435	418	394	366	333	288
Surgery	454	371	349	328	310	288	265	229

B Death from Any Cause (with vital-status sweep)



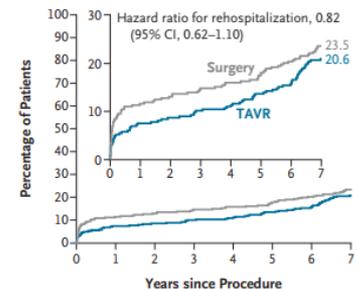
No. at Risk	0	1	2	3	4	5	6	7
TAVR	496	490	481	468	449	433	405	377
Surgery	454	441	430	418	407	390	375	353

C Stroke



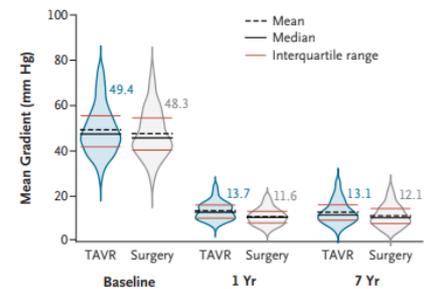
No. at Risk	0	1	2	3	4	5	6	7
TAVR	496	486	470	454	432	407	372	333
Surgery	454	416	398	379	363	344	326	291

D Rehospitalization



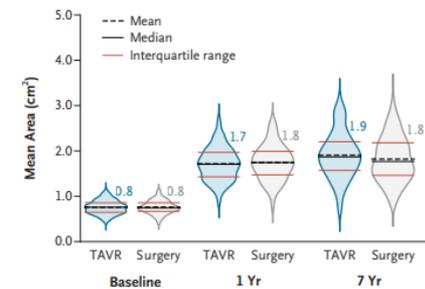
No. at Risk	0	1	2	3	4	5	6	7
TAVR	496	455	440	422	399	375	342	298
Surgery	454	380	359	339	322	301	277	240

A Mean Aortic-Valve Gradient



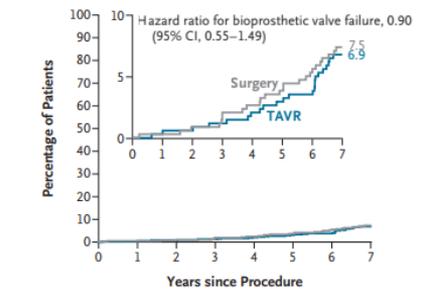
No. of Echos	Baseline	1 Yr	7 Yr
TAVR	483	473	287
Surgery	442	391	246

B Aortic-Valve Area



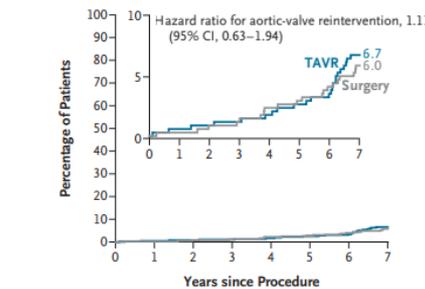
No. of Echos	Baseline	1 Yr	7 Yr
TAVR	458	449	283
Surgery	424	371	241

C Bioprosthetic Valve Failure



No. at Risk	0	1	2	3	4	5	6	7
TAVR	495	487	475	458	432	407	373	329
Surgery	453	426	407	390	372	348	327	288

D Aortic-Valve Reintervention



No. at Risk	0	1	2	3	4	5	6	7
TAVR	496	488	477	461	437	413	378	333
Surgery	454	426	407	391	373	352	332	294



Long-Term Durability of Transcatheter Heart Valves

Insights From Bench Testing to 25 Years

OBJECTIVES This study assessed the long-term durability of nominally deployed transcatheter heart valves (THV) to 1 billion cycles (equivalent to 25 years) and non-nominal (overexpansion, underexpansion, and elliptical) THV deployments to 200 million cycles (equivalent to 5 years) with accelerated wear testing.

BACKGROUND The long-term durability of THVs is currently unknown. As transcatheter aortic valve replacement expands to lower-risk patients, durability will be of increasing importance.

METHODS SAPIEN 3 THVs, sized 20, 23, 26, and 29 mm were assessed. Nominally deployed THVs underwent hydrodynamic performance and mechanical durability as assessed with accelerated wear testing to 1 billion cycles. Magna Ease surgical valves were used as comparators. Durability of non-nominal THV deployments was tested to 200 million cycles. Valves were tested to International Standards Organization 5840:2013 standard.

RESULTS THV durability was excellent for both the nominal and non-nominal THV deployments to 1 billion and 200 million cycles, respectively.

CASE 02

Demographics (age 68 yrs old, M)

HPI:

The patient was admitted urgently with profound bilateral lower extremity edema, excessive weight gain about 50 lb over the last 3-4 weeks. The patient developed profound orthopnea and PND. The patient has poor appetite. He reports shortness of breath at distances of <1 block and has several hospitalizations for congestive heart failure. Symptoms developed over the last 6-12 months.

The patient was previously evaluated for non ischemic cardiomyopathy with baseline ejection fraction about 20%. The patient also has moderate to severe functional mitral regurgitation.

The patient is a Jehovah's Witness and non transplant candidate. The patient has been evaluated before at Mayo Clinic and Cleveland Clinic. The patient is s/p mitral clip in 2018 and has been on optimized medical therapy by heart failure service.

Right heart catheterization indicated profound intravascular fluid overload, low output state.

Intra-aortic balloon pump support was used as initial approach to support aggressive diuresis. Eventually, balloon pump was exchanged for Impella supporting device to improve unloading and forward flow.

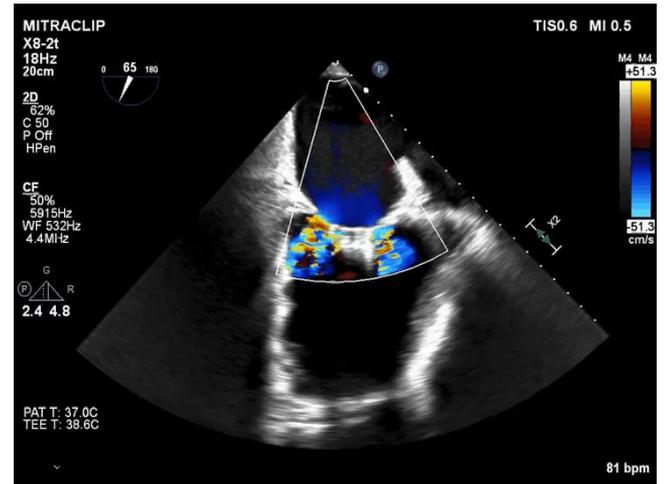
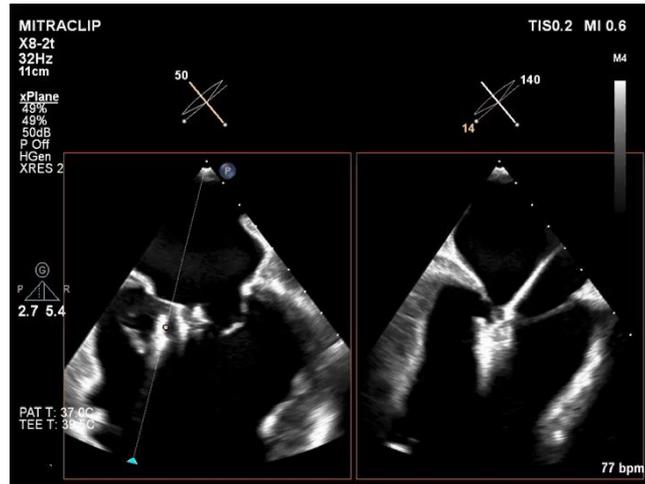
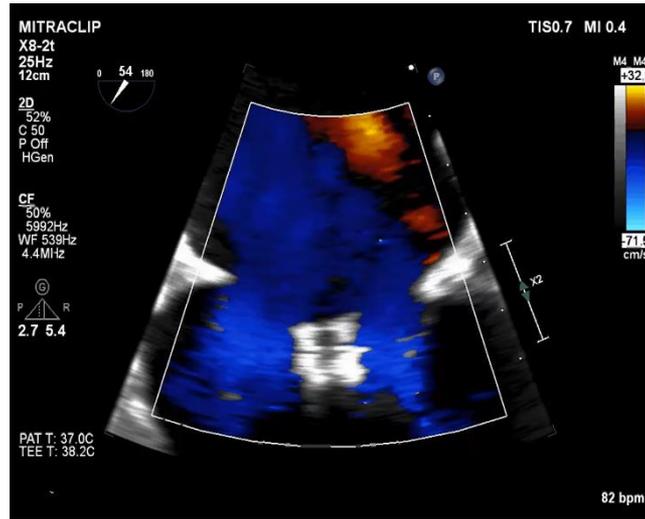
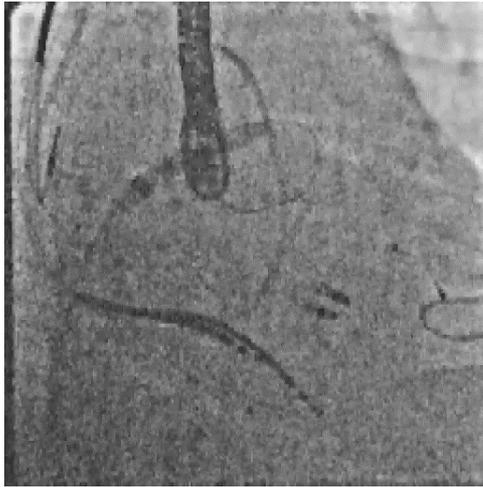
PMH:

Aortic insufficiency
HFrEF with baseline EF at 20%
Status post CRTD
Persistent atrial fibrillation with history of ablation
HTN
HLD
T2DM
OSA on CPAP
GERD
Jehovah's Witness
Gallbladder removed 1985
Appendectomy
Rotator cuff repair 2003

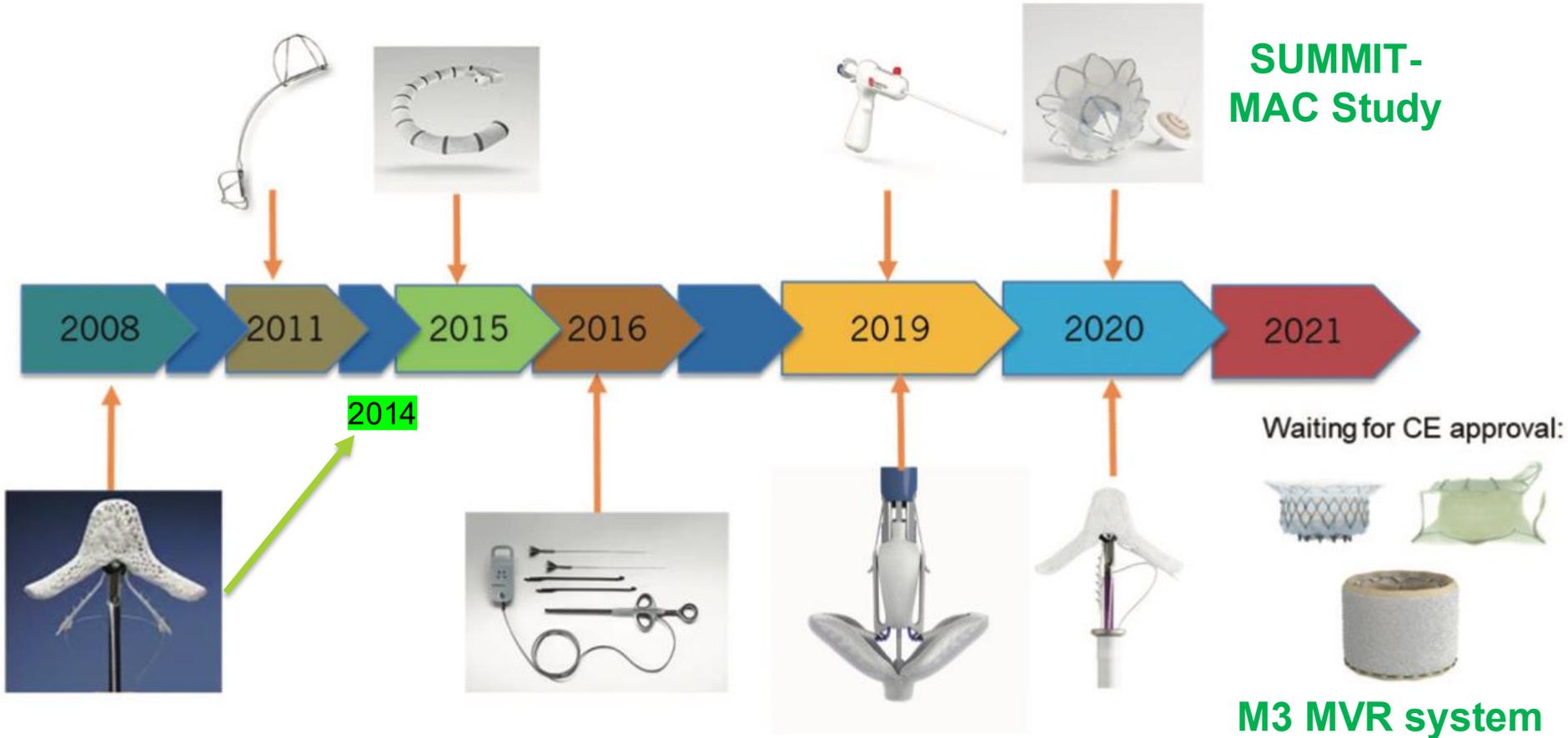
Diagnostic Tests:

11/14/23 TTE:

- LVEF normal w/ evidence of DD
- Mild MR + TR
- Severe AS (pV 4.1, mG 40, AVA 0.8), mod AI



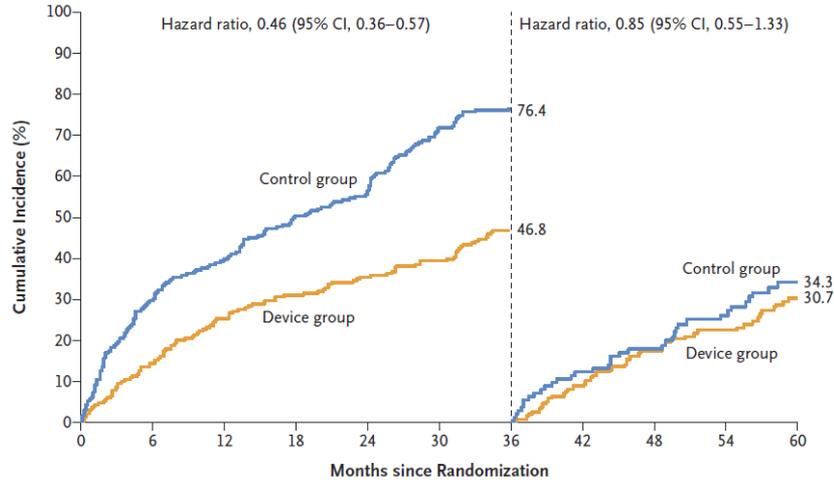
Perspectives on Transcatheter Mitral Therapy



Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation

COAPT ClinicalTrials.gov number, NCT01626079

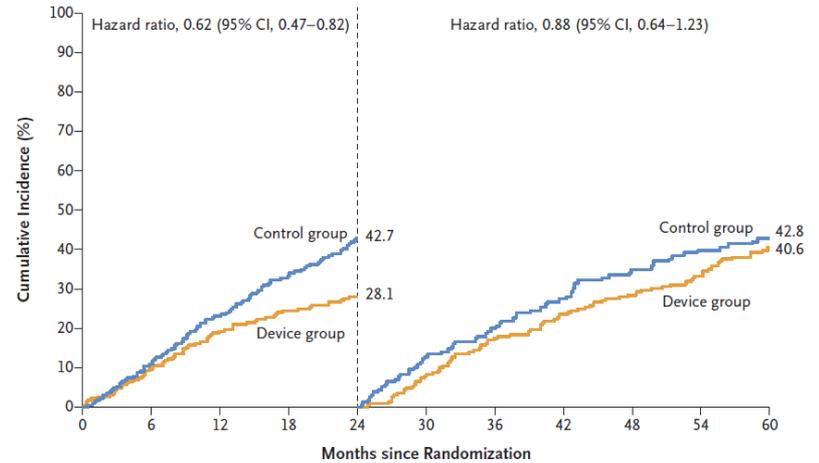
A First Hospitalization for Heart Failure



No. at Risk
Control group
Device group

	0	6	12	18	24	30	36	42	48	54	60
Control group	312	157	95	119	82	43					
Device group	302	194	158	167	119	63					

B Death from Any Cause



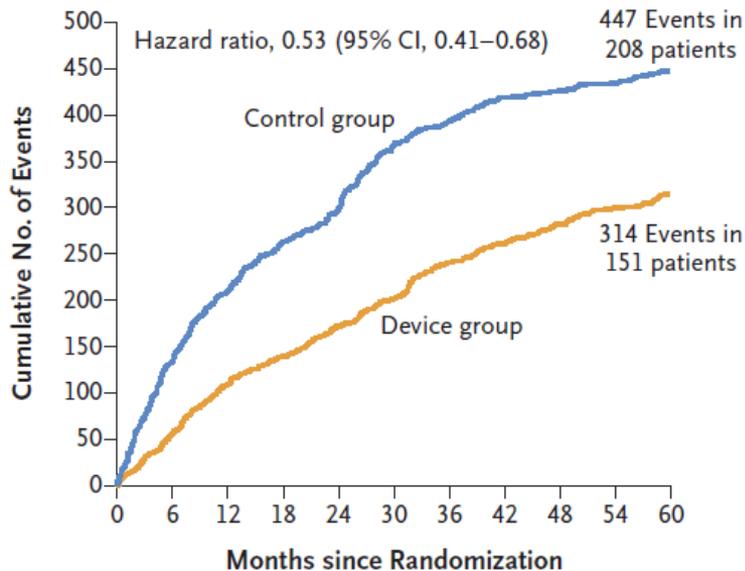
No. at Risk
Control group
Device group

	0	6	12	18	24	30	36	42	48	54	60
Control group	312	224	157	122	94	59					
Device group	302	238	205	167	138	79					

Five-Year Follow-up after Transcatheter Repair of Secondary Mitral Regurgitation

COAPT ClinicalTrials.gov number, NCT01626079

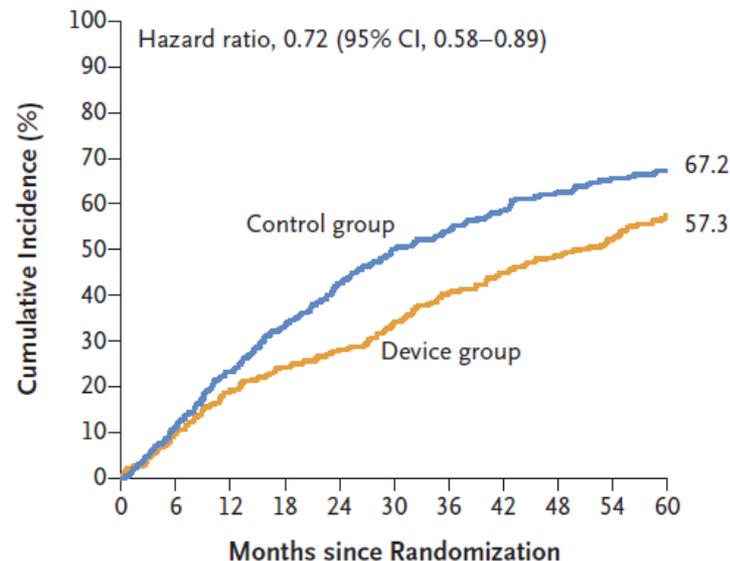
A Hospitalizations for Heart Failure



No. at Risk

Control group	312	272	224	188	156	133	120	106	94	84	59
Device group	302	269	238	219	205	186	167	151	138	124	79

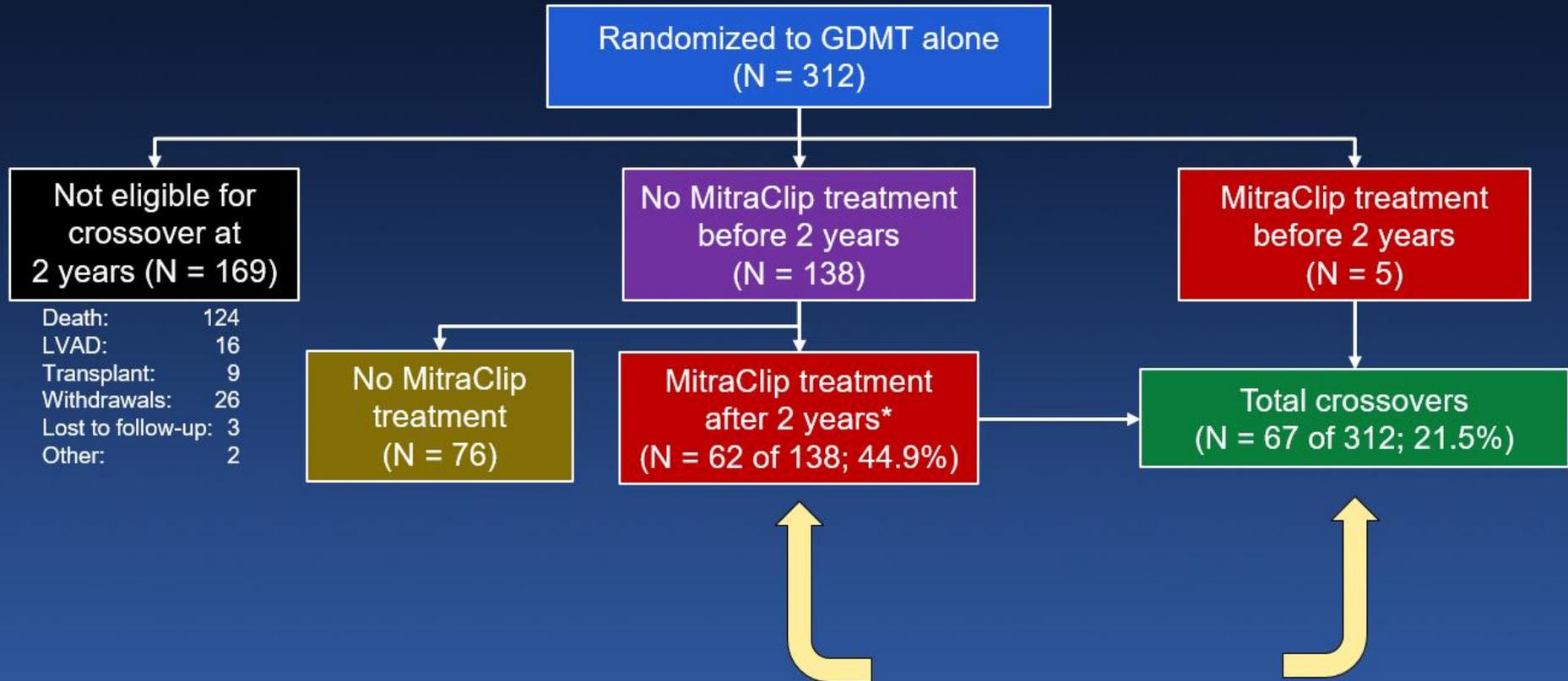
C Death from Any Cause



No. at Risk

Control group	312	272	224	189	157	135	122	107	94	84	59
Device group	302	269	238	219	205	186	167	151	138	124	79

Crossover Treatment in the Control Arm

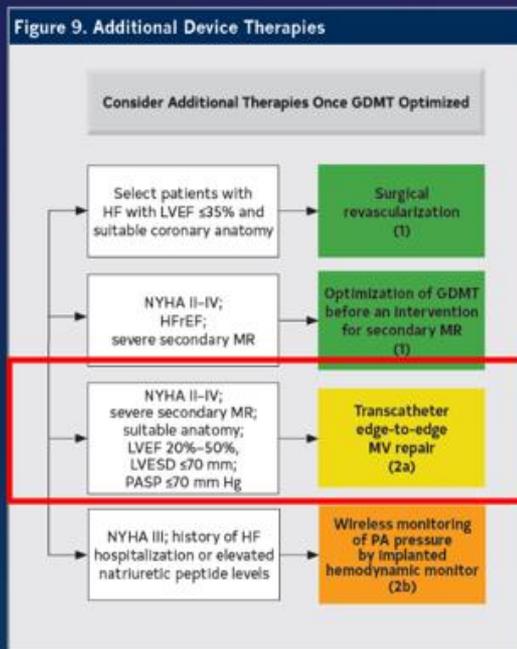


2022 AHA/ACC/HFSA HEART FAILURE GUIDELINE

New Class 2A Recommendation for COAPT-like* Secondary MR Patients with Persistent Symptoms Despite Optimal GDMT

CLASS OF
RECOMMENDATION

IIA



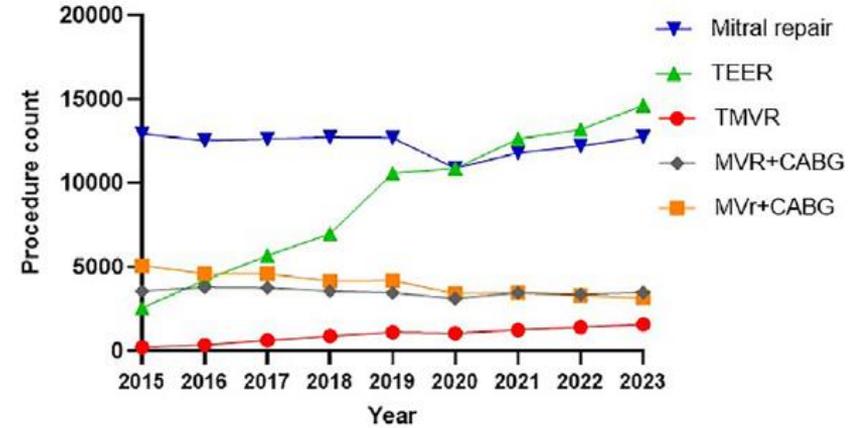
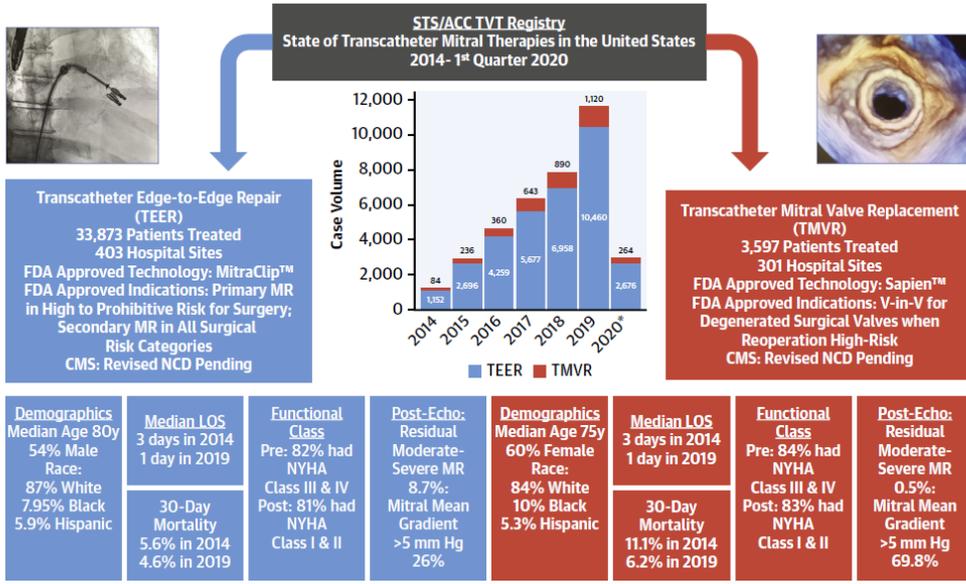
*COAPT-like: NYHA II-IV; severe secondary MR; suitable anatomy; LVEF 20%-50%; LVESD \leq 70 mm; PASP \leq 70 mm Hg

1. Heidenreich PA, et al. "2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association. Joint Committee on Clinical Practice Guidelines." J Am Coll Cardiol. Apr 01, 2022. Epublshed DOI: 10.1016/j.jacc.2021.12.012
2. Otto C, et al. "2020 ACC/AHA Guideline for the Management of Patients With Valvular Heart Disease...." J Am Coll Cardiol. Dec 17, 2020. Epublshed DOI: 10.1016/j.jacc.2020.11.018

See Important Safety Information referenced within.

Transcatheter Mitral Valve Therapy in the United States: A Report from the STS/ACC TVT Registry

Overview of Transcatheter Mitral Valve Procedures in the United States



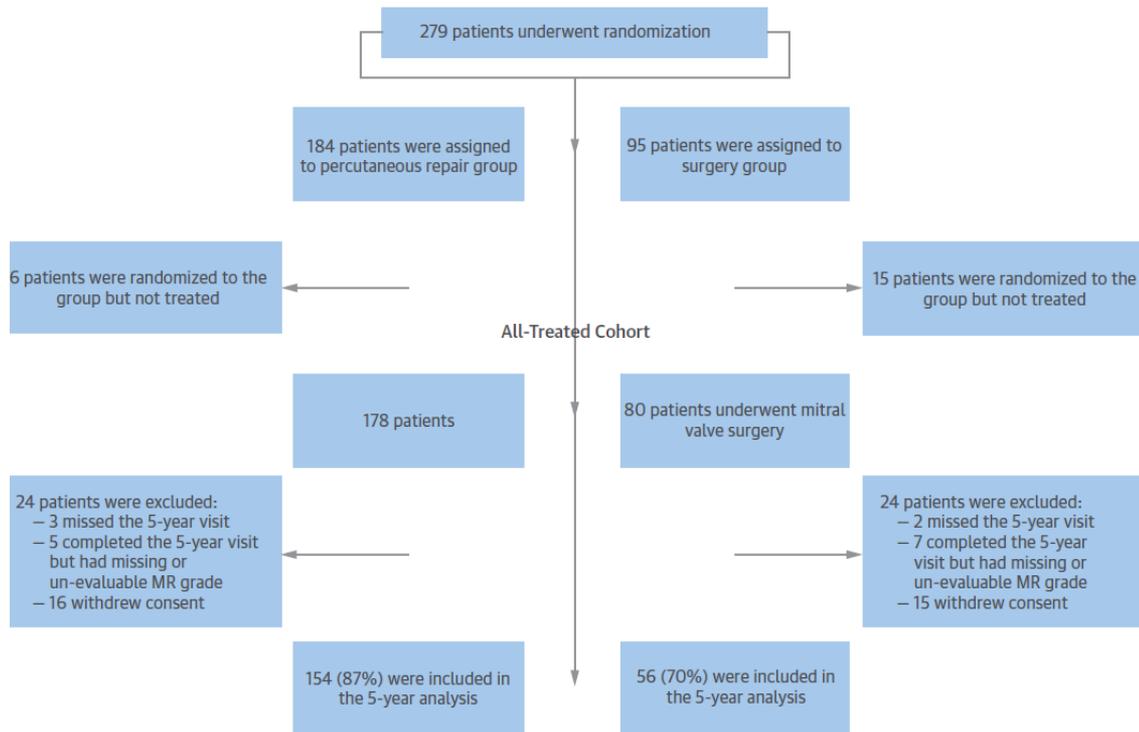
Ann Thorac Surg 2022;113:337-65)

Ann Thorac Surg 2025;119:1139-50

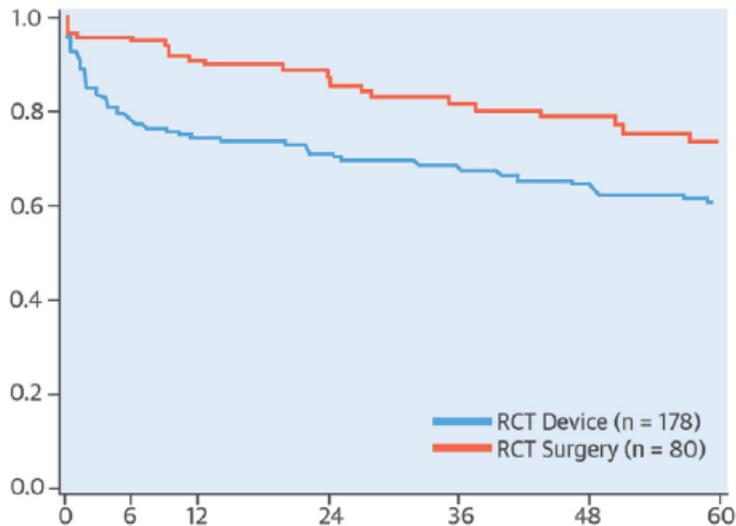
Randomized Comparison of Percutaneous Repair and Surgery for Mitral Regurgitation

5-Year Results of EVEREST II

FIGURE 1 Study Flow: All-Treated Group

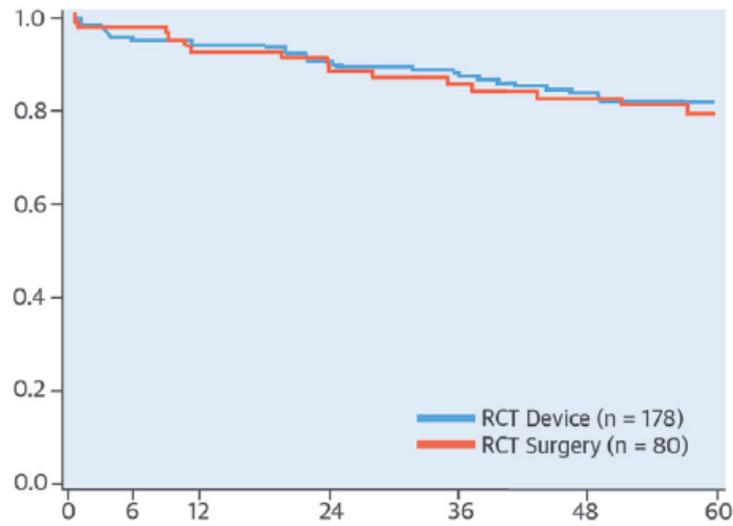


A. Freedom From Death, MV Surgery or Reoperation



Patients At Risk	Months							
	0	6	12	24	36	48	60	
Device Group	178	136	128	117	109	98	45	
Control Group	80	75	69	63	54	49	21	

B. Freedom From Death



Patients At Risk	Months							
	0	6	12	24	36	48	60	
Device Group	178	165	158	143	133	119	58	
Control Group	80	76	70	65	57	52	24	

CASE 03

Demographics (age 91 yrs old, F)

HPI:

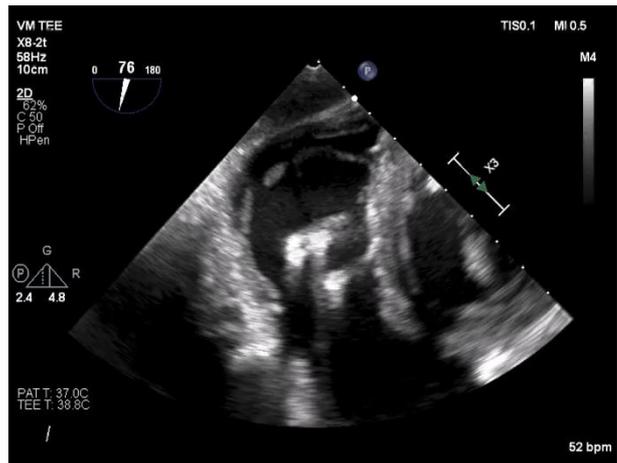
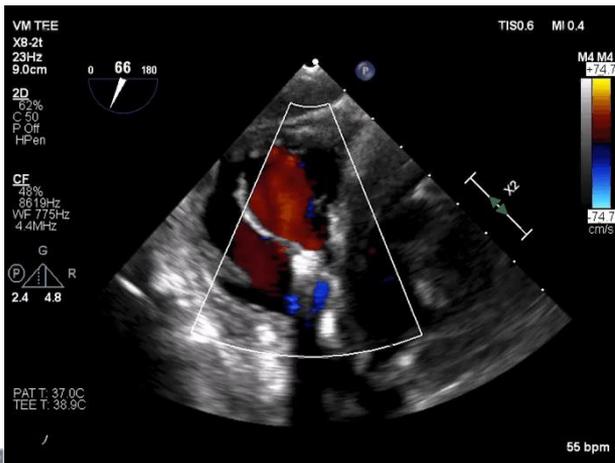
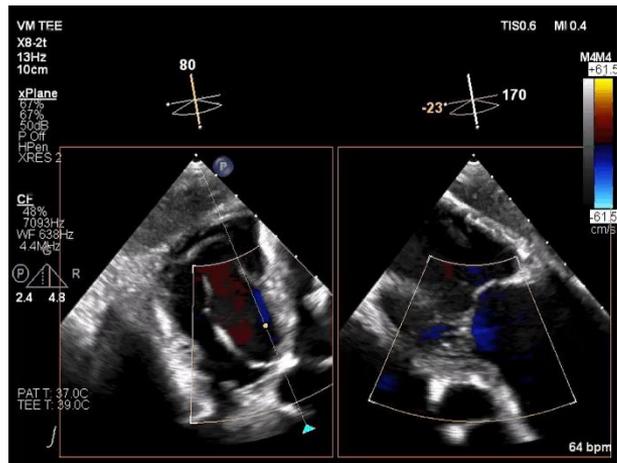
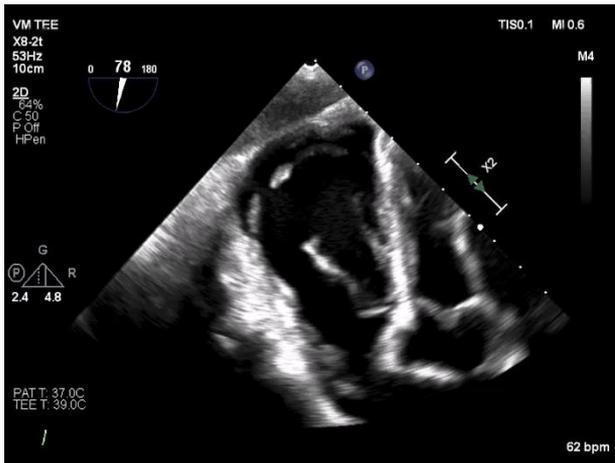
She reports progressive fatigue while walking to bathroom or mailbox. Symptoms developed over the last 6-12 months. She "feels tired all the time". There has been no syncope/near syncope. The patient further denies orthopnea, PND, or peripheral edema. Murmur was appreciated in PCP office.

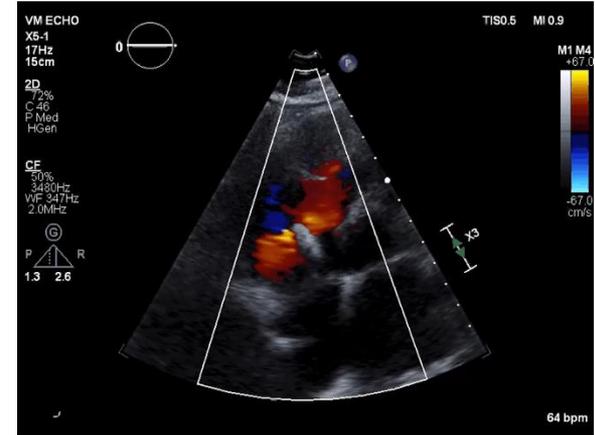
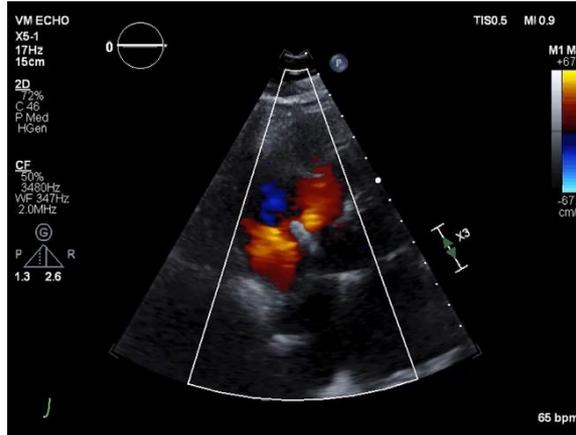
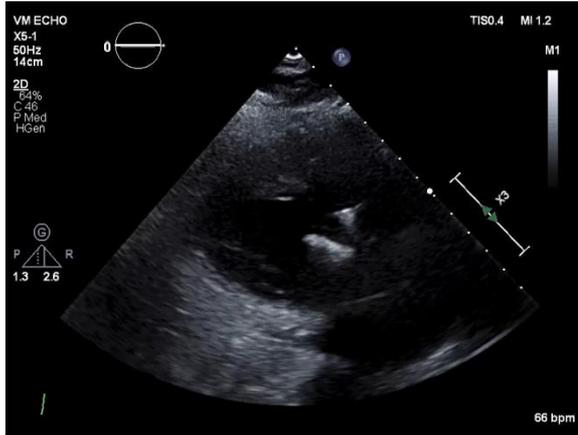
Echo 8/2021: G2DD, LVEF 78%, abnormal septal motion consistent with cardiac surgery. Severe pulmonary HTN and severe TR.

She has been turned down for percutaneous tricuspid valve replacement at the University of Washington.

PMH:

AFL s/p ablation, severe PHTN, HTN, DLD, CKD, Pre DM, CAD and multivessel PCI CTO PCI of the LCX and subsequently the RCA CTO PCI in 12/09/16.





TR: Community Prevalence

≥65 years, n=2500

Screening for undiagnosed VHD

51% had newly diagnosed VHD

2X ↑ Low socioeconomic status, 3x ↑ in AF

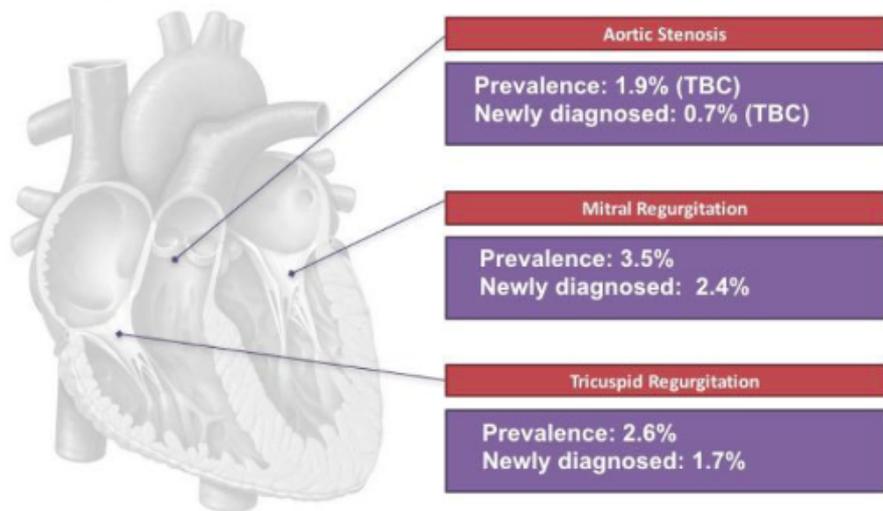
21,020 TTEs, 1990-2000

N=417 with ≥ mod TR

0.55% age/sex-adjusted US prevalence

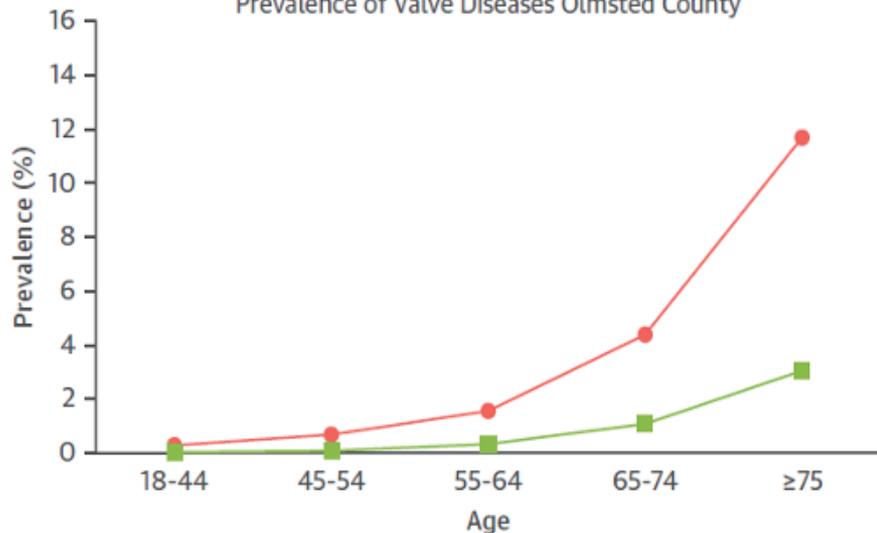


Moderate/Severe Heart Valve Disease



By 2050, projected doubling in incidence of VHD

Prevalence of Valve Diseases Olmsted County



● Combined Prevalence of AS, MS, AR and MR

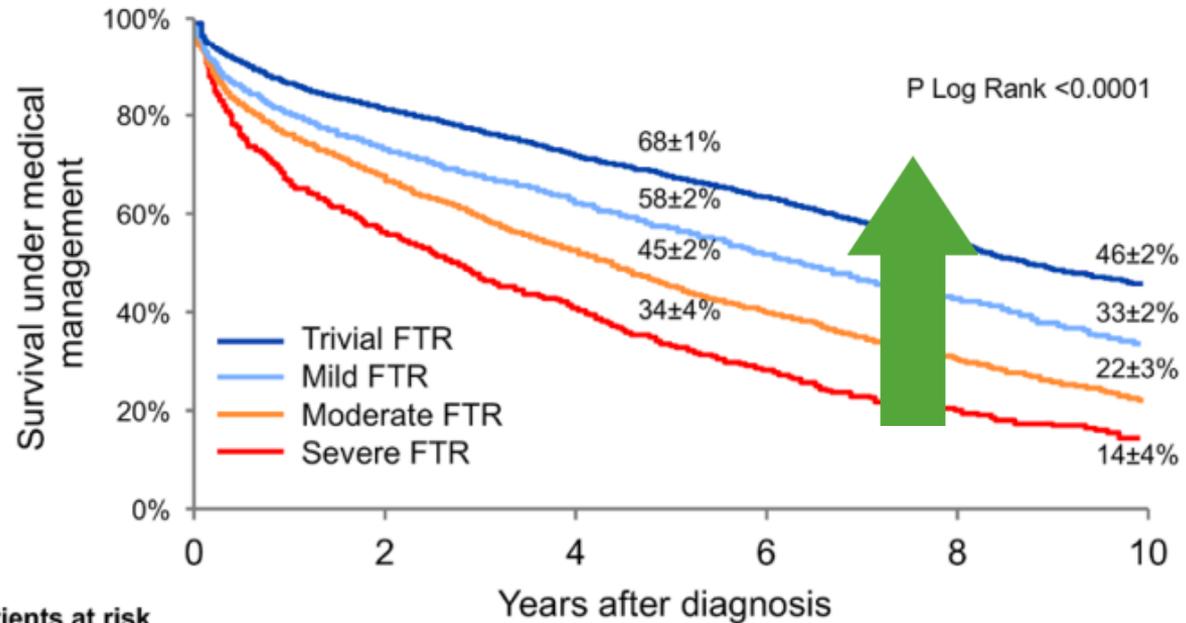
■ Prevalence of All Cause TR ≥ Moderate

Excess Mortality Associated With Functional Tricuspid Regurgitation Complicating Heart Failure With Reduced Ejection Fraction

The cohort of all Mayo Clinic patients from 2003 to 2011 diagnosed with heart failure stage B-C

EF<50%

FTR grading by Doppler

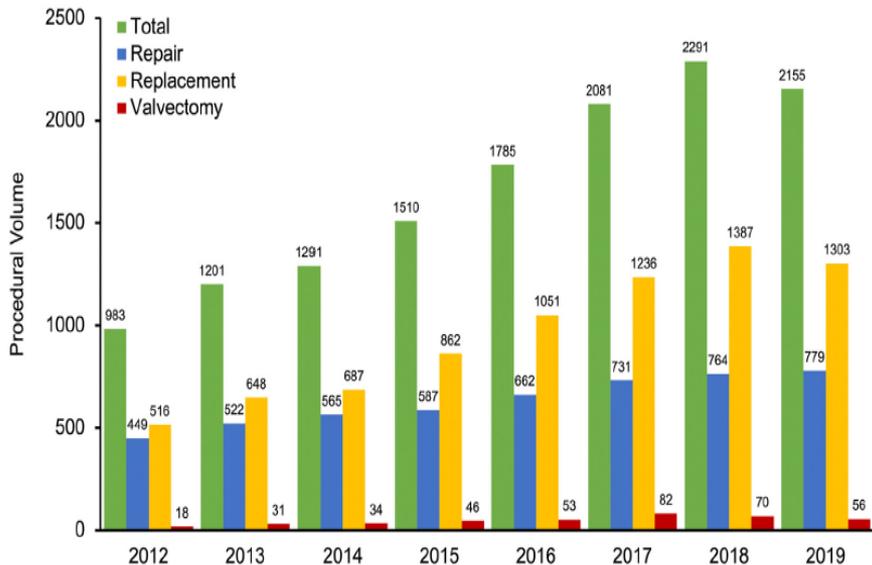


Patients at risk

Trivial FTR	4329	3218	3069	2384	1640	762
Mild FTR	4178	2789	2119	1384	809	359
Moderate FTR	2255	1336	935	555	307	119
Severe FTR	745	352	230	135	65	23

Isolated Tricuspid Operations: The Society of Thoracic Surgeons Adult Cardiac Surgery Database Analysis

A Trends in procedural volume stratified by isolated tricuspid surgery type



B

Trends in procedural volume stratified by presence of endocarditis

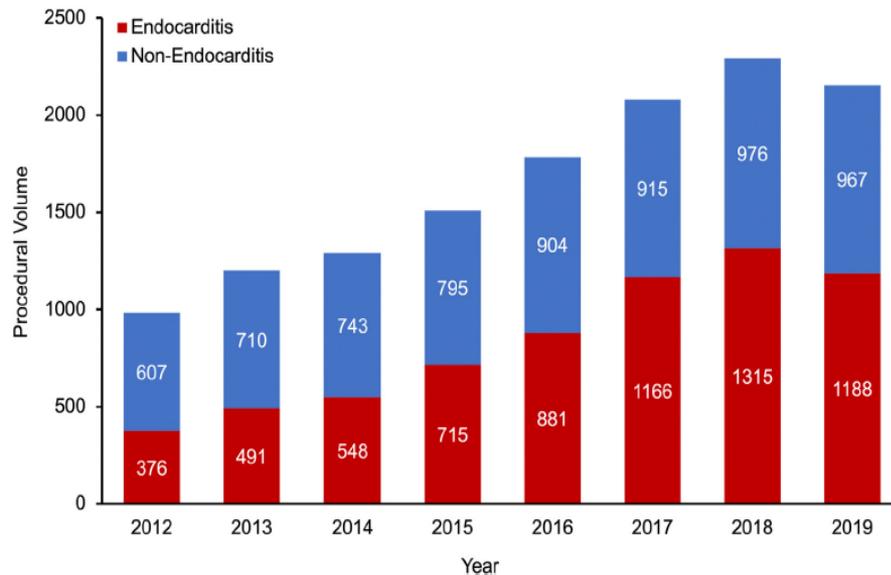
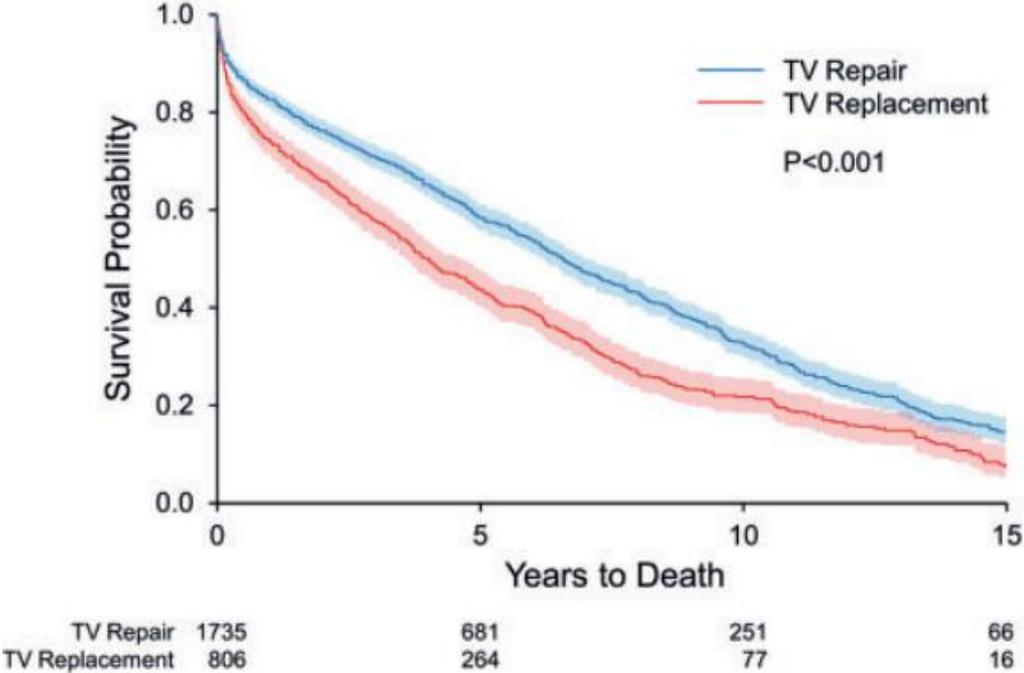


TABLE 3 Short-term Outcomes Stratified by Tricuspid Repair vs Replacement and Beating Heart vs Full Arrest Operations

Characteristics	All Patients (n = 6507)	Repair (n = 3308)	Replacement (n = 3199)	P Value	Beating Heart (n = 2435)	Full Arrest (n = 3901)	P Value
Operative mortality	7.3 (474)	5.2 (173)	9.4 (301)	<.001	9.2 (225)	6.0 (235)	<.001
Composite major complications	32.0 (2082)	23.1 (765)	41.3 (1320)	<.001	34.7 (845)	30.2 (1179)	<.001
Permanent stroke	1.5 (100)	1.2 (38)	1.9 (62)	.01	1.9 (47)	1.2 (48)	.03
Prolonged ventilation	20.2 (1315)	14.8 (490)	25.8 (825)	<.001	24.4 (594)	17.4 (677)	<.001
Cardiac reoperation	4.3 (281)	5.1 (167)	7.4 (238)	<.001	7.4 (179)	5.6 (217)	.004
New PPM/ICD implantation	10.8 (702)	6.1 (200)	15.7 (502)	<.001	9.2 (223)	11.9 (464)	<.001
Renal failure	6.8 (444)	4.5 (148)	9.3 (296)	<.001	8.1 (196)	6.1 (237)	.003
New dialysis requirement	5.5 (359)	3.4 (113)	7.7 (246)	<.001	6.7 (163)	4.8 (186)	.001
Deep sternal wound infection	0.4 (28)	0.3 (9)	0.6 (19)	.05	0.4 (10)	0.5 (18)	.77
Blood product transfusions	46.4 (3022)	37.6 (1242)	55.6 (1779)	<.001	52.7 (1284)	42.2 (1646)	<.001
Hospital length of stay, d	8 (6-12)	7 (5-11)	9 (6-14)	<.001	9 (6-14)	7 (5-11)	<.001

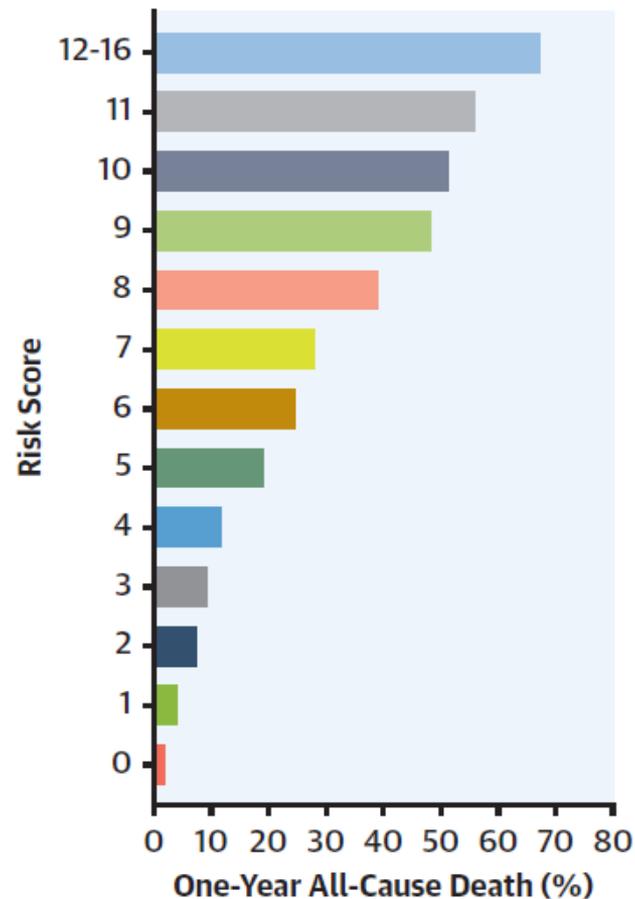
Values are in % (n) or median (interquartile range). ICD, implantable cardioverter-defibrillator; PPM, permanent pacemaker.

Long-term Outcomes of Patients Undergoing Tricuspid Valve Surgery

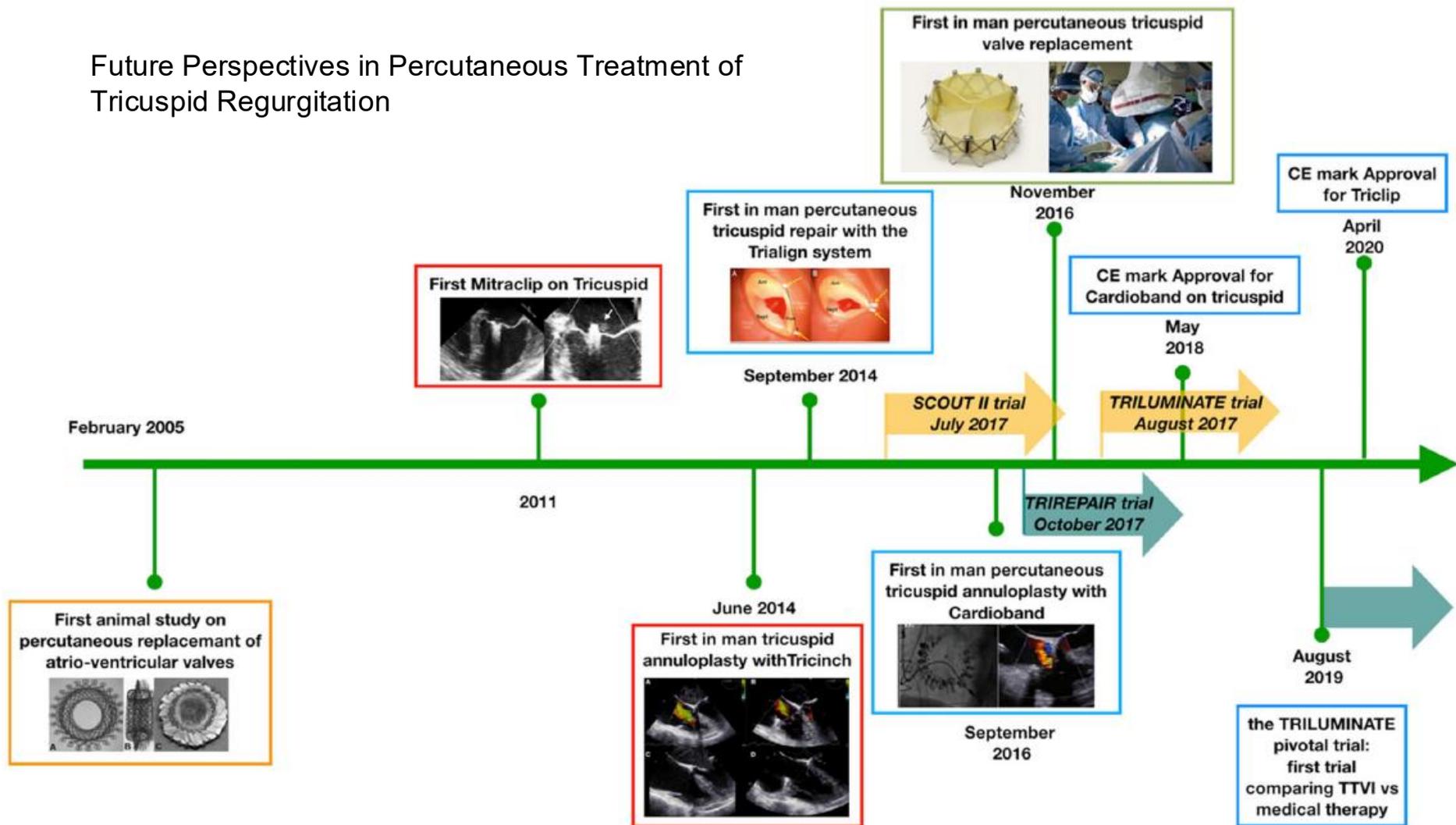


Risk Model for 1-Year All-Cause Mortality in Isolated Secondary TR

Parameter	Score
Age	
65-74 years	1
75+ years	2
Myocardial infarction	1
Peripheral vascular disease	1
Chronic lung disease	1
Chronic kidney disease (creatinine >1.4 mg/dL)	1
Loop diuretic use	1
Anemia (hemoglobin <10 g/dL)	1
Thrombocytopenia (platelet <15 k/ μ L)	1
International normalized ratio >1.5	1
Albumin <3.0 g/dL	2
Right ventricle systolic function	
Mildly impaired	1
Moderately impaired	2
Severely impaired	3
Right ventricular systolic pressure >50 mm Hg	1
Total score	16

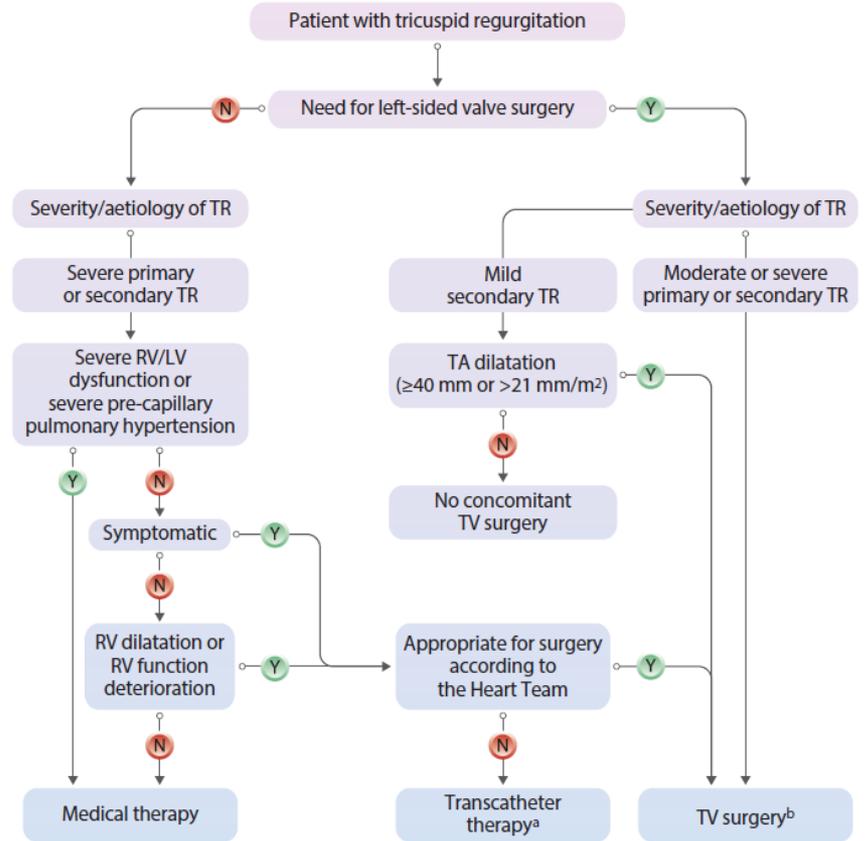
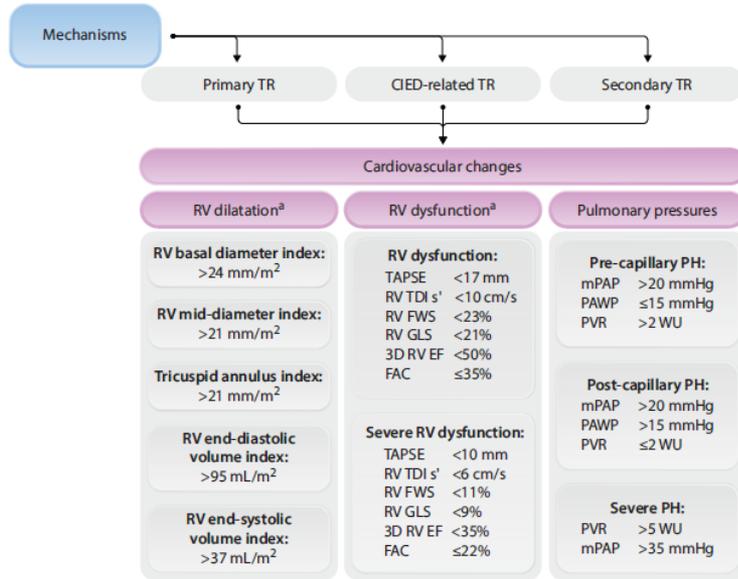


Future Perspectives in Percutaneous Treatment of Tricuspid Regurgitation



2025 ESC/EACTS Guidelines for the management of valvular heart disease

Developed by the task force for the management of valvular heart disease of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS)



Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation: 3-Year Outcomes From the TRILUMINATE Study

for the TRILUMINATE Pivotal Investigators

350 patients, 175 to each group.

The mean age of the patients was 78 years,
54.9% were women.

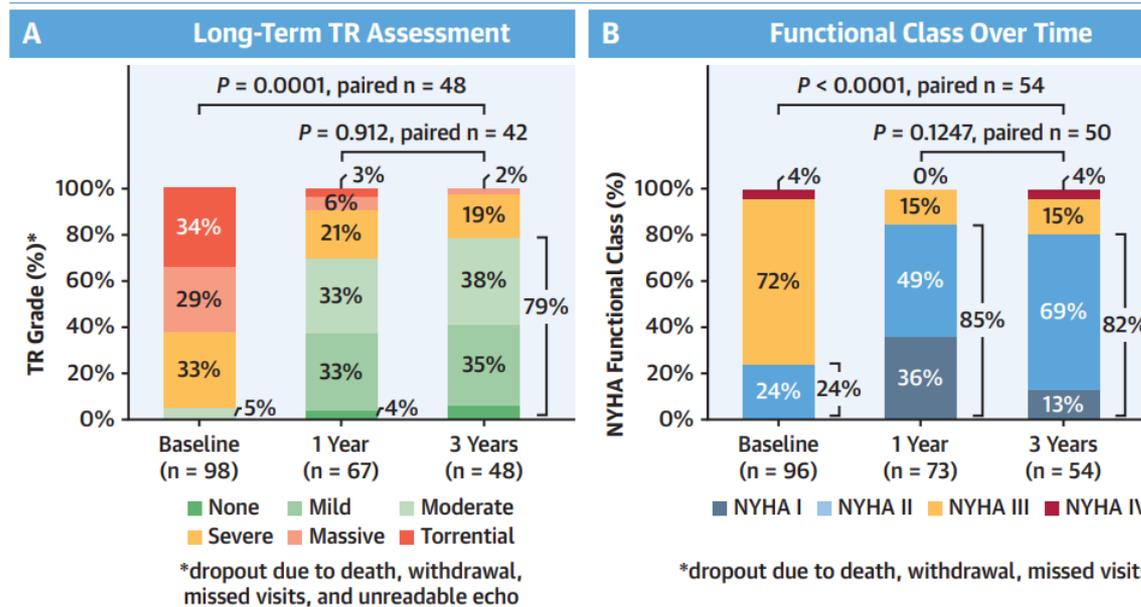
The results for the primary end point favored the TEER group (win ratio, 1.48; 95% confidence interval, 1.06 to 2.13; $P=0.02$).

The incidence of death or tricuspid-valve surgery and the rate of hospitalization for heart failure did not appear to differ between the groups.

The KCCQ quality-of-life score changed by a mean (\pm SD) of 12.3 ± 1.8 points in the TEER group, as compared with 0.6 ± 1.8 points in the control group ($P<0.001$).

Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation: 3-Year Outcomes From the TRILUMINATE Study

for the TRILUMINATE Pivotal Investigators

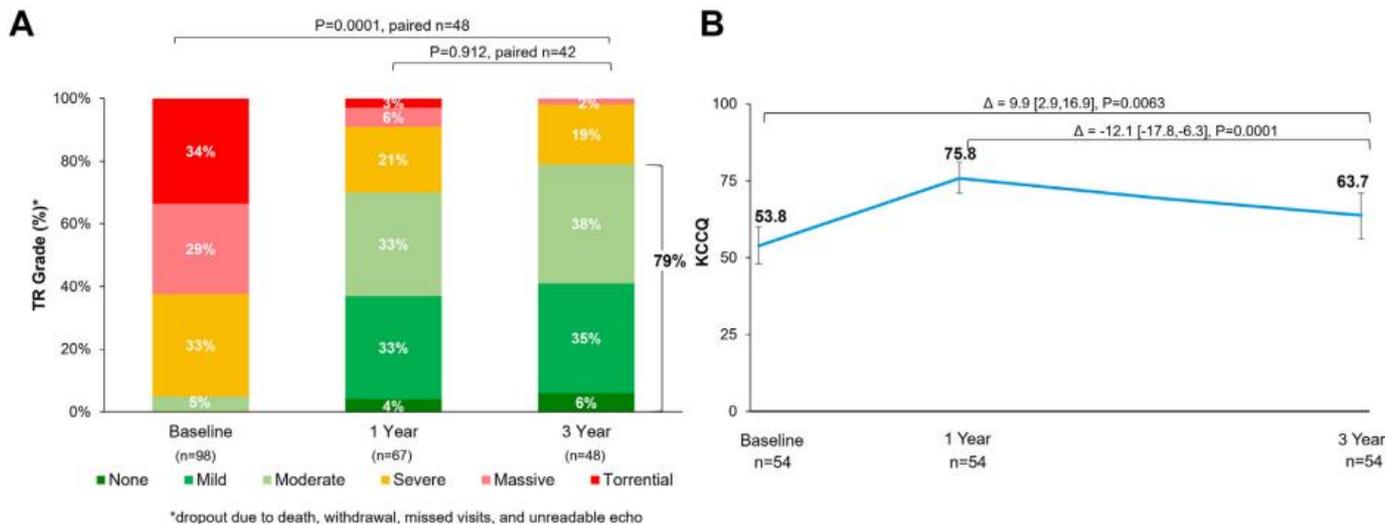


- At 3-year follow-up, there was a substantial and durable reduction in TR following TEER
- NYHA functional class improved following TEER, and this benefit remained over time

Percutaneous Edge-to-Edge Repair for Tricuspid Regurgitation: 3-Year Outcomes From the TRILUMINATE Study

for the TRILUMINATE Pivotal Investigators

FIGURE 1 TR Reduction and KCCQ Improvement

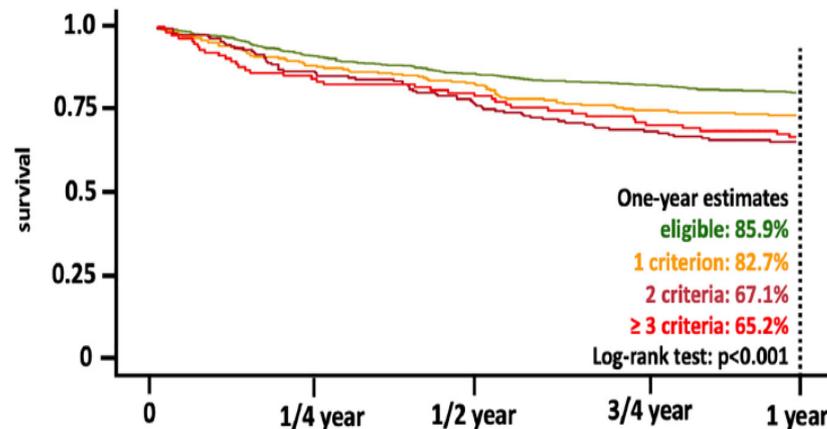


(A) Tricuspid regurgitation (TR) reduction sustained from 1 year to 3 years. (B) The decrease in the Kansas City Cardiomyopathy Questionnaire (KCCQ) score observed from 1 year to 3 years, although a significant improvement from baseline to 3 years remains.

Applying the TRILUMINATE Eligibility Criteria to Real-World Patients Receiving Tricuspid Valve Transcatheter Edge-to-Edge Repair

TABLE 1 Study Characteristics

	All Patients (N = 962)	TRILUMINATE Eligible (n = 527)	TRILUMINATE Ineligible (n = 435)	P Value
Clinical characteristics				
Age, y	78.3 ± 7.3	78.6 ± 6.8	78.0 ± 7.8	0.439
Female	482 (50.1)	273 (51.8)	209 (48.0)	0.249
BMI, kg/m ²	26.0 ± 5.0	26.2 ± 5.2	25.9 ± 4.7	0.493
EuroSCORE II, %	6.2 ± 6.0	5.6 ± 4.9	7.0 ± 7.0	<0.001
Laboratory data				
NT-proBNP, pg/mL	5262 ± 10836	3531 ± 4672	7326 ± 14962	<0.001
Bilirubin, mg/dL	0.99 ± 0.70	0.91 ± 0.56	1.07 ± 0.81	0.007
GGT, U/L	149.4 ± 145.6	139.3 ± 137.6	161.1 ± 153.7	0.002
AP, U/L	132.0 ± 81.3	130.4 ± 79.3	133.4 ± 82.2	0.688
AST, U/L	31.7 ± 18.8	32.1 ± 21.3	31.2 ± 15.1	0.307
ALT, U/L	22.6 ± 21.8	22.7 ± 20.0	22.5 ± 23.7	0.245
CHS	333 (38.0)	150 (31.8)	183 (45.6)	<0.001
Creatinine, mg/dL	1.6 ± 0.9	1.5 ± 0.7	1.8 ± 1.1	<0.001
eGFR, mL/min	46.5 ± 22.2	48.9 ± 21.9	44.0 ± 19.2	0.003
eGFR <60 mL/min	472 (75.6)	235 (71.6)	237 (80.1)	0.014
Heart failure symptoms and QoL				
Number of HFHs <12 mo	0.86 ± 0.84	0.66 ± 0.69	1.10 ± 0.93	<0.001
Any HFH <12 mo	618 (64.8)	290 (55.8)	328 (75.6)	<0.001
MLHFQ score	38.5 ± 18.6	38.7 ± 19.0	38.3 ± 18.3	0.943
6MWD, m	239.8 ± 116.2	248.0 ± 115.8	229.3 ± 116.0	0.028
NYHA functional class ≥III	850 (89.0)	460 (88.0)	390 (90.3)	0.253
Medications				
Beta-blockers	826 (86.2)	444 (84.7)	382 (88.0)	0.142
RAS inhibitors	383 (61.2)	201 (60.9)	182 (61.5)	0.882
Loop diuretic agents	901 (93.8)	494 (93.9)	407 (93.6)	0.822
Furosemide-equivalent dose, mg/d	64.3 ± 88.2	65.8 ± 78.3	62.8 ± 96.9	0.040
Thiazide diuretic agent	138 (23.5)	47 (19.1)	91 (26.8)	0.031
MRA	373 (39.0)	198 (37.9)	175 (40.3)	0.437



TRILUMINATE eligible	527 (100)	404 (92)	300 (57)
1 exclusion criterion	202 (100)	254 (97)	116 (57)
2 exclusion criteria	148 (100)	116 (83)	71 (48)
≥ 3 exclusion criteria	85 (100)	42 (68)	44 (52)

Inclusion Criteria

- Age \geq 18 years
- Signs and/or symptoms or prior heart failure hospitalization from TR despite optimal medical therapy (OMT) per the local Heart Team
- Functional or degenerative TR \geq moderate
- Patient appropriate for transcatheter tricuspid valve replacement

Exclusion Criteria

- Tricuspid valve anatomy precludes proper device deployment and function
- Previous tricuspid intervention interfering with the device
- Severe right ventricular dysfunction
- LVEF $<$ 25%

Inclusion Criteria

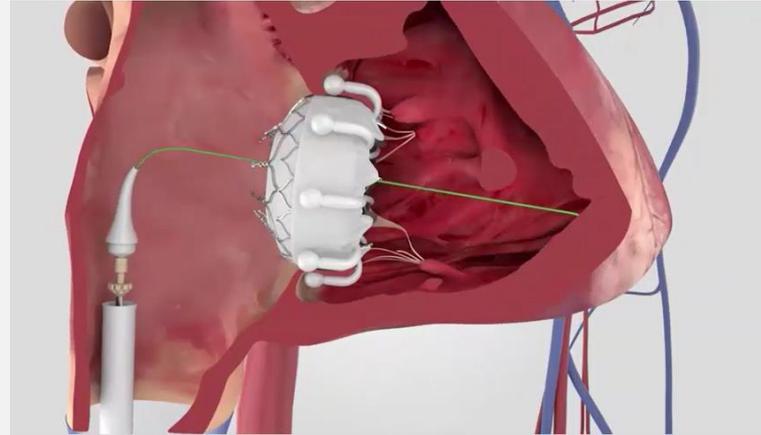
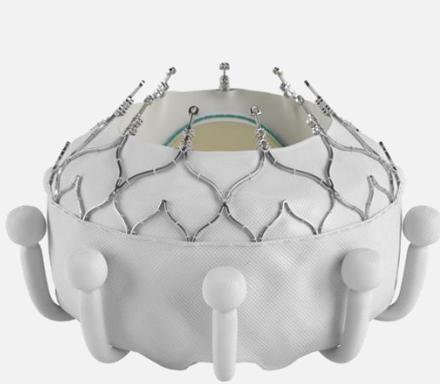
- Age \geq 18 years
- Symptomatic TR despite optimal medical therapy
- TR graded as \geq severe
- Patient appropriate for transcatheter tricuspid valve replacement per the local heart team

Exclusion Criteria

- Tricuspid valve anatomic contraindications
- Need for emergent or urgent surgery or any planned cardiac surgery within the next 12 months
- Hemodynamic instability
- Refractory heart failure requiring advanced intervention
- Currently participating in another investigational study in which the patient has not reached a primary endpoint

EVOQUE Tricuspid Valve Replacement System

Unique valve design engages leaflets, chords, and annulus to achieve secure placement



Atraumatic anchors compatible with pre-existing leads and respect the native anatomy

Conforming frame designed to achieve optimal retention force

Multiple sizes offer treatment for a broad range of tricuspid pathologies and anatomies (44, 48, 52 mm)

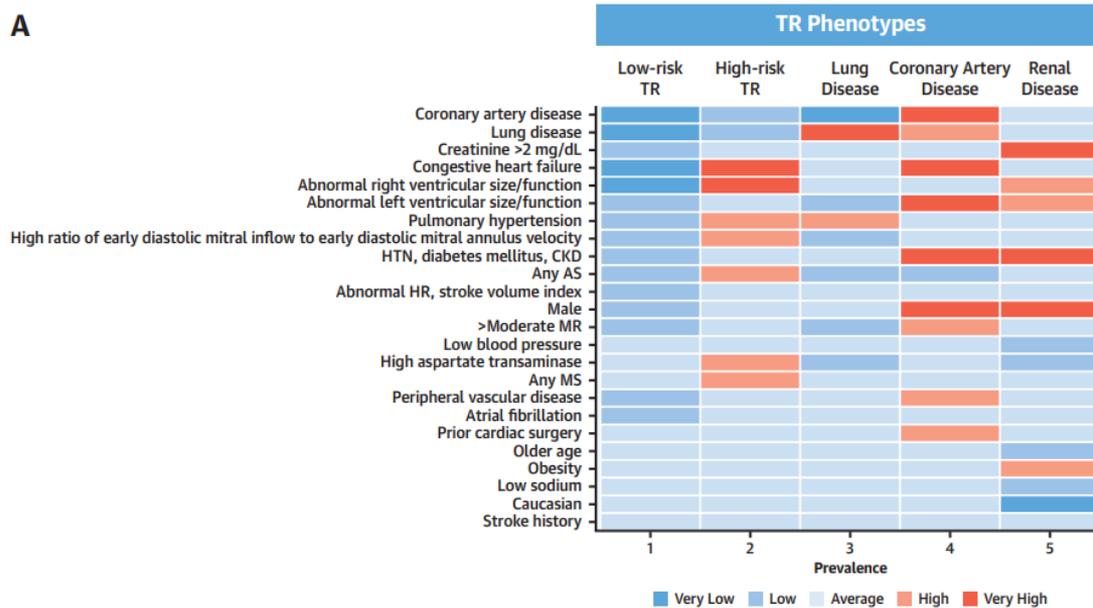
28F transfemoral delivery system compatible with all valve sizes



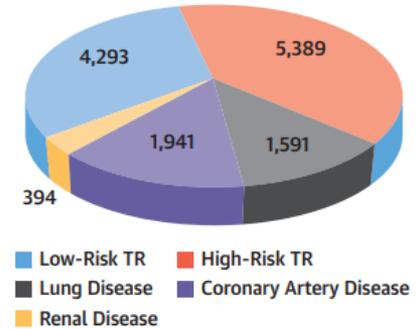
The 5 Phenotypes of Tricuspid Regurgitation

Insight From Cluster Analysis of Clinical and Echocardiographic Variables

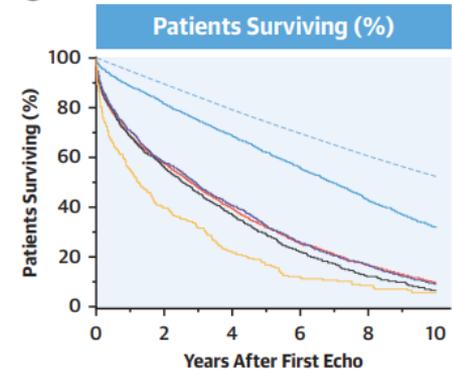
A



B



C



Long-term outcomes of phenoclusters in severe tricuspid regurgitation

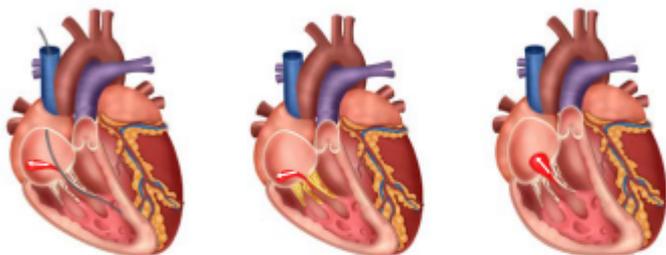
2.7% had new diagnosis of severe TR (N=3,395)

Grouped by severe TR etiology

TR with lead present

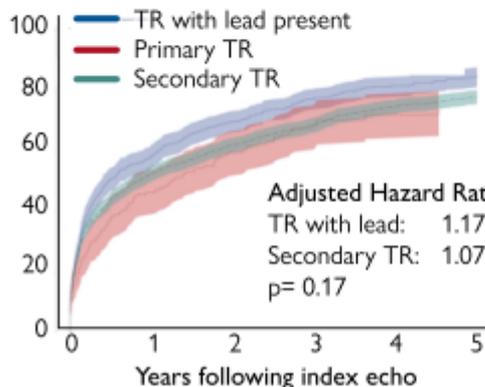
Primary TR

Secondary TR



Similar five-year composite death or HFH by TR etiology

Cumulative incidence (95%CI)



Clusters derived from supervised survival tree

Clusters exhibited different five-year outcomes

Cluster 1

- Younger age
- Heart failure
- ≥ Mod RV failure
- Severe MR
- Pulmonary HTN
- Worse kidney function
- Low blood pressure
- High RDW
- Higher LFTs

Cluster 2

- Older age
- Secondary TR
- Worse kidney function

Cluster 3

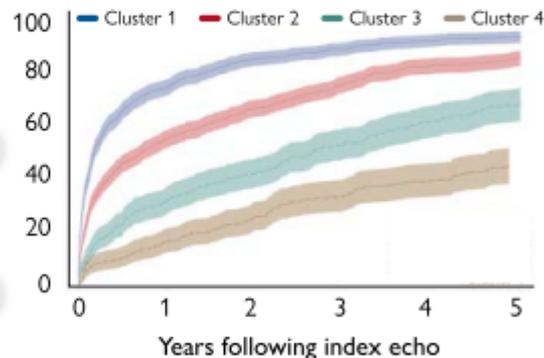
- Female
- Heart failure
- Prior cardiac surgery
- Normal kidney function
- Severe MR

Cluster 4

- Older age
- Female
- White
- Secondary TR
- No heart failure
- Normal kidney function

Five-year composite death or HFH by cluster

Cumulative incidence (95%CI)



Cluster at risk

Cluster	Year 0	Year 1	Year 2	Year 3	Year 4	Year 5
1	873	230	118	76	50	33
2	895	410	270	173	116	82
3	339	229	170	112	73	53
4	272	227	182	143	115	89



Summary

1. Transcatheter aortic valve intervention
2. Transcatheter mitral valve intervention
3. Transcatheter tricuspid valve intervention
4. Updates on clinical trial and post market data

Transcatheter Cardiac and Valve Intervention

Mitral:

Valve in Valve

Valve in Ring

Valve in Mac

Leaflet edge to edge repair (TEER)

Valve replacement

Paravalvular leak closure*

Tricuspid:

Valve in valve*

Paravalvular leak closure

Leaflet edge to edge repair procedure
(TEER)

Transcatheter valve implantation

Aortic:

Complex vascular access (TAVR)

Complex leaflet modification (TAVR)

Paravalvular leak closure*

Pulmonic:

Valve in valve (post Ross or tetralogy repair)

Pulmonic valvuloplasty

ASD/PFO/VSD/PDA closure

Alcohol septal ablation for hypertrophic cardiomyopathy (joint service with HOCM program) *

Foreign Body/Vegetation Retrieval (snare, forceps, and Angiovac)

Thank You

