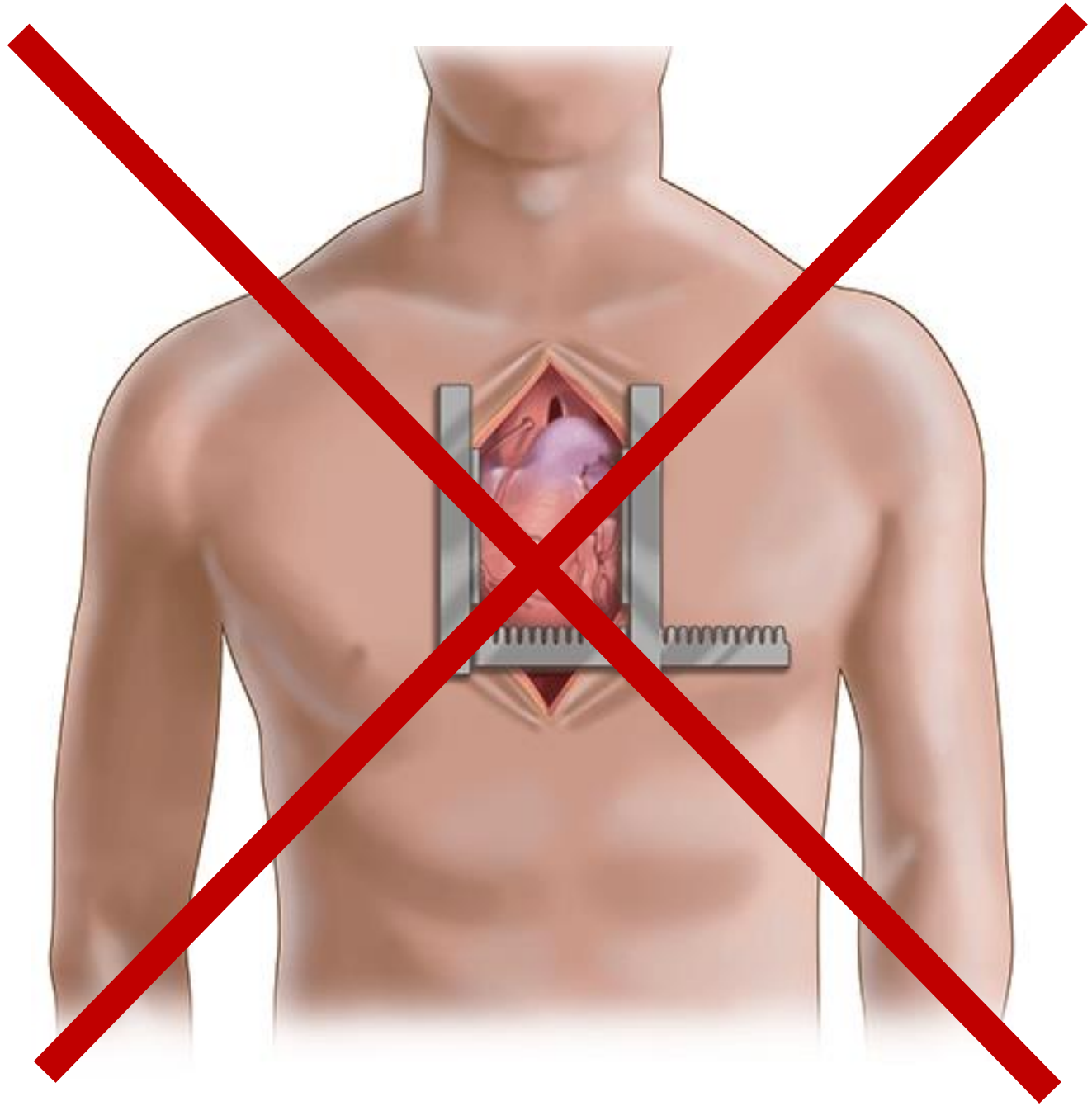
Percutaneous Heart Valve Update

James G. Jollis, MD FACC

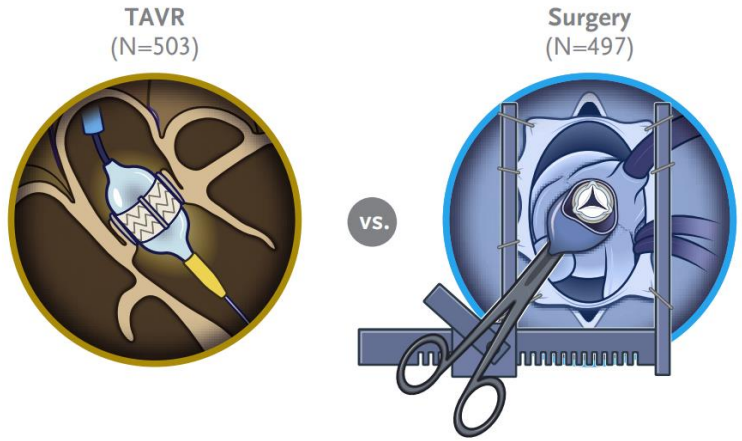
Duke University

Percutaneous Heart Valve Update

- Aortic
  - Low risk aortic stenosis
  - Aortic regurgitation
- Mitral
  - Edge-to-edge clip with heart failure
- Tricuspid
  - Evoque valve



Partner 3



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

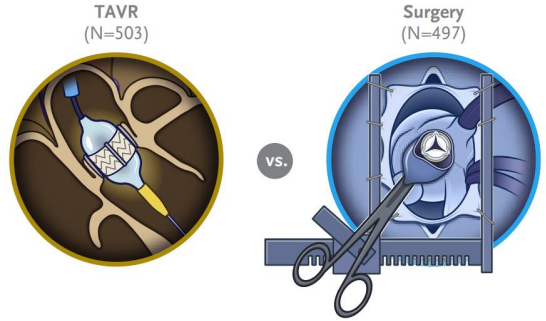
Transcatheter Aortic-Valve Replacement in Low-Risk Patients at Five Years

M.J. Mack, M.B. Leon, V.H. Thourani, P. Pibarot, R.T. Hahn, P. Genereux, S.K. Kodali, S.R. Kapadia, D.J. Cohen, S.J. Pocock, M. Lu, R. White, M. Szerlip, J. Ternacle, S.C. Malaisrie, H.C. Herrmann, W.Y. Szeto, M.J. Russo, V. Babaliaros, C.R. Smith, P. Blanke, J.G. Webb, and R. Makkar, for the PARTNER 3 Investigators*

N Engl J Med 2023;389:1949-60.

Partner 3

Low risk AS, 5-year result



- 1000 pts.
- Symptomatic severe aortic stenosis
- Age >= 65
- Low risk

STS 1.9% - Age 73, 69% male, 9% non-white, CAD 28%, DM 30%

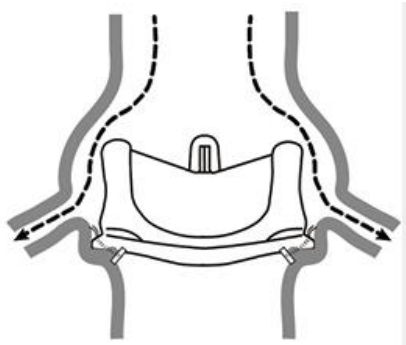
- 1:1 Surgical or TAVR Aortic Valve Replacement
- 1^0 end point - death, stroke, or rehosp.

N Engl J Med 2023;389:1949-60.

Partner 3

Implanted valve type

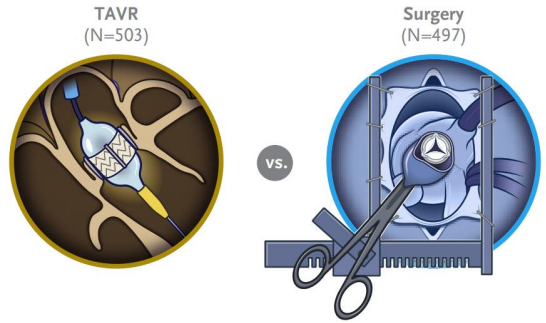
Manufacturer and Model, No (%)	TAVR (N=495)	Surgery (N=453)
Edwards Lifesciences		
SAPIEN 3 transcatheter heart valve	495 (100)	-
Carpentier Edwards Perimount		15 (3.3)
Magna		56 (12.4)
Magna Ease		231 (51)
Intuity / Intuity Elite		20 (4.4)
Medtronic		
Mosaic / Mosaic Ultra		25 (5.5)
Freestyle		3 (0.7)
Hancock II		4 (0.9)
Abbott / St Jude Medical		
Trifecta		72 (15.9)
Epic / Epic Ultra		5 (1.1)
LivaNova		
Perceval / Perceval S		10 (2.2)
Crown PRT		3 (0.7)
Mitroflow		1 (0.2)
Unknown		8 (1.7)



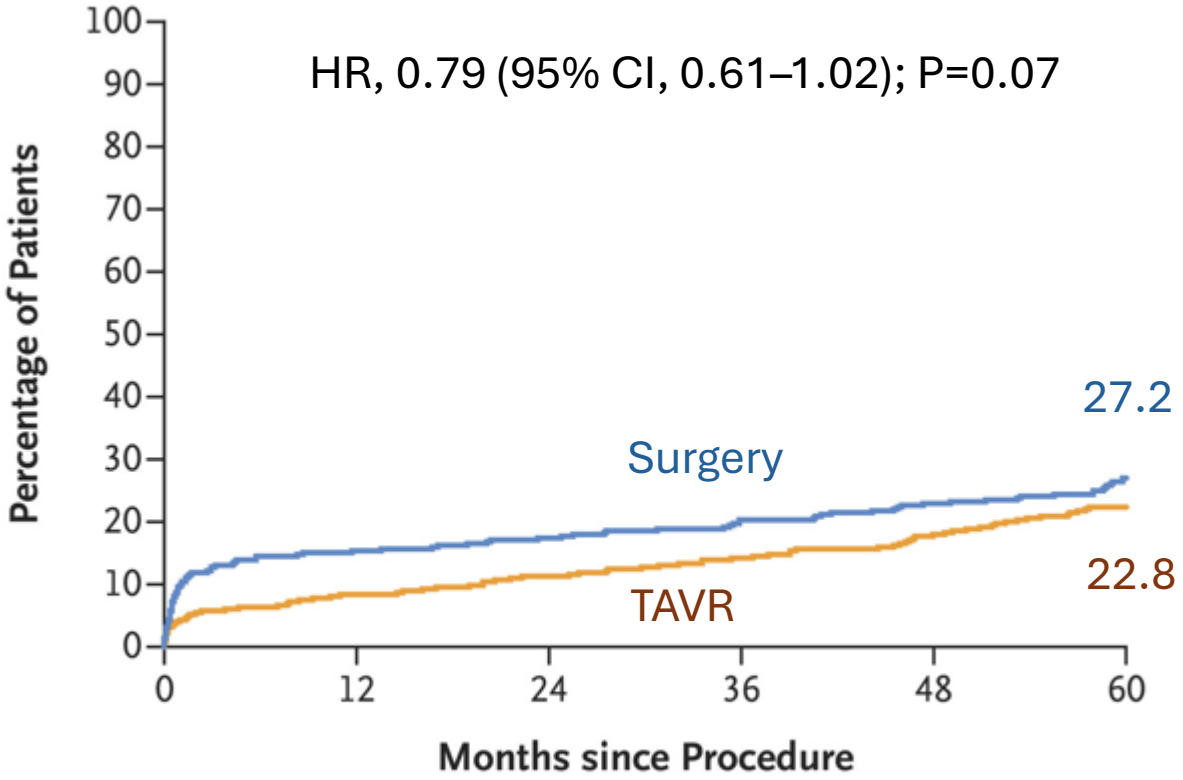
J Med 2023;389:1949-60.

Partner 3

Low risk AS, 5-year result



A | Death, stroke, or rehospitalization

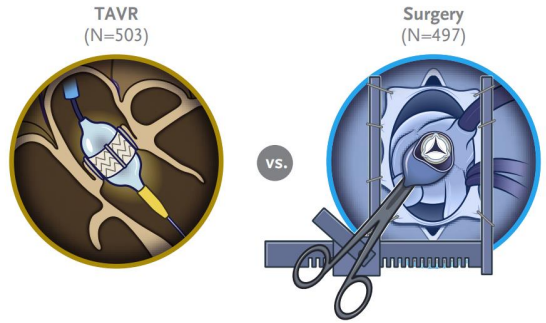


No. at Risk						
Surgery	454	372	349	328	309	276
TAVR	496	453	434	415	391	353

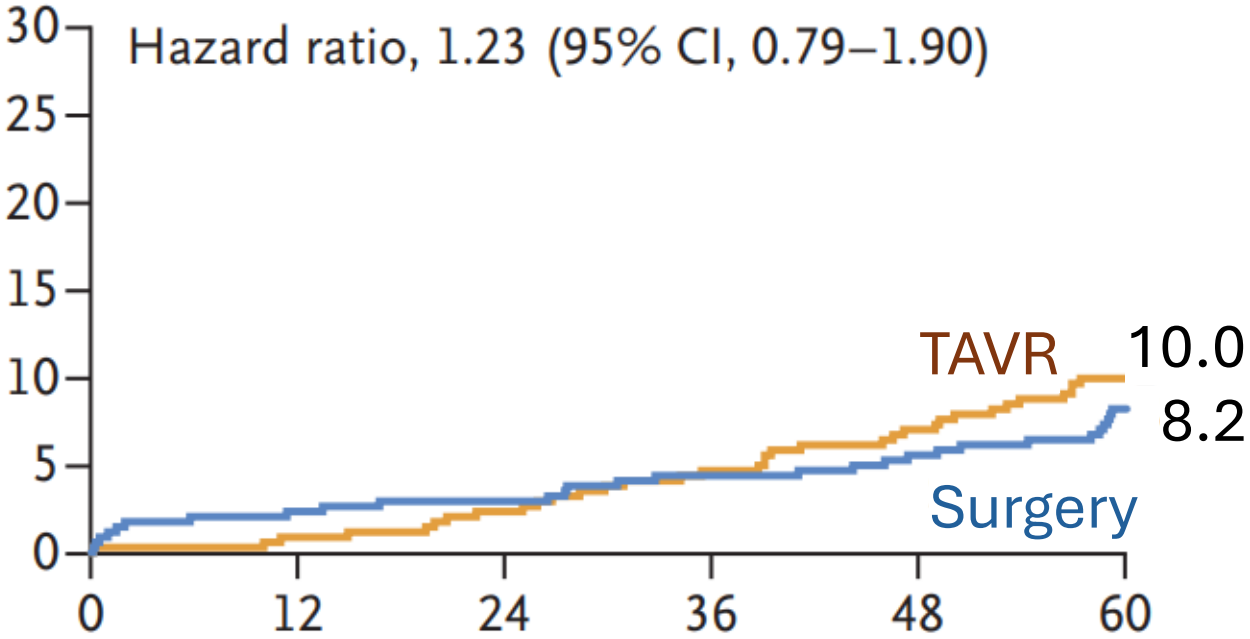
N Engl J Med 2023;389:1949-60.

Partner 3

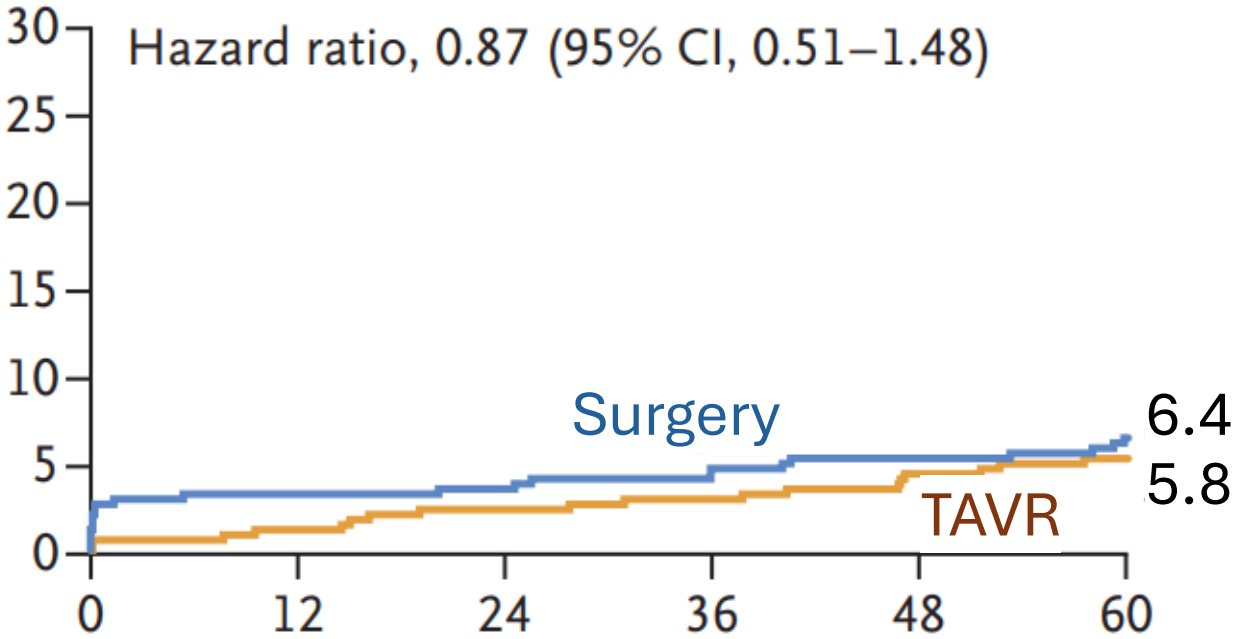
Low risk AS, 5-year result



Death



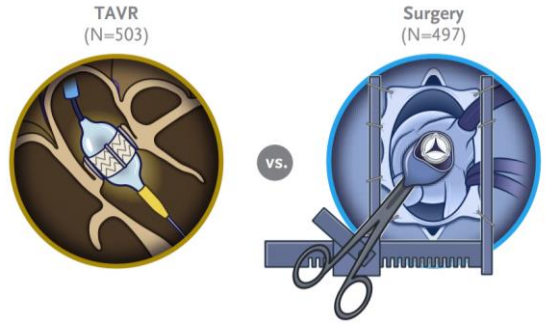
Stroke



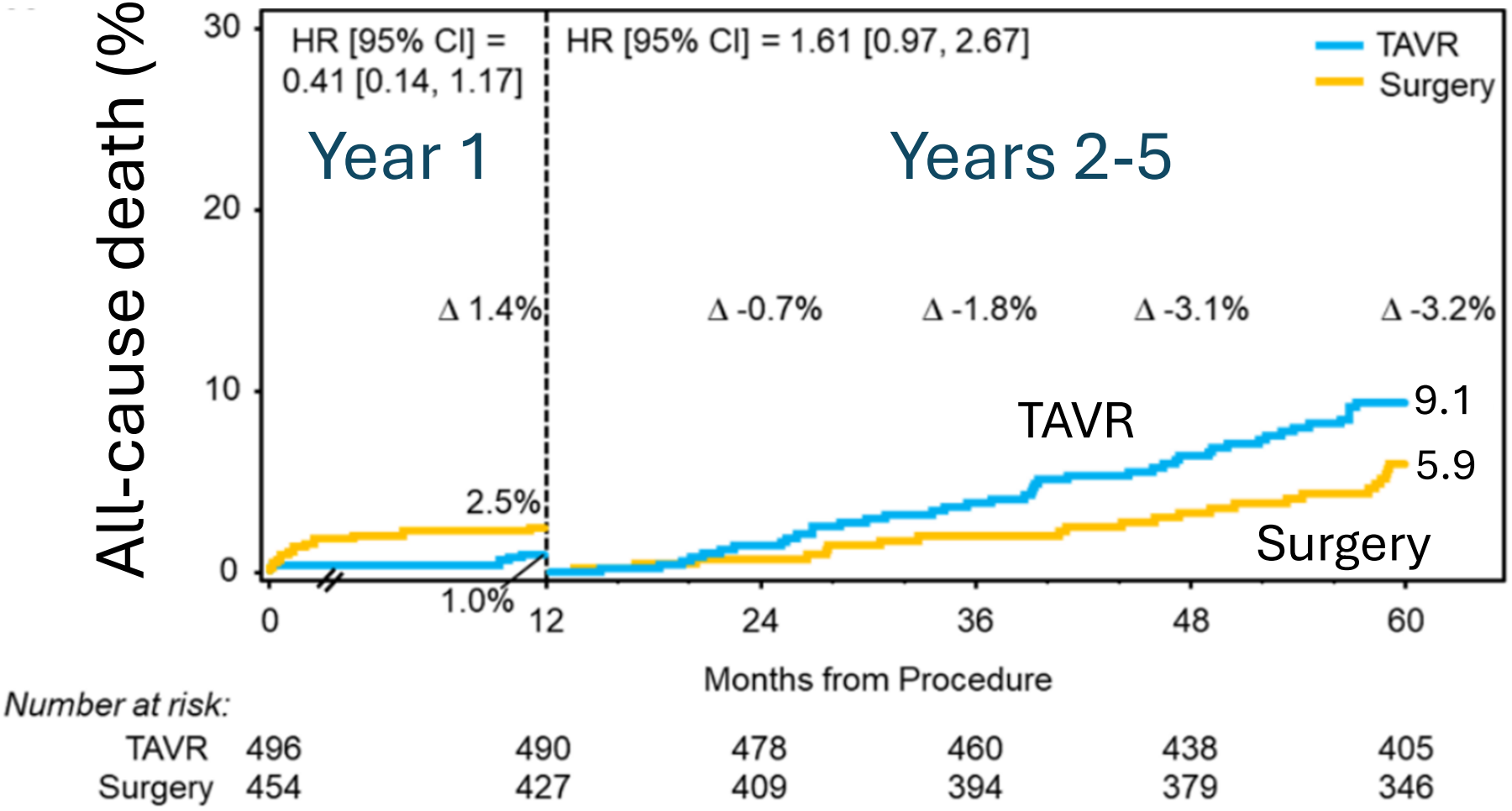
N Engl J Med 2023;389:1949-60.

Partner 3

Low risk AS, 5-year result



Death, Landmark analysis



Number at risk:

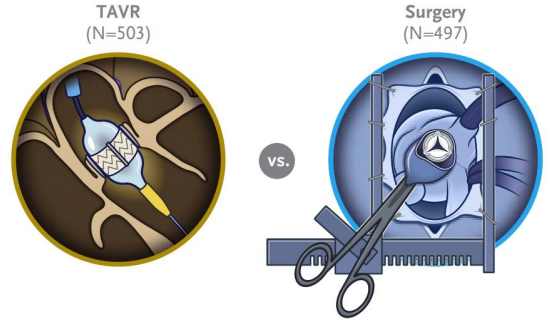
TAVR	496	490	478	460	438	405
Surgery	454	427	409	394	379	346

5.8

N Engl J Med 2023;389:1949-60.

Partner 3

Low risk AS, 5-year result

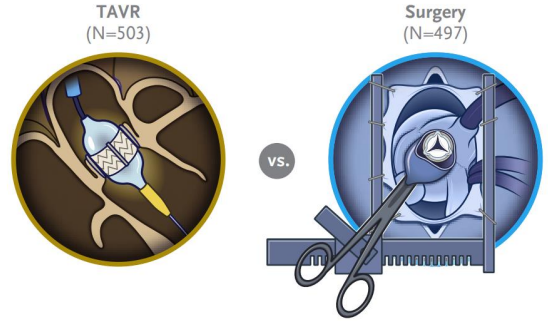


- In a 1000 patient comparison of low-risk patients with severe aortic stenosis, Sapien valves placed transcutaneously have similar outcomes to tissue aortic valves placed surgically

N Engl J Med 2023;389:1949-60.

Partner 3

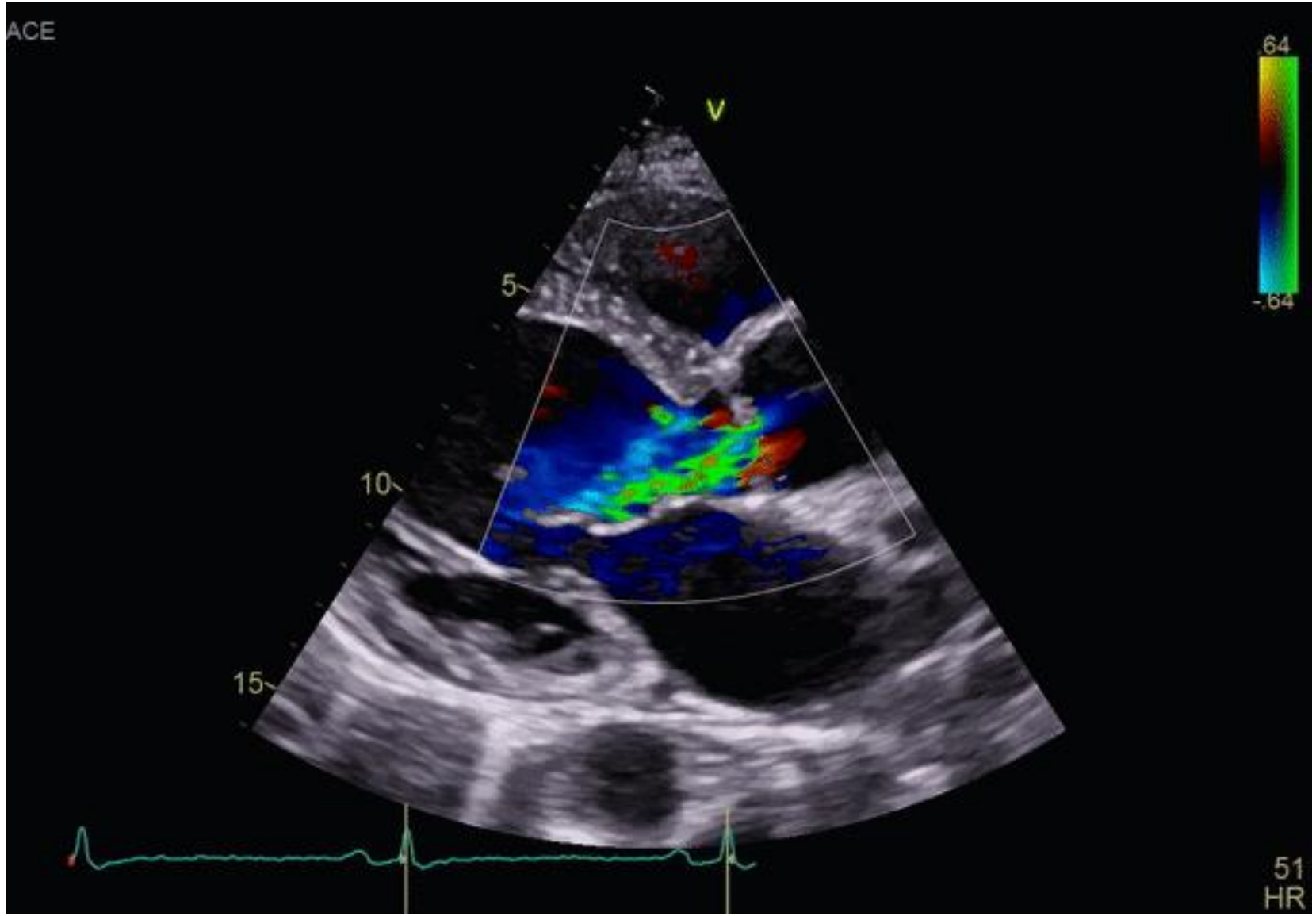
Low risk AS, 5-year result



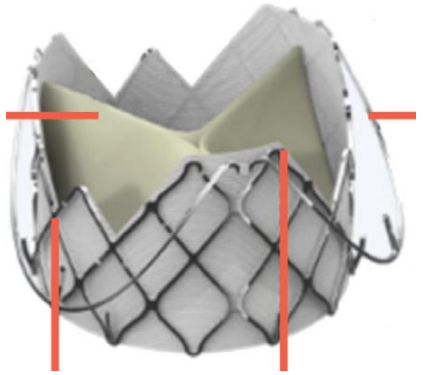
- Although the numbers are small, surgically placed valves have a trend for higher death and stroke rates early, and transcutaneously placed valves have a similar trend after 1 year.

N Engl J Med 2023;389:1949-60.

Aortic regurgitation



Aortic regurgitation



NEW RESEARCH PAPER: STRUCTURAL

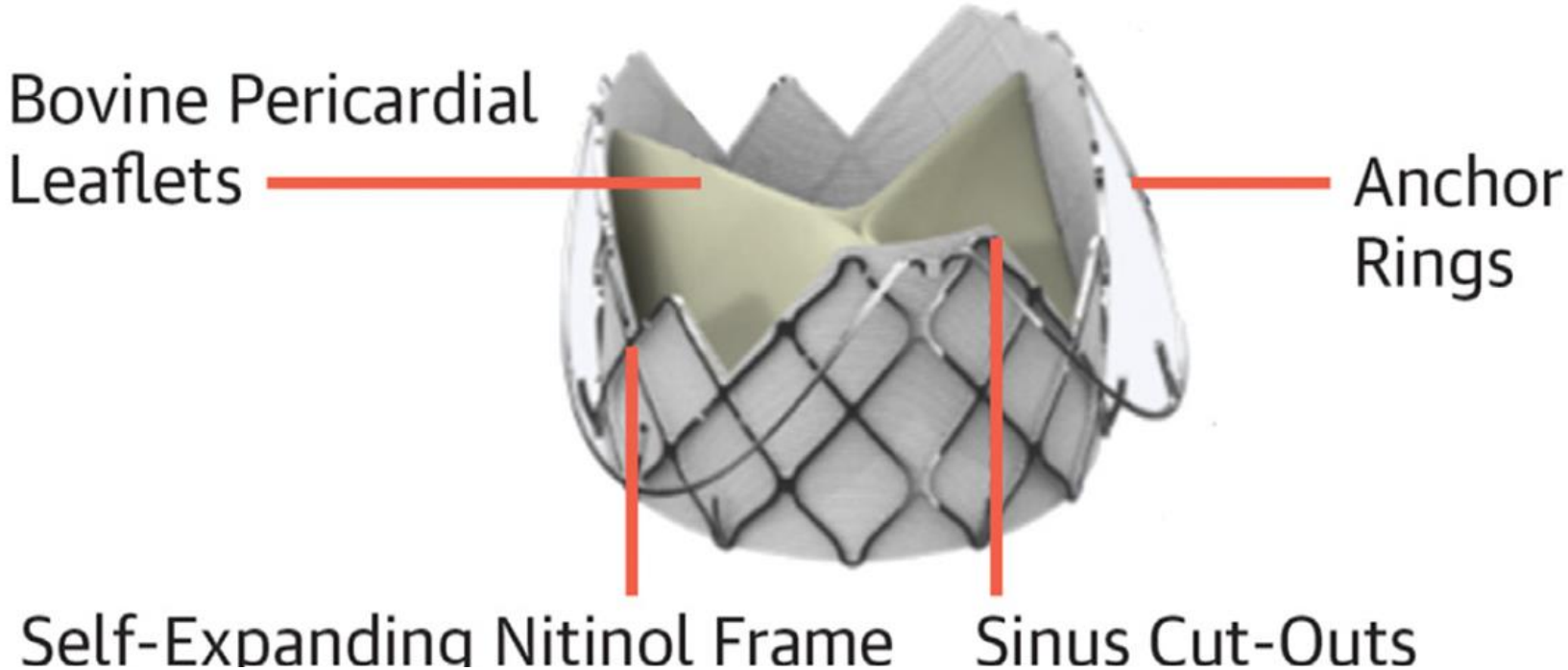
Transcatheter Treatment of Native Aortic Valve Regurgitation

The North American Experience With a Novel Device

Santiago Garcia, MD,[a] Jian Ye, MD,[b] John Webb, MD,[b] Michael Reardon, MD,[c] Neal Kleiman, MD,[c] Sachin Goel, MD,[c] Taha Hatab, MD,[c] Neil Fam, MD,[d] Mark Peterson, MD,[d] Samantha Liauw, MD,[d] Tiberio M. Frisoli, MD,[e] Hanad Bashir, MD,[a] Debra Paige, RN,[a] Darlene Rock, RN,[a] Christian Schmidt, MS,[a] James G. Jollis, MD,[a]

J Am Coll Cardiol Intv 2023;16:1953–1960.

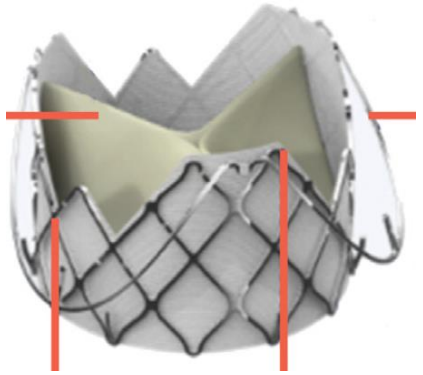
Aortic regurgitation
J-valve



5 sizes- annular perimeters 57-104 mm

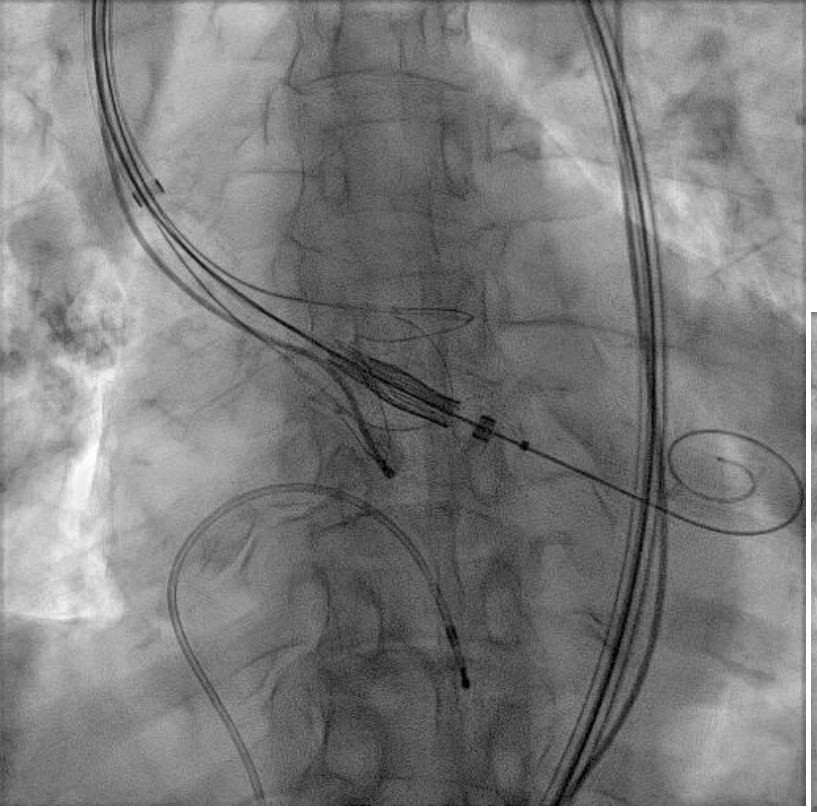
J Am Coll Cardiol Intv 2023;16:1953–1960.

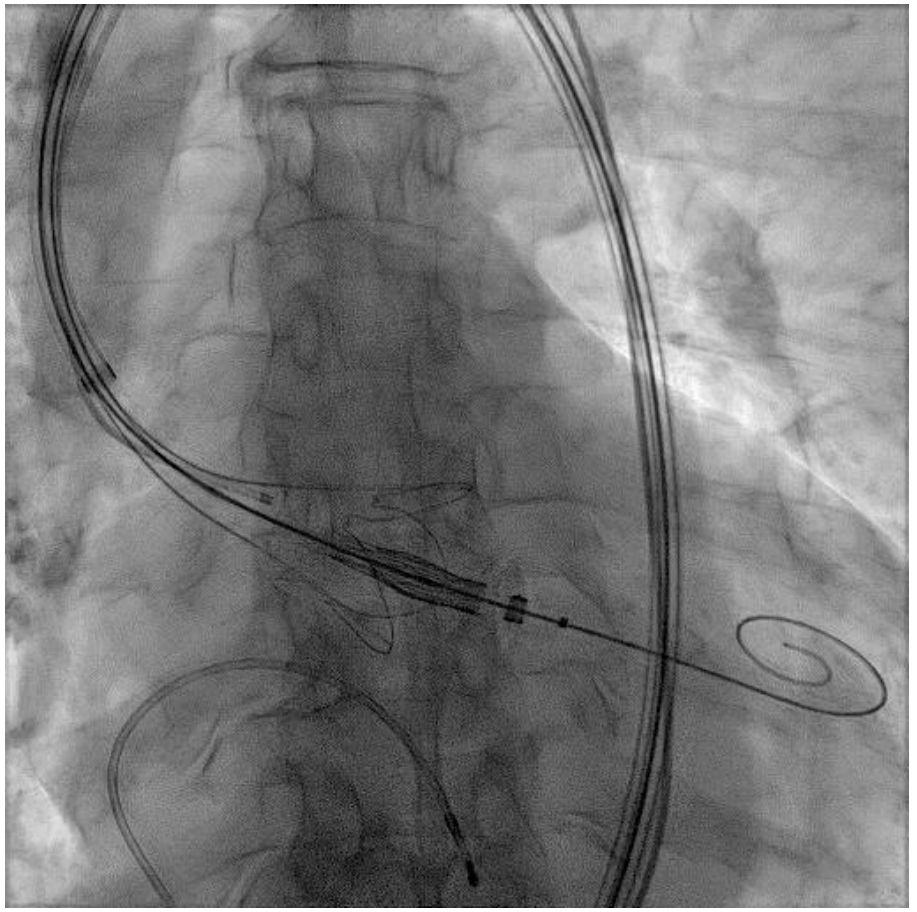
Aortic regurgitation
J-valve

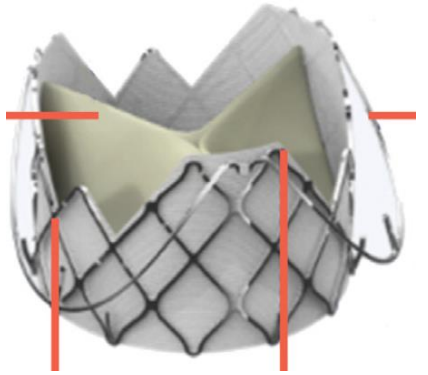


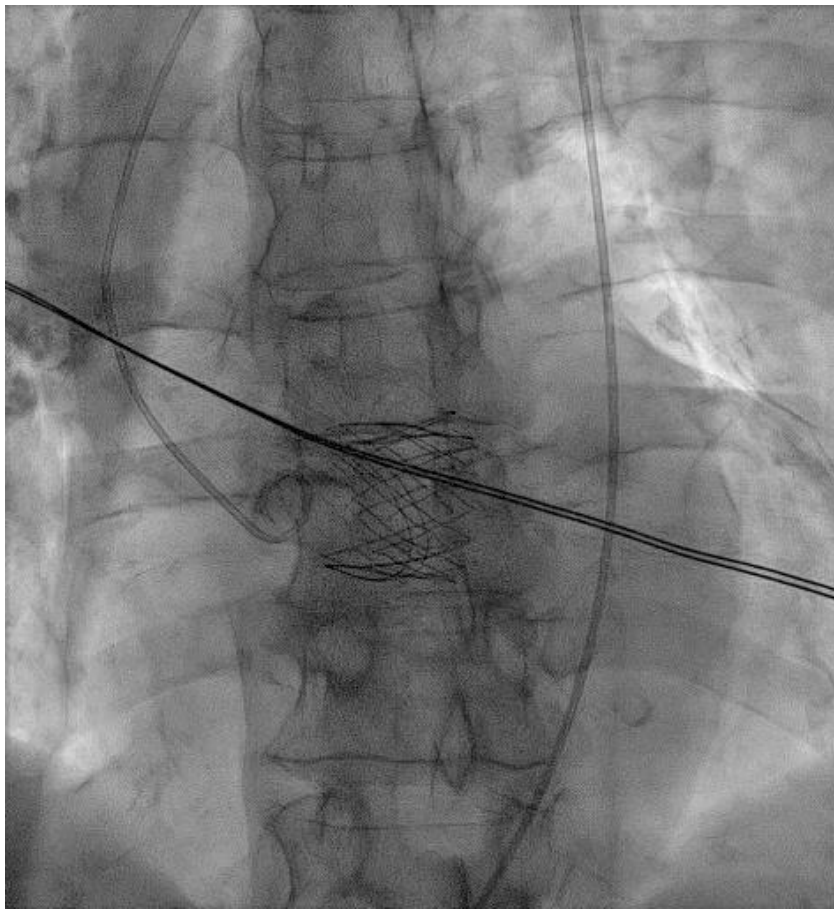
- Compassionate use case series (*not a trial*)
- 27 patients
- median age 81 years [IQR: 72-85 years],
- 81% at high surgical risk, 96% in NYHA functional class III or IV) with aortic regurgitation.
- Procedural success 81% (22 of 27 cases)
- 30 days -1 death, 1 stroke, and 3 new pacemakers (13%), and 88% of patients were in NYHA functional class I or II.
- No patient had residual AR of moderate or greater degree at 30 days.

J Am Coll Cardiol Intv 2023;16:1953–1960.









Percutaneous Heart Valve Update

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  - Aortic regurgitation
- Mitral
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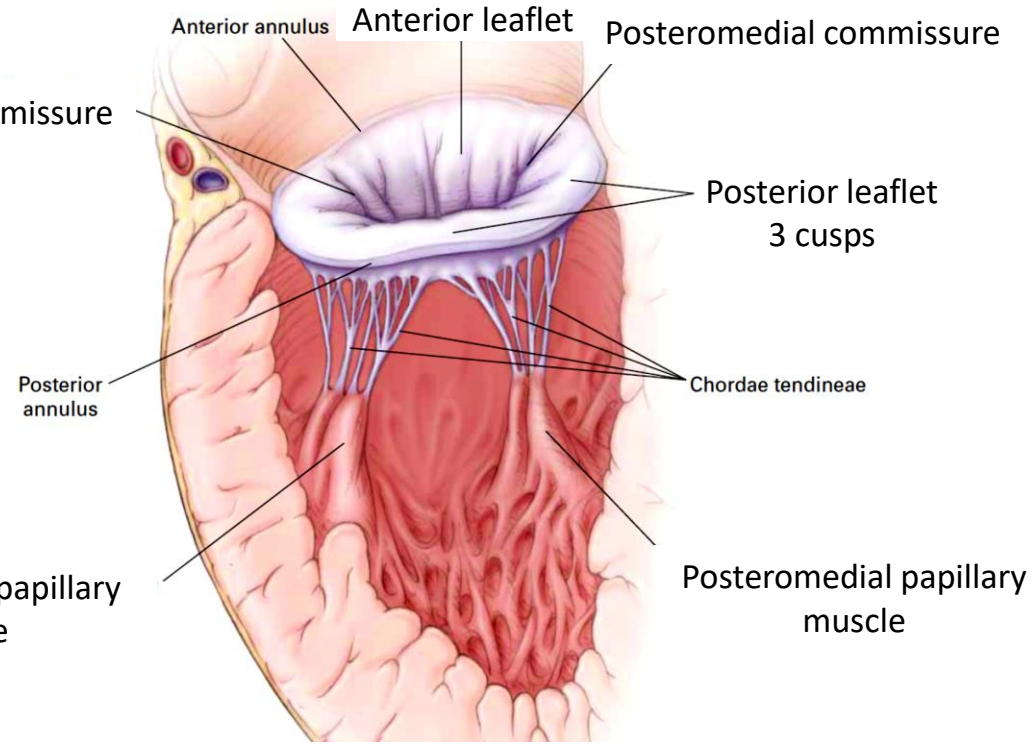
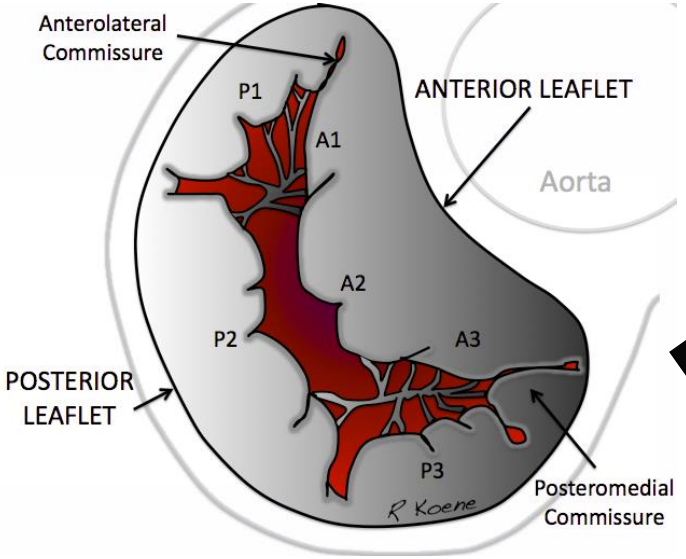
- Tricuspid
  - Evoque valve

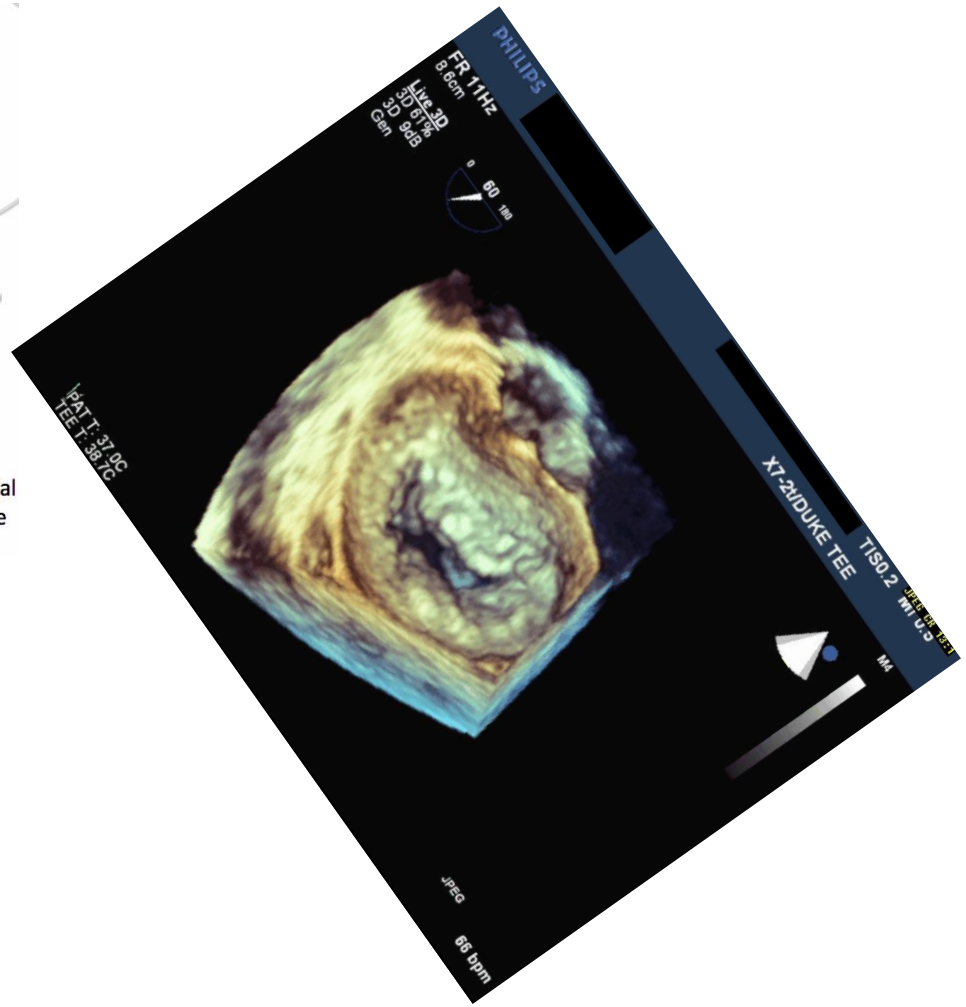
Mitral valve



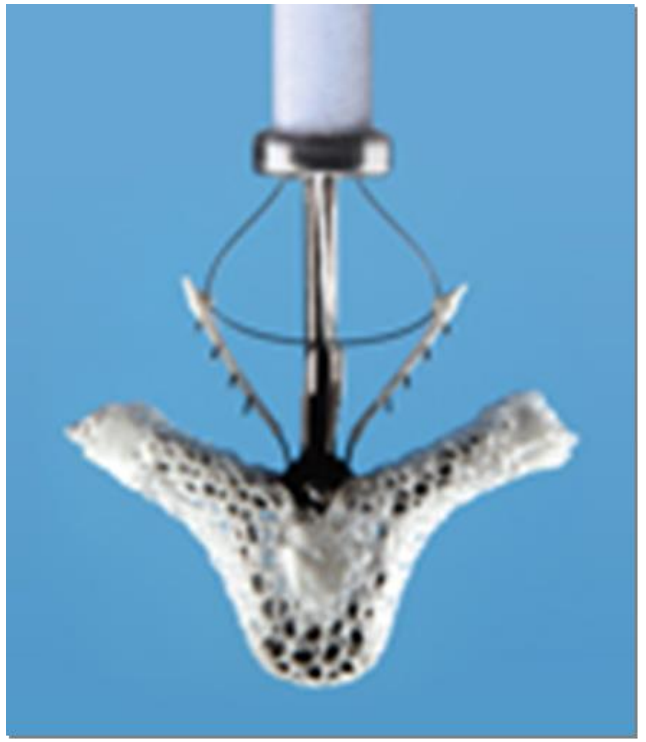
Corrected labels from Otto CM. N Engl J Med 2001; 345:740-746

Mitral valve





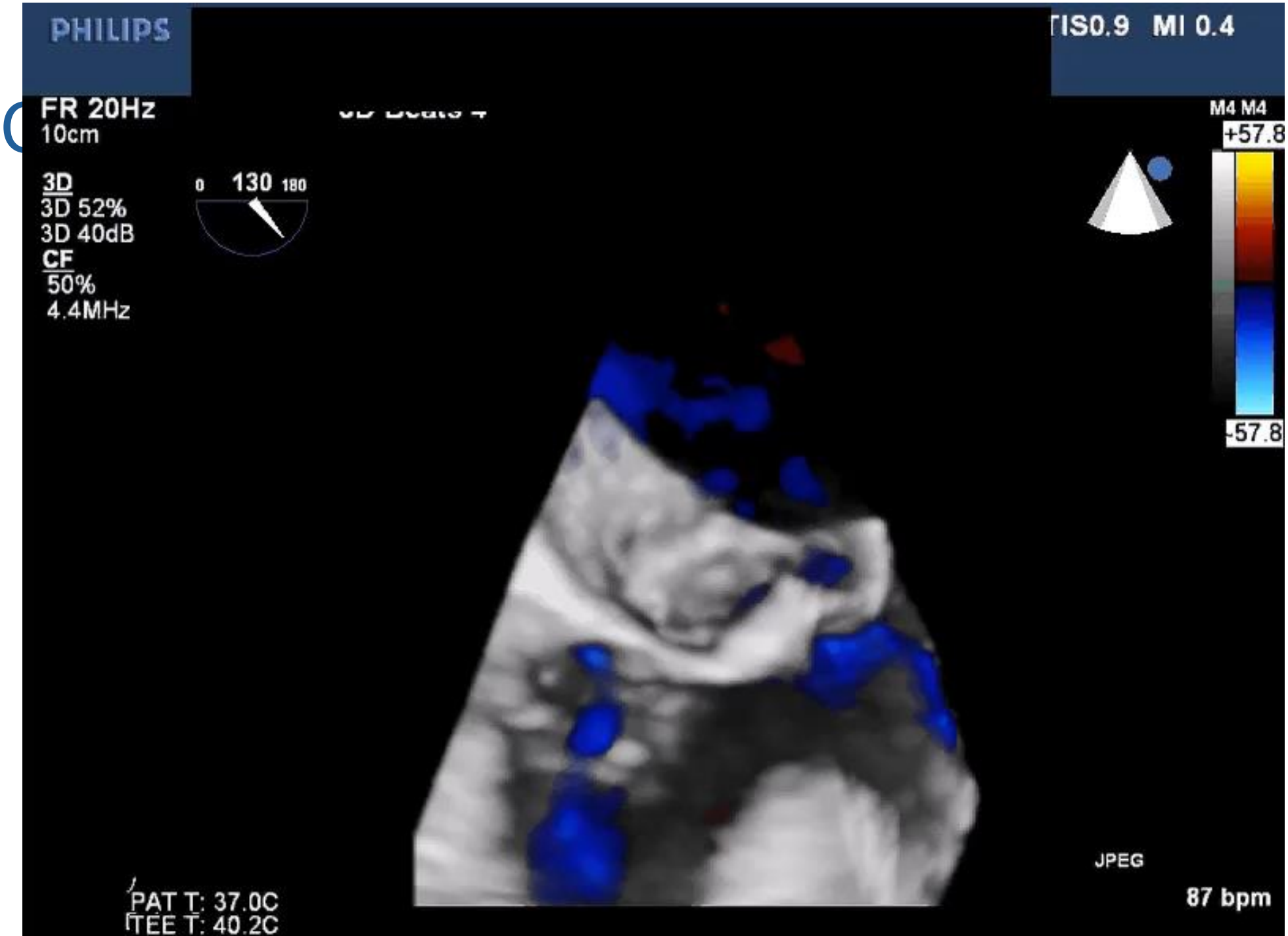
Mitral transcatheter edge-to-edge repair (TEER)



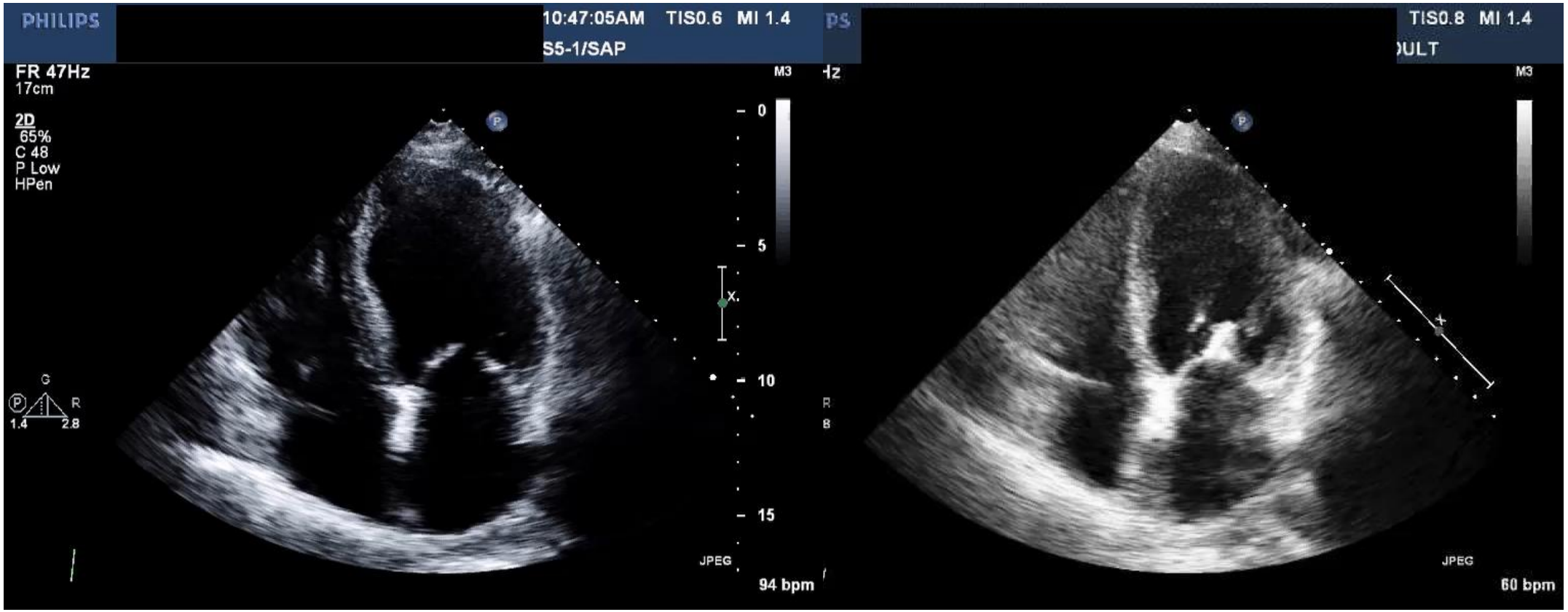
MC


PHILIPS
56PM TIS0.2 MI 0.5
t/Adult
FR 13Hz
8.5cm
3D Beats 1
M4
3D
3D 52%
3D 40dB
0 130 180
JPEG
PAT T: 37.0C
TEE T: 40.3C
86 bpm

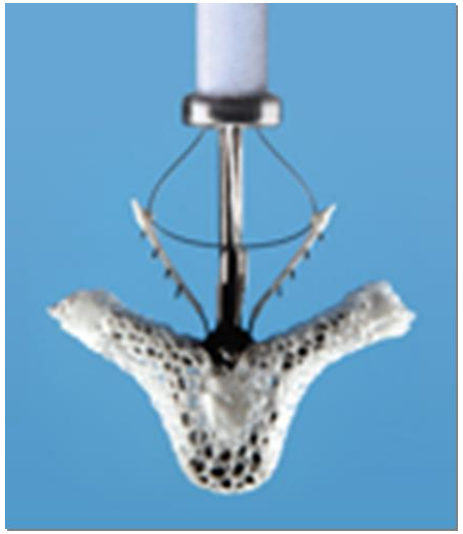
MC


PHILIPS
TIS0.9 MI 0.4
FR 20Hz
10cm
3D
3D 52%
3D 40dB
CF
50%
4.4MHz
0 130 180
M4 M4
+57.8
-57.8
JPEG
87 bpm
PAT T: 37.0C
TEE T: 40.2C

MC 78 y.o. woman



COAPT 5 year follow up



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

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

Gregg W. Stone, M.D., William T. Abraham, M.D., JoAnn Lindenfeld, M.D., Saibal Kar, M.D., Paul A. Grayburn, M.D., D. Scott Lim, M.D., Jacob M. Mishell, M.D., Brian Whisenant, M.D., Michael Rinaldi, M.D., Samir R. Kapadia, M.D., Vivek Rajagopal, M.D., Ian J. Sarembock, M.B., Ch.B., M.D., Andreas Brieke, M.D., Steven O. Marx, M.D., David J. Cohen, M.D., Federico M. Asch, M.D., and Michael J. Mack, M.D., for the COAPT Investigators

N Engl J Med 2023;388:2037-48.

COAPT 5 year follow up

Transcatheter repair of secondary mitral regurgitation with heart failure

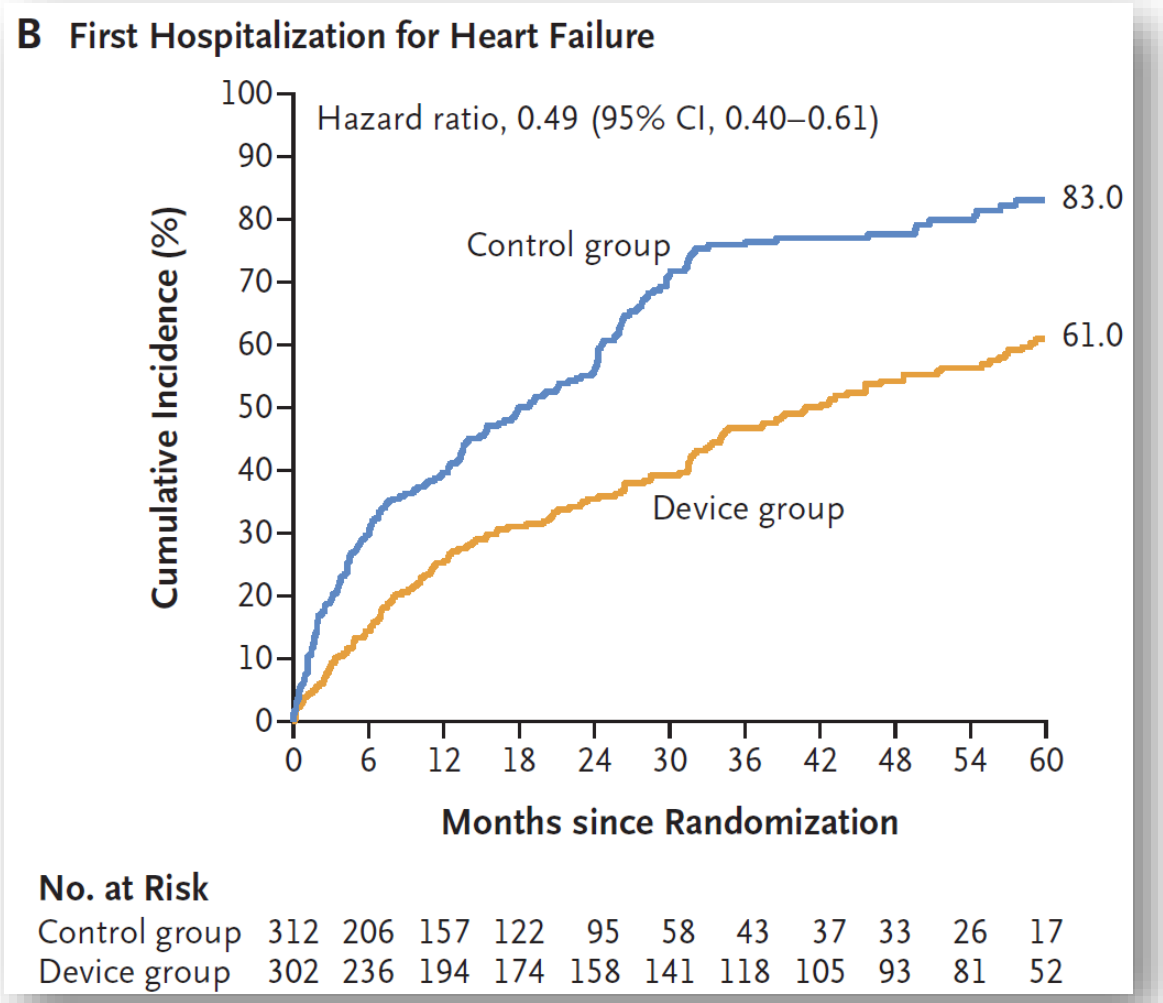
- 614 patients
- Class II-IVa heart failure and 3-4+ mitral regurgitation
- EF 20 to 50%
- Remained symptomatic despite maximal medical rx.

- Age 72, 36% women
- 36% cardiac resynch
- 61% ischemic cardiomyopathy
- NYHA class II 39%, III 52
- LVEDV = 101 mL/m2
- EF 31%

N Engl J Med 2023;388:2037-48.

COAPT 5 year follow up

Transcatheter repair of secondary mitral regurgitation with heart failure



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COAPT 5 year follow up

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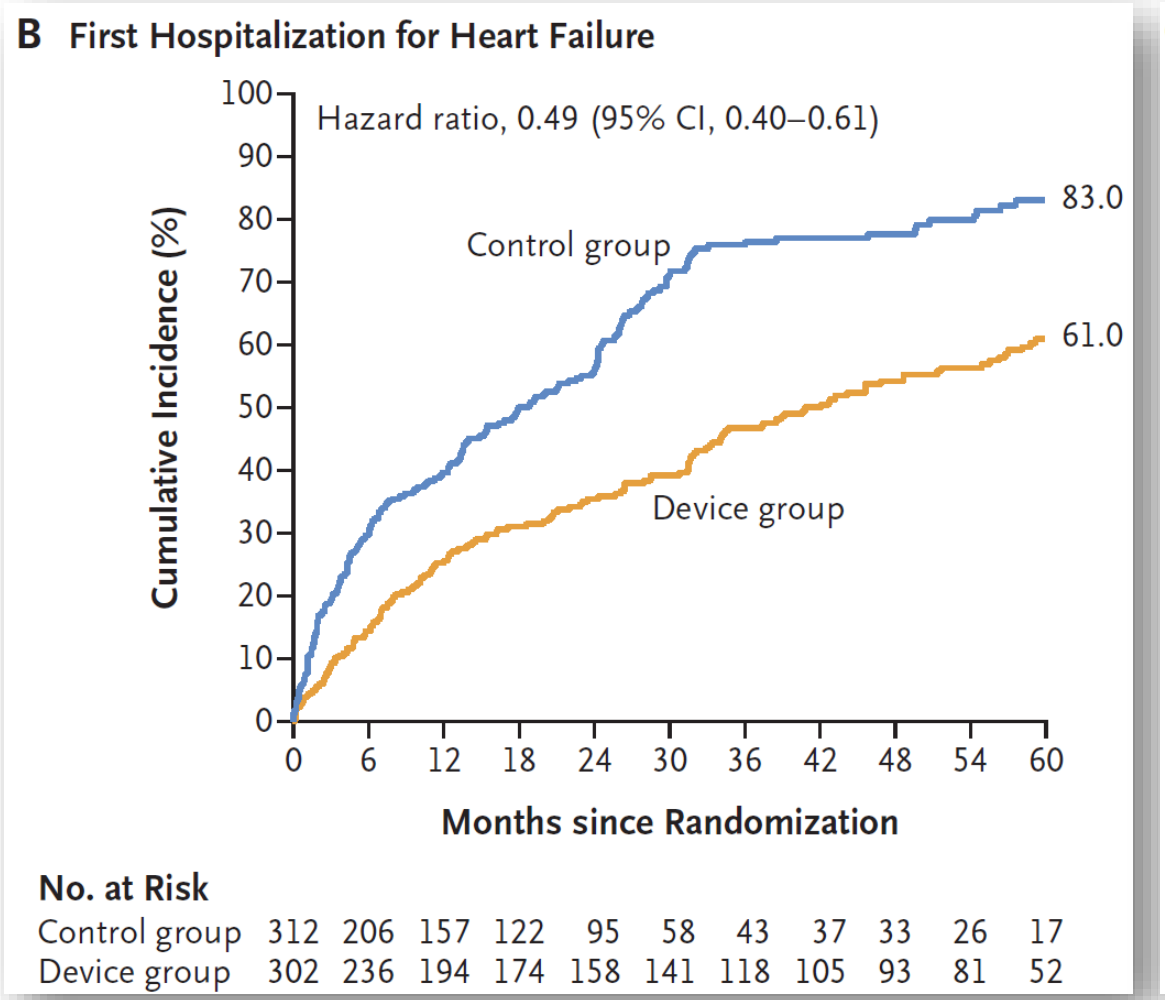
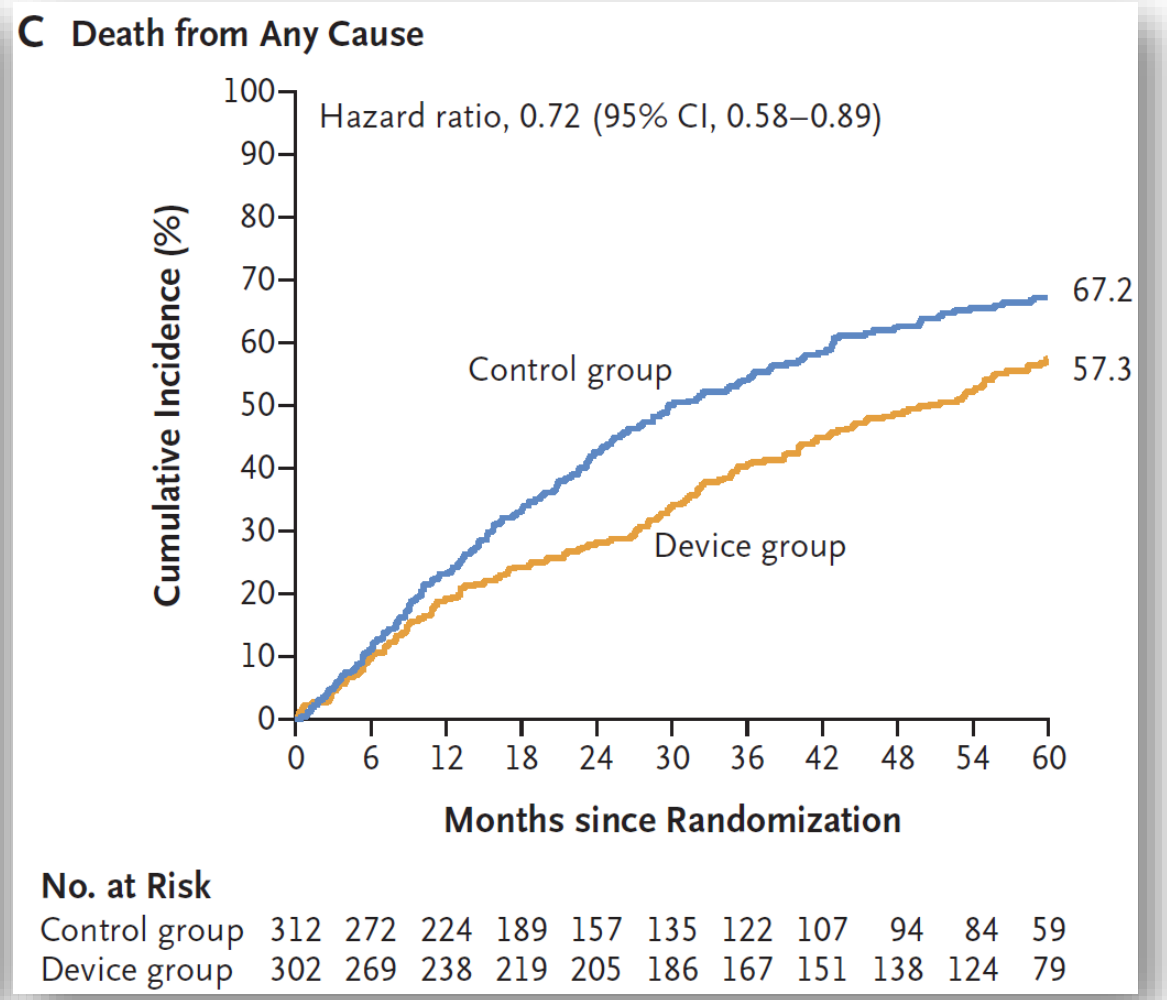




N Engl J Med 2023;388:2037-48.

COAPT 5 year follow up

Transcatheter repair of secondary mitral regurgitation with heart failure

- At 5 years, patients with class II-IV heart failure and severe mitral regurgitation treated with edge-to-edge mitral valve clipping had significantly fewer hospitalizations and fewer deaths.

N Engl J Med 2023;388:2037-48.

COAPT 5 year follow up

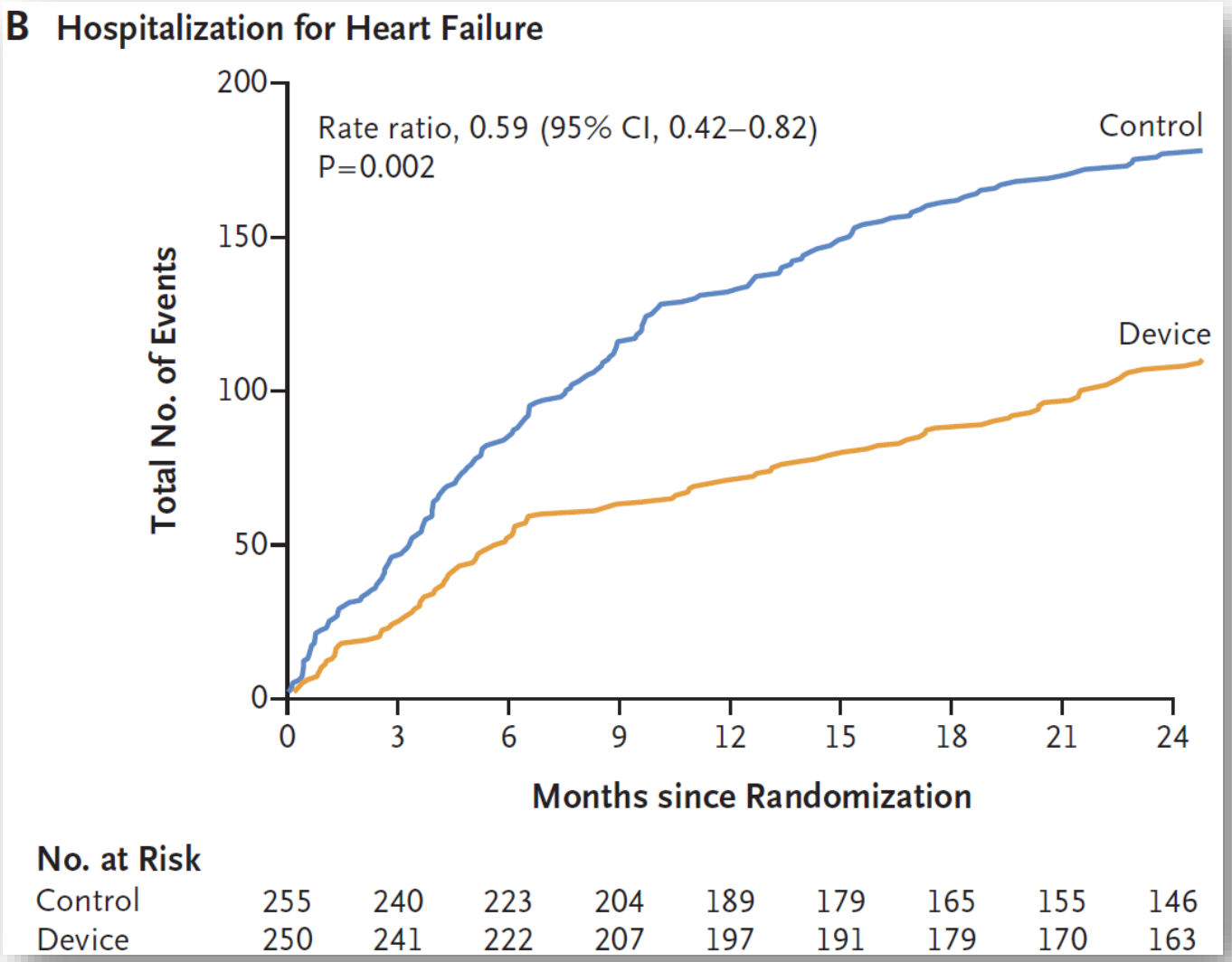
Transcatheter repair of secondary mitral regurgitation with heart failure

- The benefit was mainly seen in the first 3 years, likely due to patient attrition or reaching the initial hospitalization end point.

N Engl J Med 2023;388:2037-48.

RESHAPE-HF2

Transcatheter Valve Repair in Heart Failure with Moderate to Severe Mitral Regurgitation - 505 patients, European sites

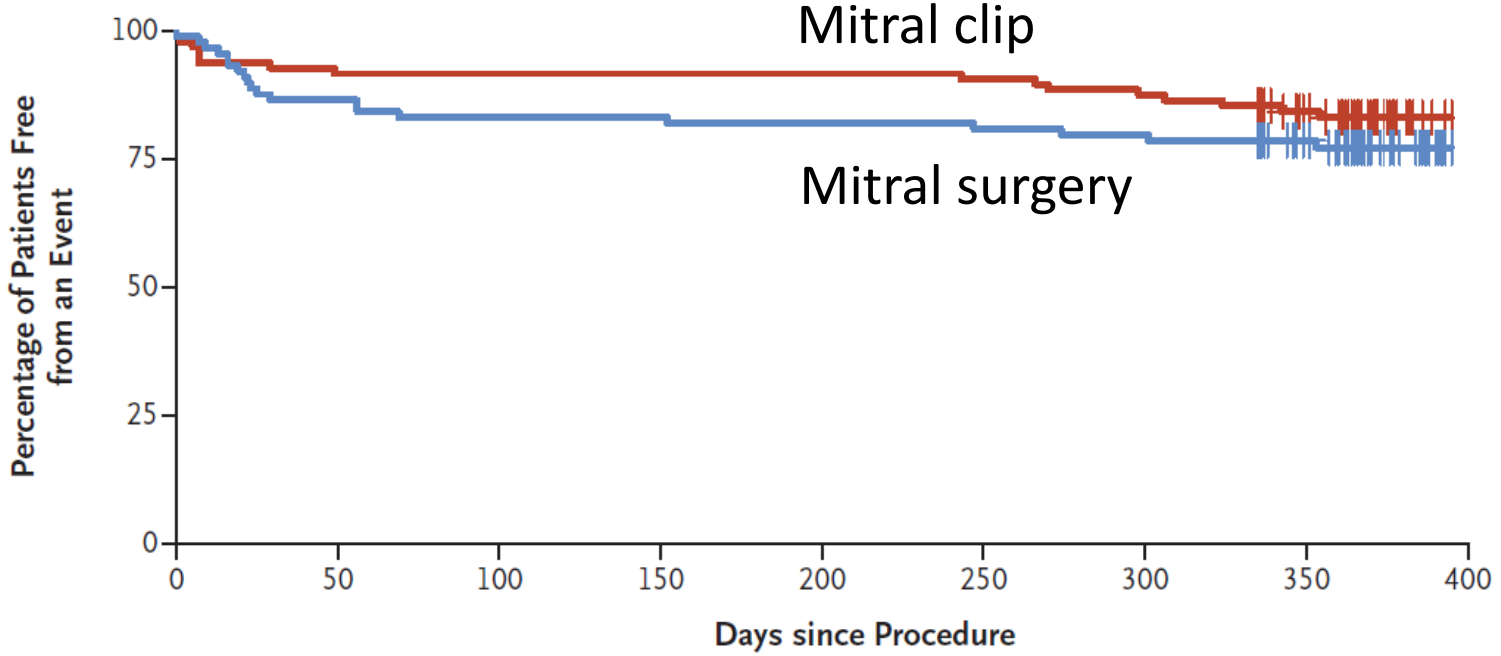


N Engl J Med 2024;391:1799-809.

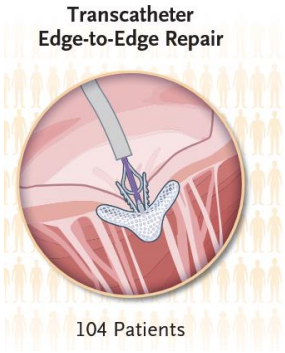
MATTERHORN

Transcatheter Repair versus Mitral-Valve Surgery for Secondary Mitral Regurgitation- 210 patients, Germany

Death, heart failure hospitalization, mitral-valve reintervention, implantation of an assist device, or stroke



No. at Risk (%)									
Intervention group	96 (100)	88 (92)	88 (92)	88 (92)	88 (92)	87 (91)	84 (88)	71 (74)	0 (0)
Surgery group	89 (100)	77 (87)	74 (83)	74 (83)	73 (82)	72 (81)	71 (80)	58 (65)	0 (0)



N Engl J Med 2024;391:1787-98.

RESHAPE-HF2 / MATTERHORN

- The RESHAPE-HF2 and MATTERHORN trials demonstrate that

  -similar results can be achieved in Europe, and

  -mitral valve clipping has similar outcomes to mitral valve surgery in a small cohort of patients

N Engl J Med 2024;391:1787-98.
N Engl J Med 2024;391:1799-809.

RESHAPE-HF2 / MATTERHORN / COAPT

- When performed in select centers by experienced operators, edge-to-edge mitral valve clipping reduces hospitalization and improves quality of life for patients with medically refractory heart failure and severe mitral regurgitation.

N Engl J Med 2023;388:2037-48.
N Engl J Med 2024;391:1787-98.
N Engl J Med 2024;391:1799-809.

Percutaneous Heart Valve Update

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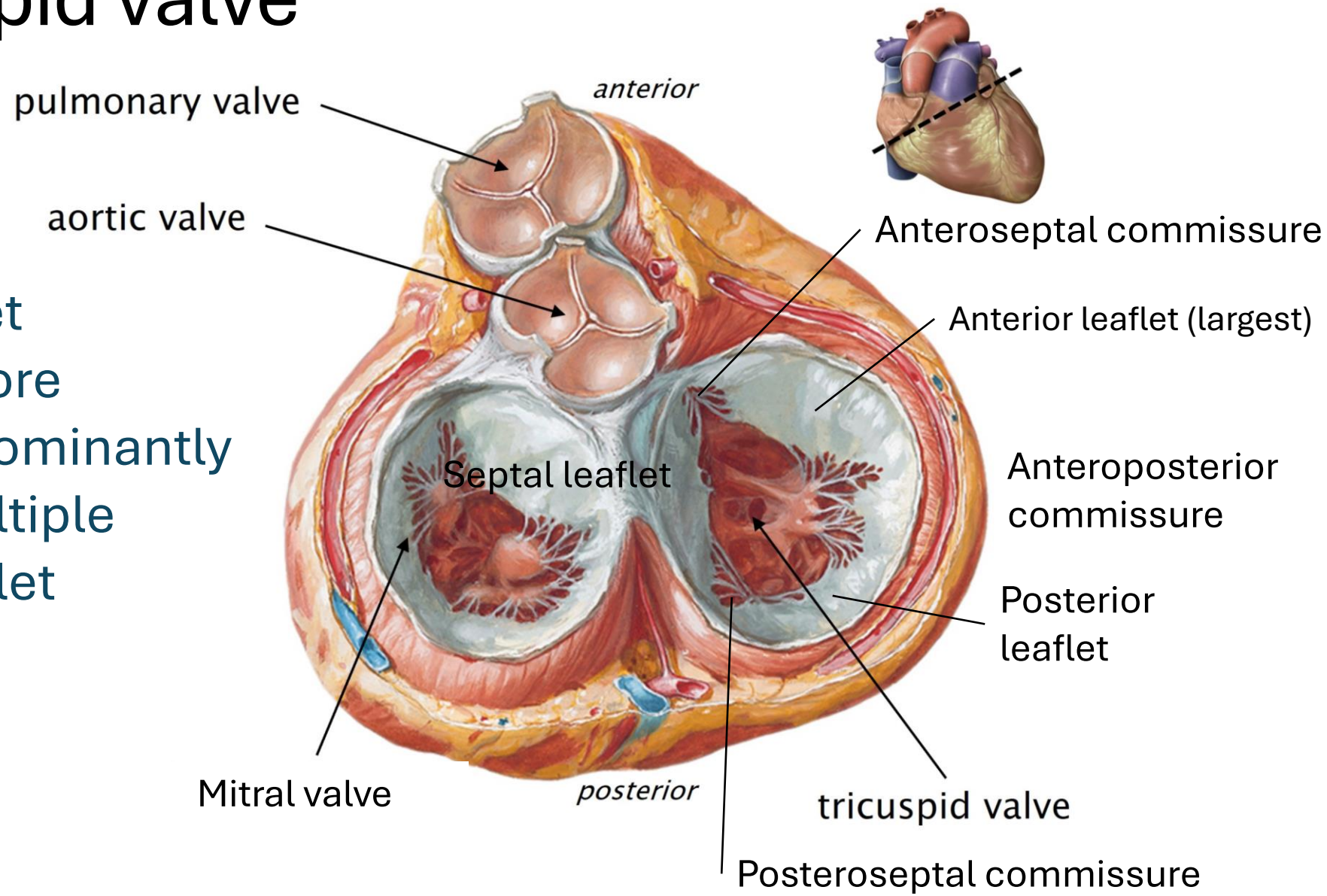
- Tricuspid
  - Evoque valve

Tricuspid valve

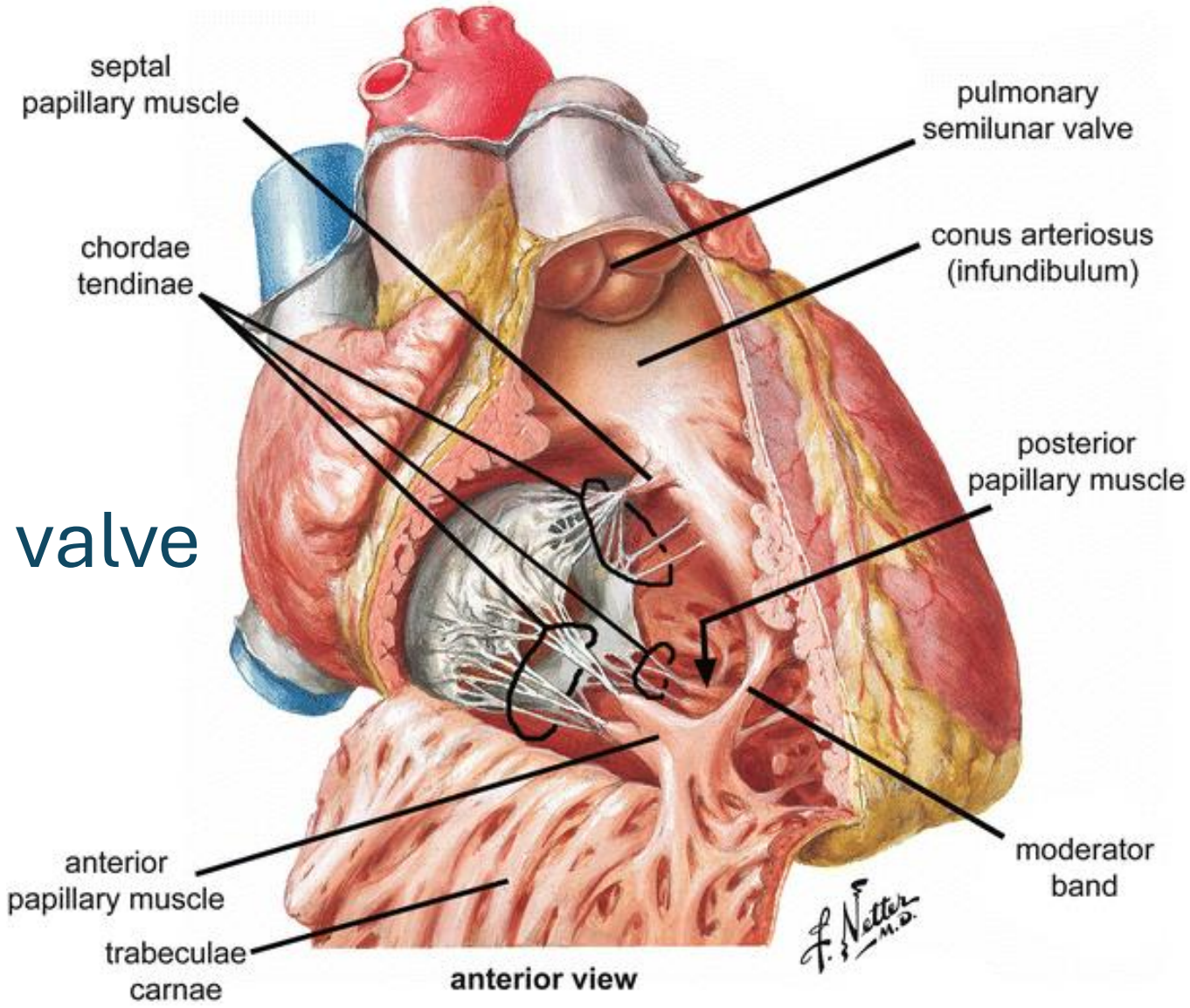
7-9 cm orifice

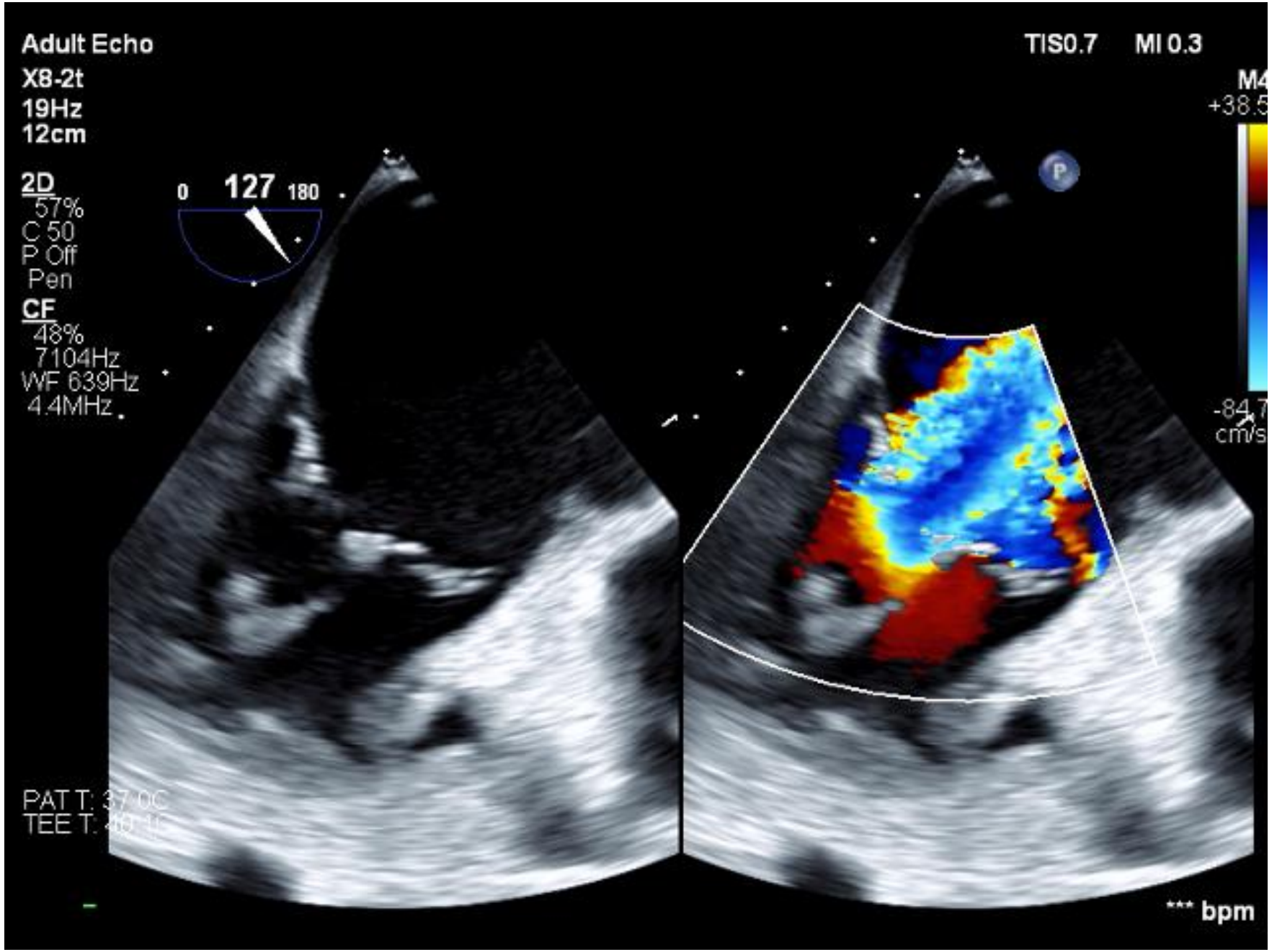
54% - 3-leaflet
39% - 4 or more leaflets, predominantly related to multiple posterior leaflet scallops



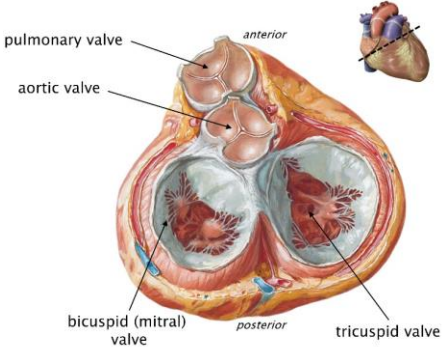
Tricuspid valve

Most anterior valve




Adult Echo
X8-2t
19Hz
12cm
2D
57%
C 50
P Off
Pen
CF
48%
7104Hz
WF 639Hz
4.4MHz
0
127
180
TIS0.7
MI 0.3
M4
+38.5
-84.7
cm/s
PAT T: 37.0C
TEE T: 40.1C
*** bpm

Tricuspid regurgitation



- Moderate or greater TR

  Community - 5%

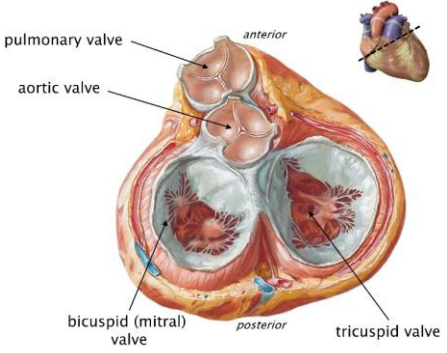
  Hospitalized patients - 12%

  Reduce EF heart failure - 23%

  Severe mitral regurgitation 30 - 60%

Otto et al. 2020 ACC/AHA Guideline for the Management of Valvular Heart Disease Circulation. 2021;143:e72–e227.

Tricuspid regurgitation

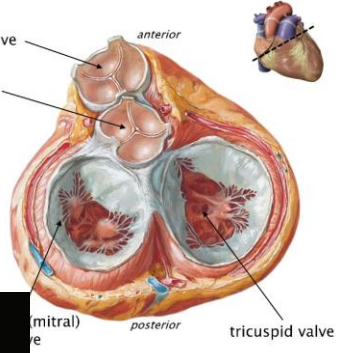


90% functional etiologies

- Left-sided valvular disease
- Pulmonary hypertension
- LV dysfunction
- Dilation of the tricuspid apparatus

Otto et al. 2020 ACC/AHA Guideline for the Management of Valvular Heart Disease Circulation. 2021;143:e72–e

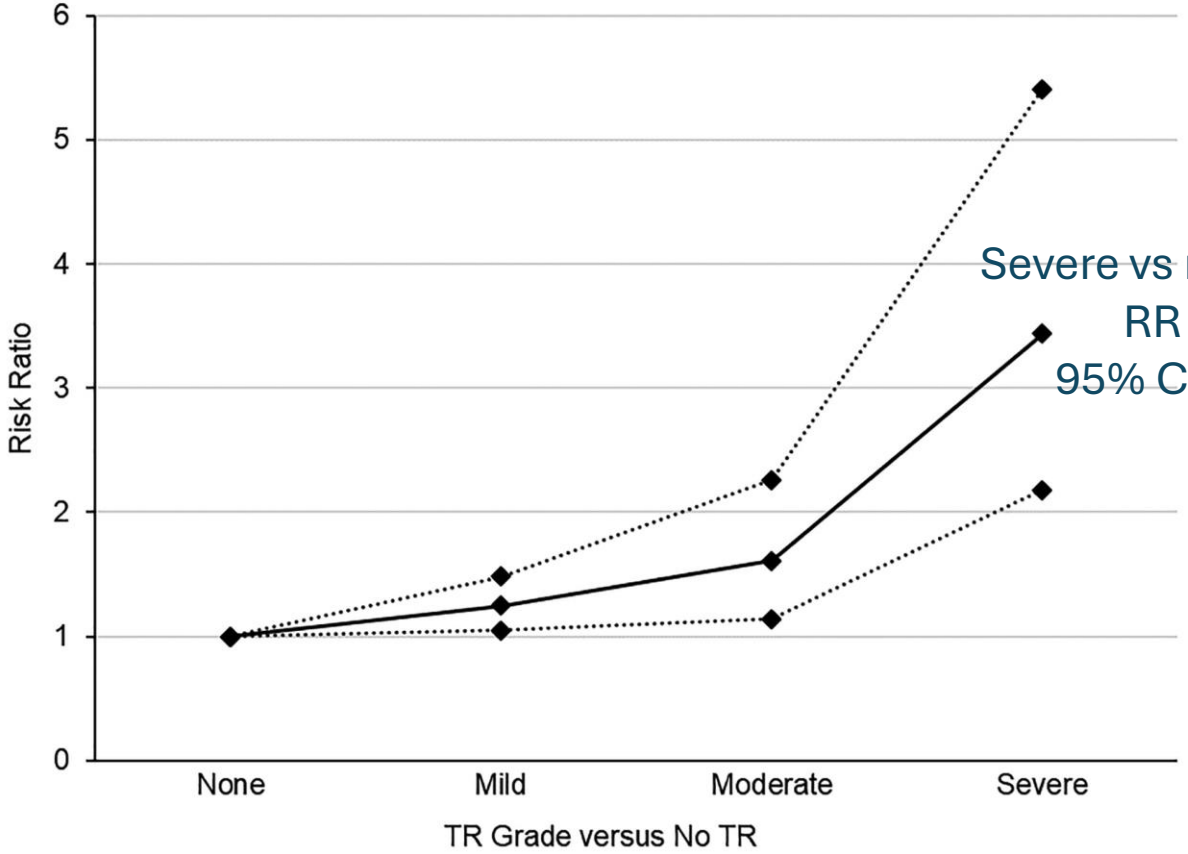
Tricuspid regurgitation



Otto et al. 2020 ACC/AHA Guideline for the Management of Valvular Heart Disease Circulation. 2021;143:e72–e

Tricuspid regurgitation

Risk of all-cause mortality according to tricuspid regurgitation grade
Meta analysis, N=26,404



Severe vs none / trivial
RR 3.44,
95% CI 2.2–5.4

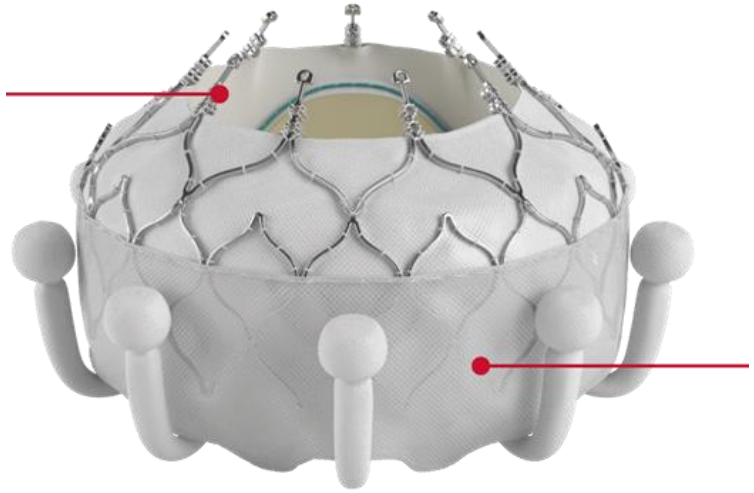
The solid line estimate.
Dotted lines represents the 95% confidence intervals.

Nelson Wang, et al. Tricuspid regurgitation is associated with increased mortality independent of pulmonary pressures and right heart failure. European Heart Journal 2019; 40: 476–484

TRISCEND II

Transcatheter Valve Replacement in Severe Tricuspid Regurgitation

Evoque valve



Nitinol expanding frame

9 ventricular anchors

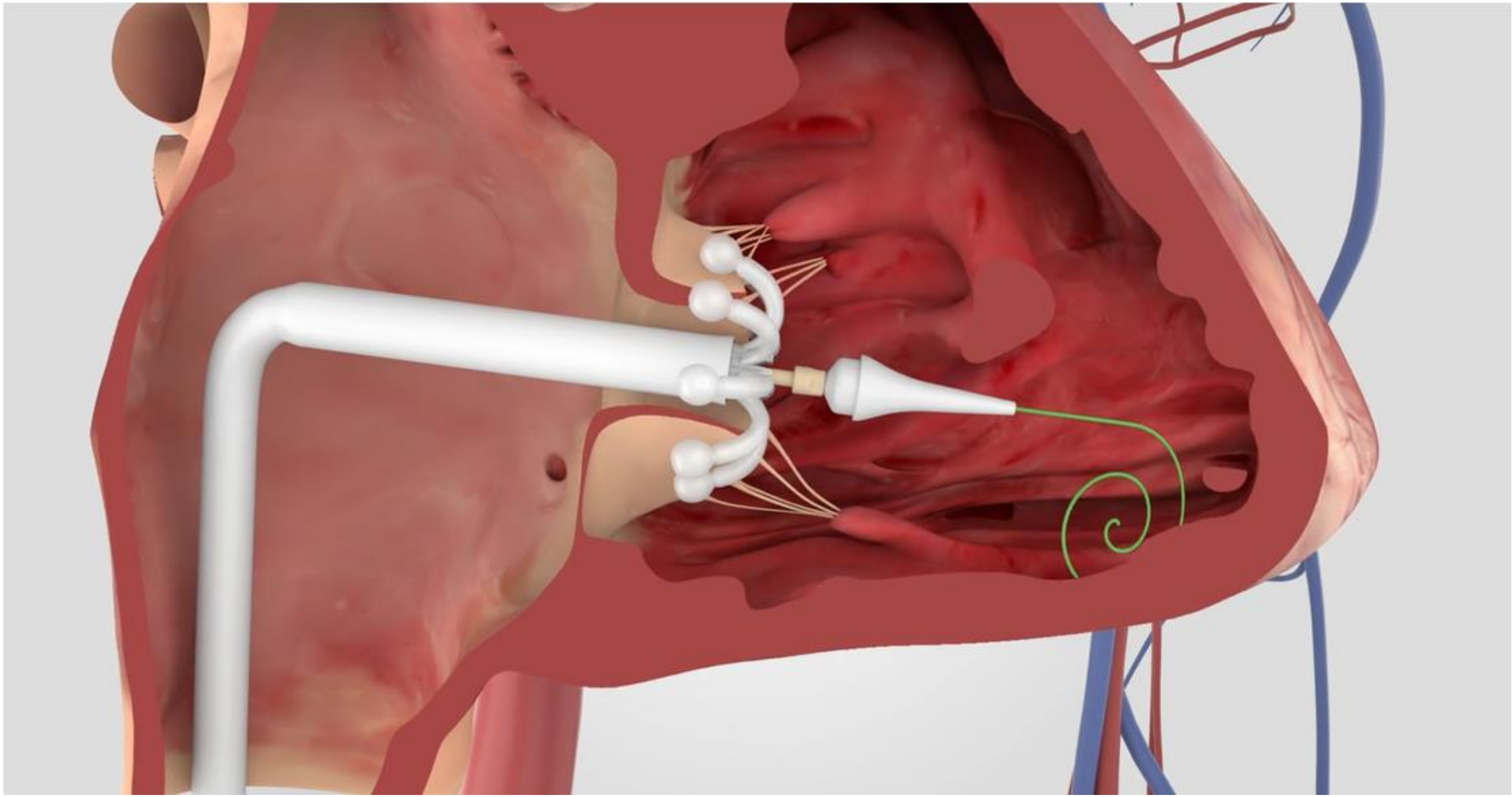
Bovine pericardial leaflets

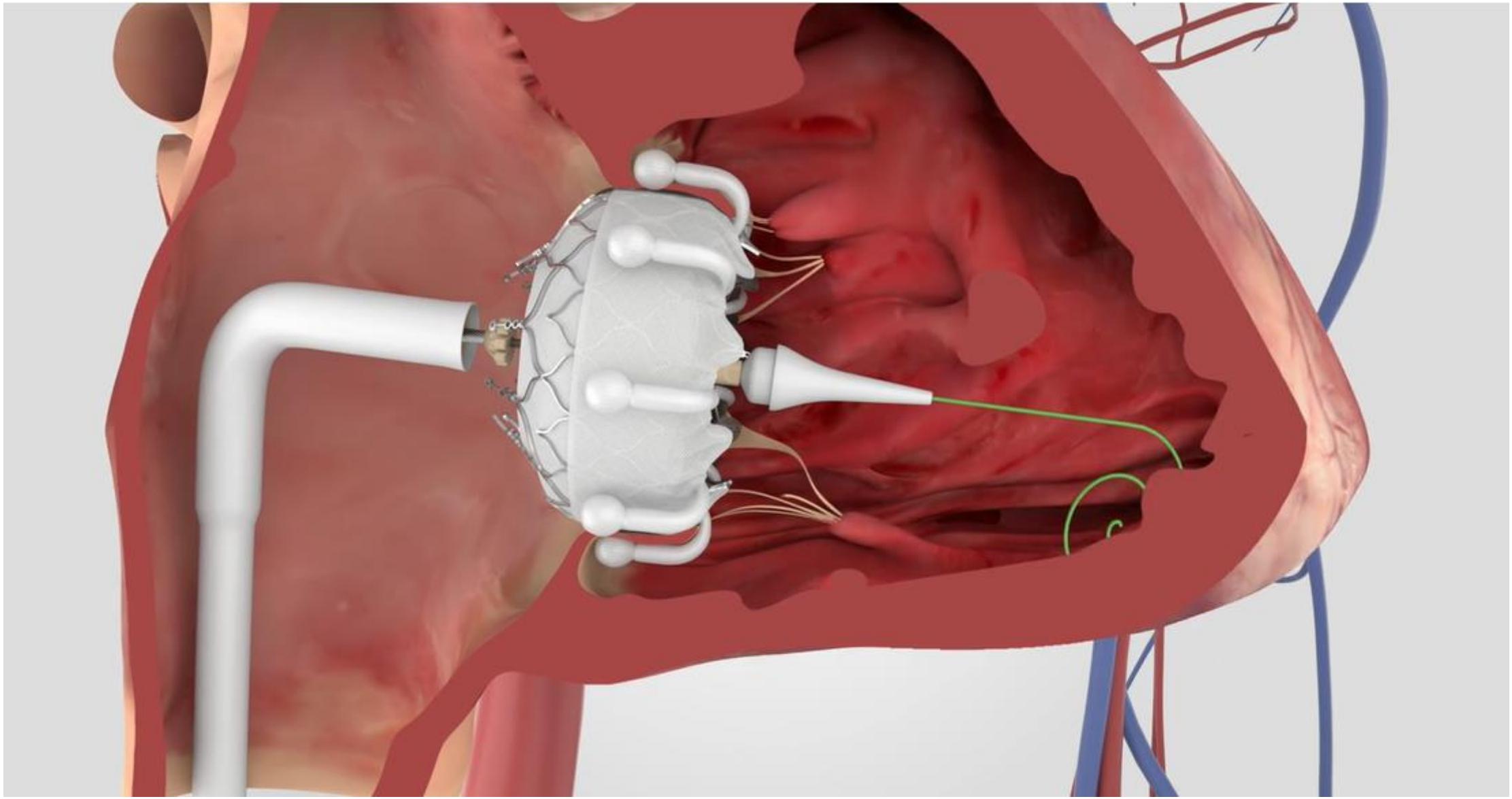
Annular sealing skirt

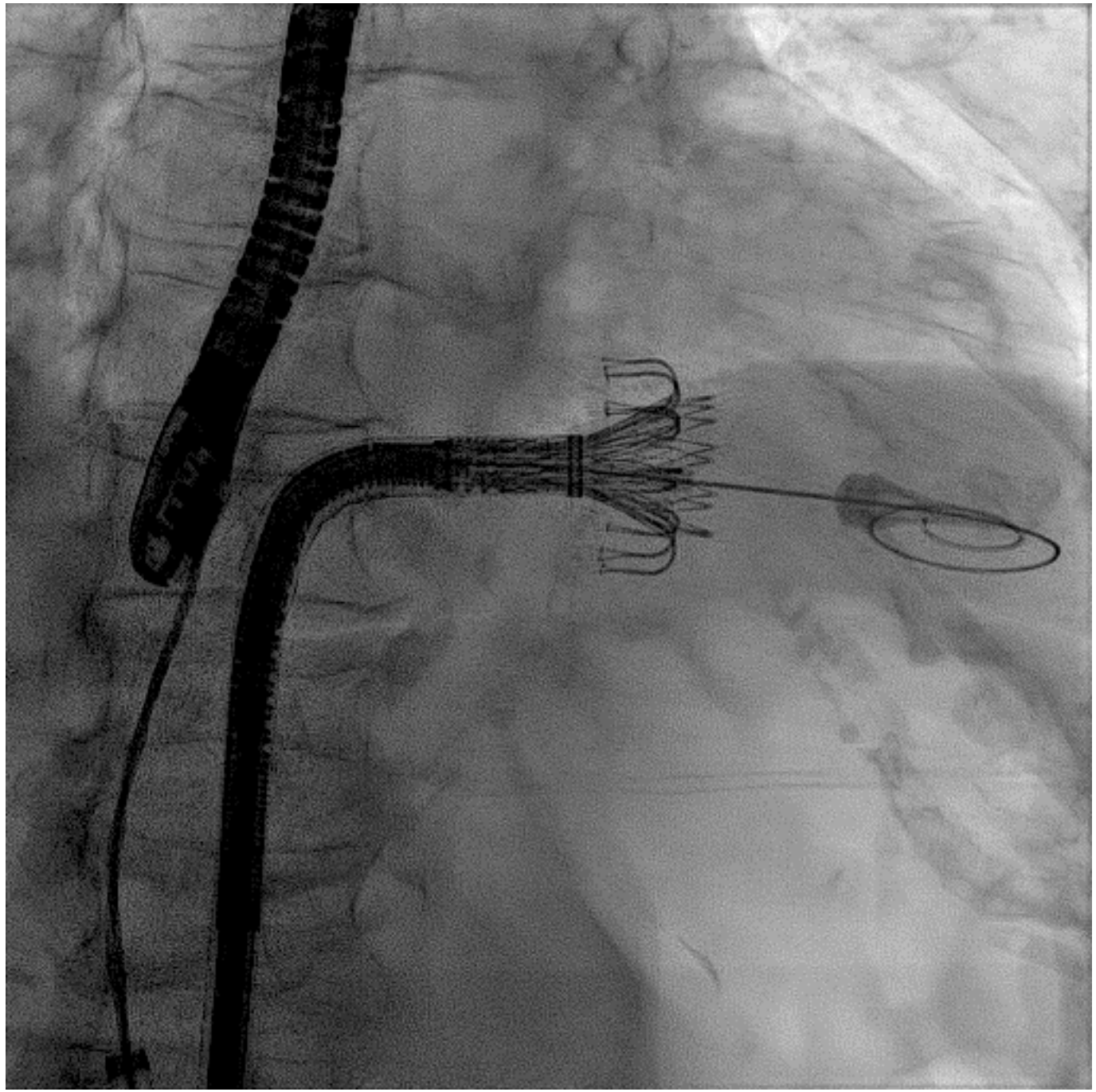
44, 48, 52 mm sizes

28-French transfemoral delivery system

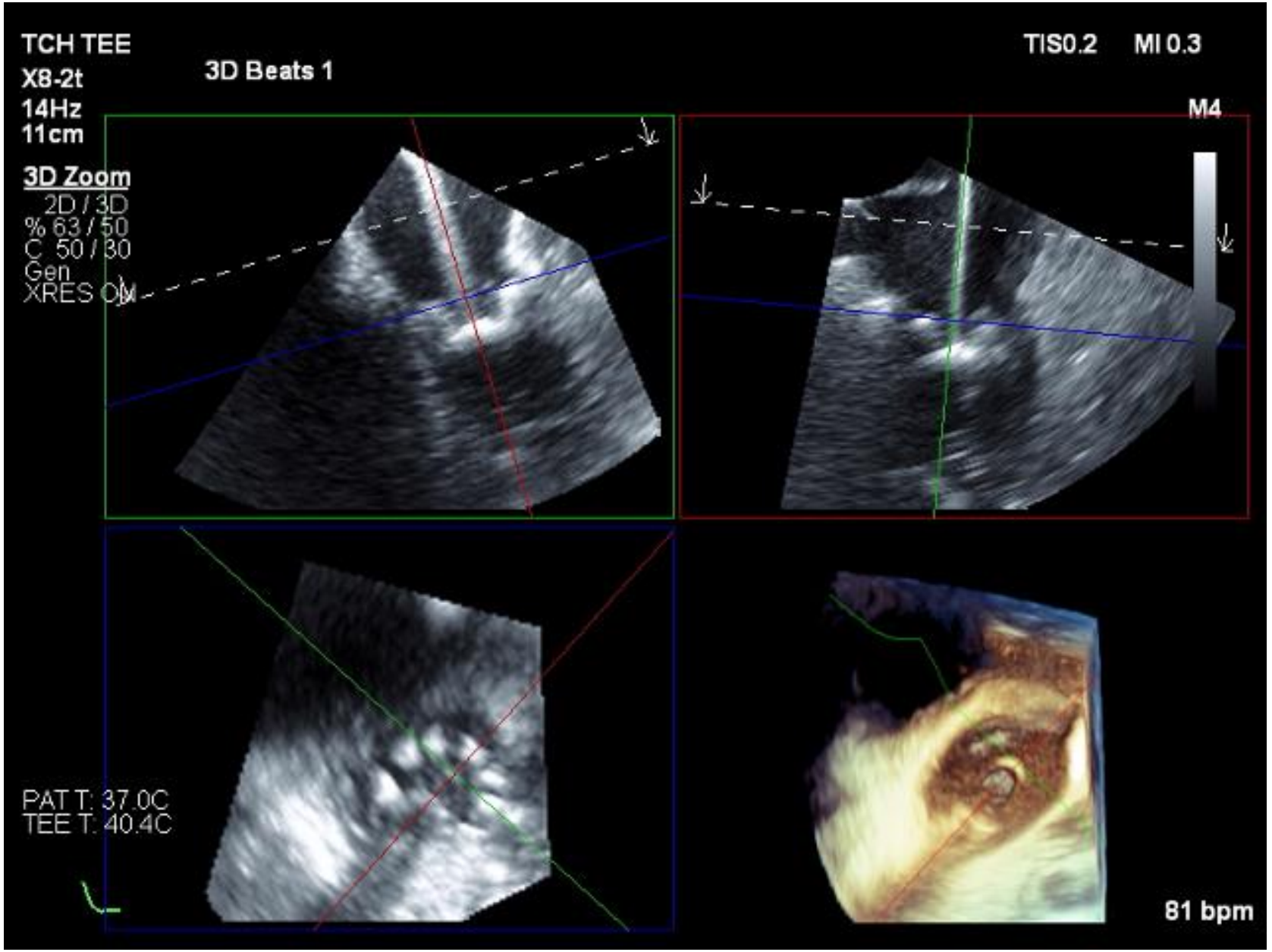
DOI: 10.1056/NEJMoa2401918.

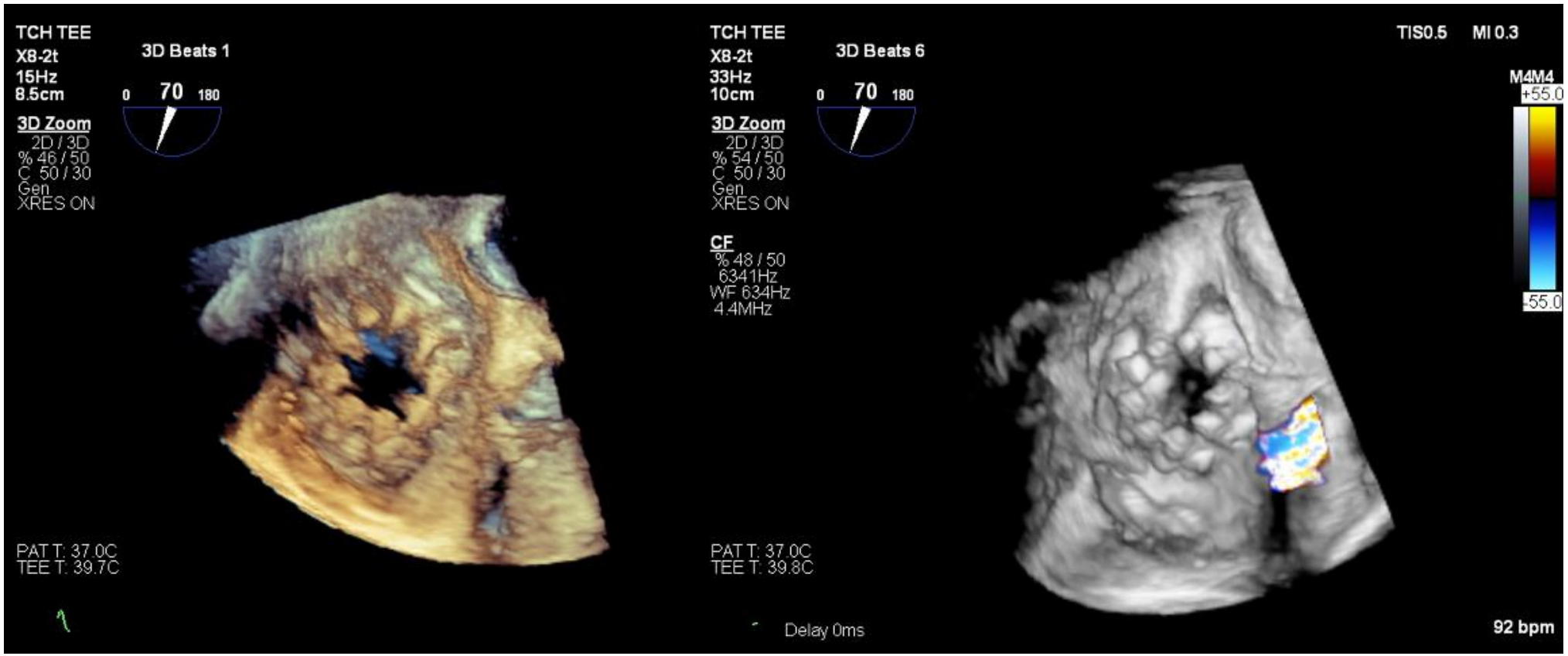




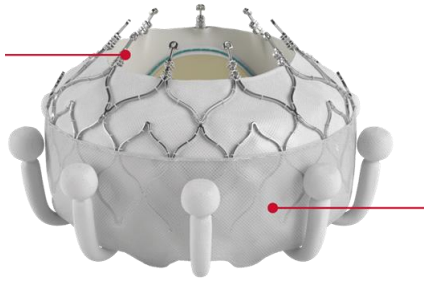


MPR, rotate to confirm 9 ventricular anchors below leaflets




TCH TEE
X8-2t
15Hz
8.5cm
3D Beats 1
0 70 180
3D Zoom
2D / 3D
% 46 / 50
C 50 / 30
Gen
XRES ON
PAT T: 37.0C
TEE T: 39.7C
TCH TEE
X8-2t
33Hz
10cm
3D Beats 6
0 70 180
3D Zoom
2D / 3D
% 54 / 50
C 50 / 30
Gen
XRES ON
CF
% 48 / 50
6341Hz
WF 634Hz
4.4MHz
PAT T: 37.0C
TEE T: 39.8C
Delay 0ms
TIS0.5 MI 0.3
M4M4
+55.0
-55.0
92 bpm

TRISCEND II



The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Valve Replacement in Severe Tricuspid Regurgitation

R.T. Hahn, R. Makkar, V.H. Thourani, M. Makar, R.P. Sharma, C. Haeffele, C.J. Davidson, A. Narang, B. O'Neill, J. Lee, P. Yadav, F. Zahr, S. Chadderdon, M. Eleid, S. Pislaru, R. Smith, M. Szerlip, B. Whisenant, N.K. Sekaran, S. Garcia, T. Stewart-Dehner, H. Thiele, R. Kipperman, K. Koulogiannis, D.S. Lim, D. Fowler, S. Kapadia, S.C. Harb, P.A. Grayburn, A. Sannino, M.J. Mack, M.B. Leon, P. Lurz, and S.K. Kodali, for the TRISCEND II Trial Investigators*

DOI: 10.1056/NEJMoa2401918.

TRISCEND II

- 267 valve-replacement 133 medical tx
- Symptomatic severe tricuspid regurgitation
- Age 79, 76% female, 94% a.fib. NYHA class 3+
- 1^0 end point - death, RVAD/transplant, surgery, hospitalization, improved quality of life / walking distance.

N Engl J Med DOI: 10.1056/NEJMoa2401918.

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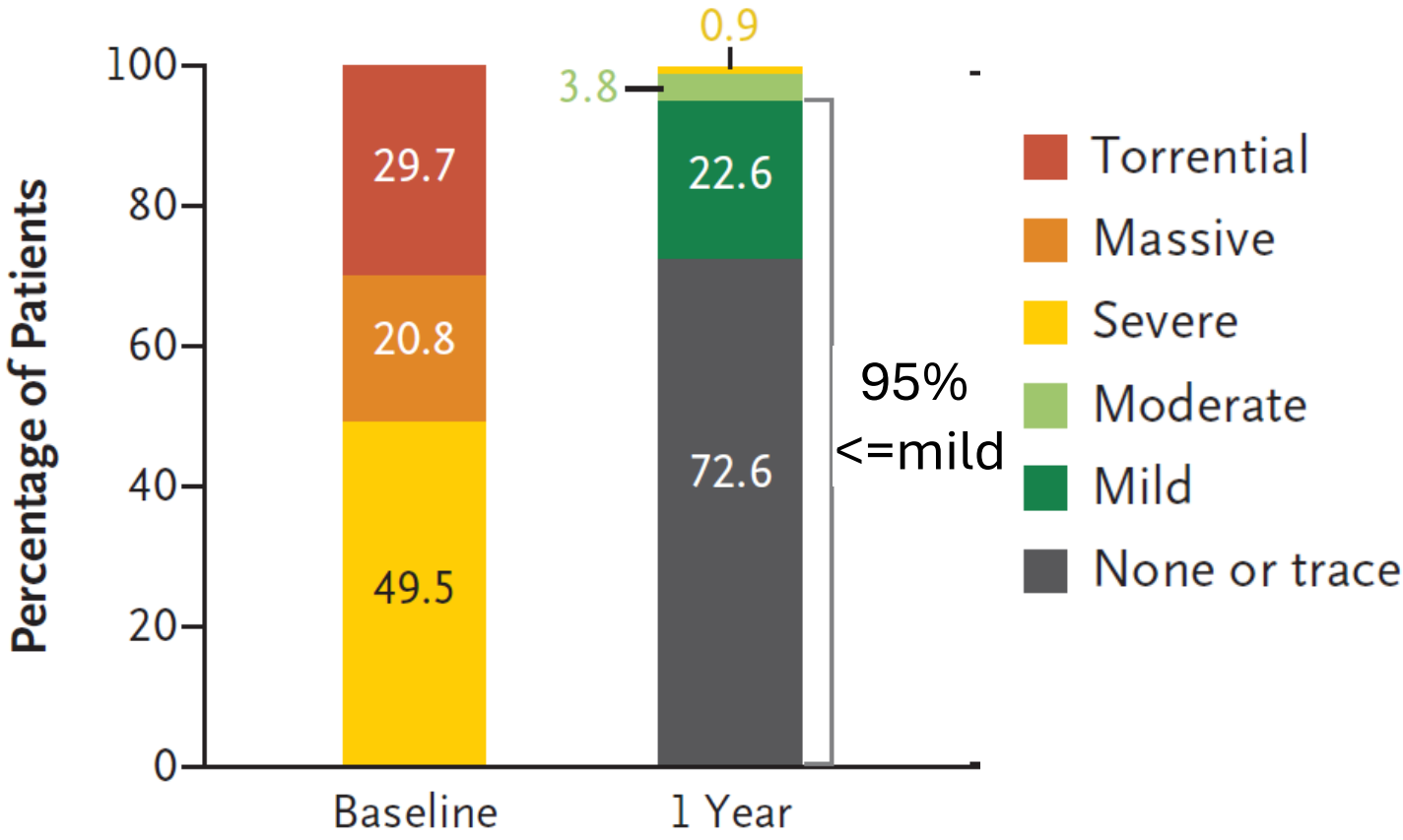
Reduction in Tricuspid Regurgitation, 1-Year

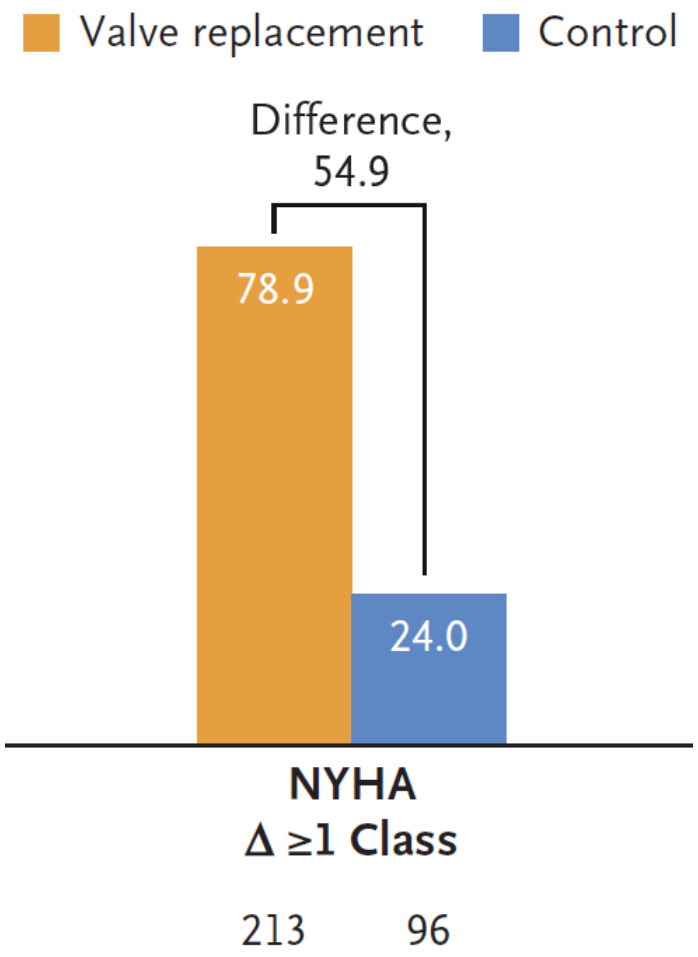


Valve replacement N=212

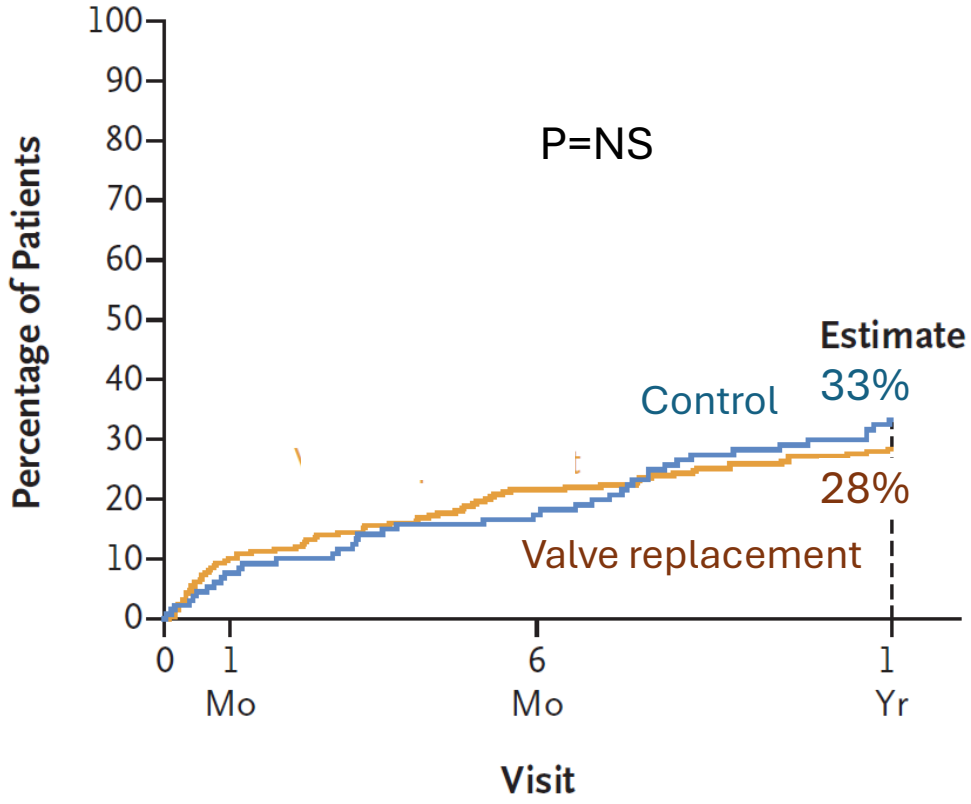
N Engl J Med DOI: 10.1056/NEJMoa2401918.

TRISCEND II

Improvement in >= 1 NYHA Class



Death or 1st hospitalization for heart failure



No. at Risk				
Valve replacement	259	229	198	176
Control	133	116	100	79

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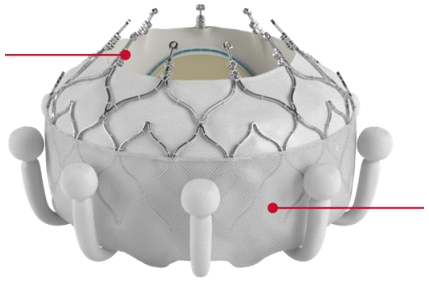
TRISCEND II



The Evoque tricuspid valve is highly effective at reducing tricuspid regurgitation via a percutaneous approach

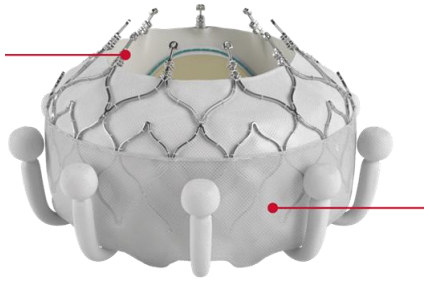
among highly select patients and placed with extensive training and procedural support personnel

with increased risk of early death, mainly from acute right ventricular failure

30 days death, 9 of 267 treated, 0 of 133 controls

N Engl J Med DOI: 10.1056/NEJMoa2401918.

TRISCEND II



Tricuspid valve replacement was superior to continued medical therapy,

mainly related to improvements in symptoms and quality of life.

N Engl J Med DOI: 10.1056/NEJMoa2401918.

Percutaneous Heart Valve Update Conclusions

- In 5-year follow up of patients with low surgical risk, transcatheter aortic valve replacement (TAVR) has similar efficacy and safety compared to surgical aortic valve replacement.
- Even longer term follow up in the 10-year range will provide the best measure of TAVR valve longevity and safety.

Percutaneous Heart Valve Update Conclusions

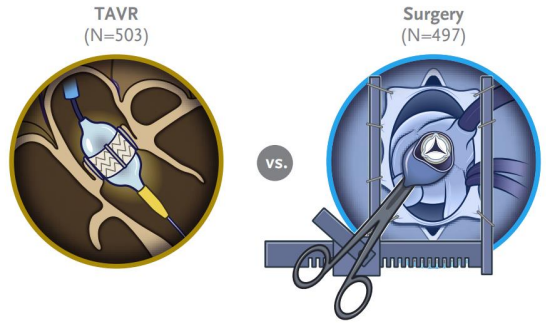
- In experienced centers with select patients with significant mitral regurgitation and symptomatic heart failure, edge-to-edge mitral valve clipping has demonstrated efficacy in multiple studies and longer follow-up.

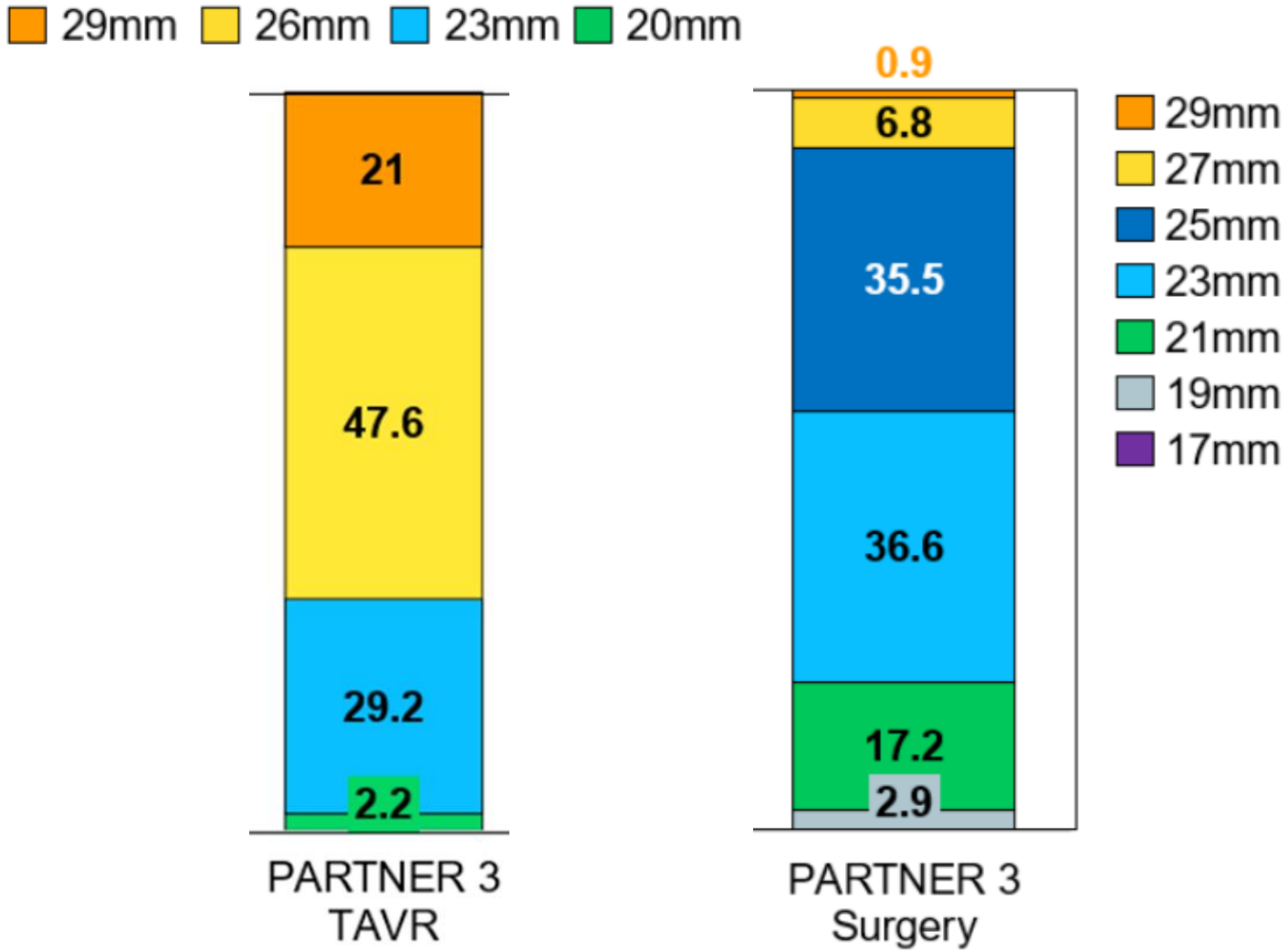
Percutaneous Heart Valve Update Conclusions

- Percutaneous replacement of tricuspid and aortic valves in the setting of severe regurgitation represents an evolving field with promising technologies / alternatives to surgery.

Partner 3

Implanted valve size distribution



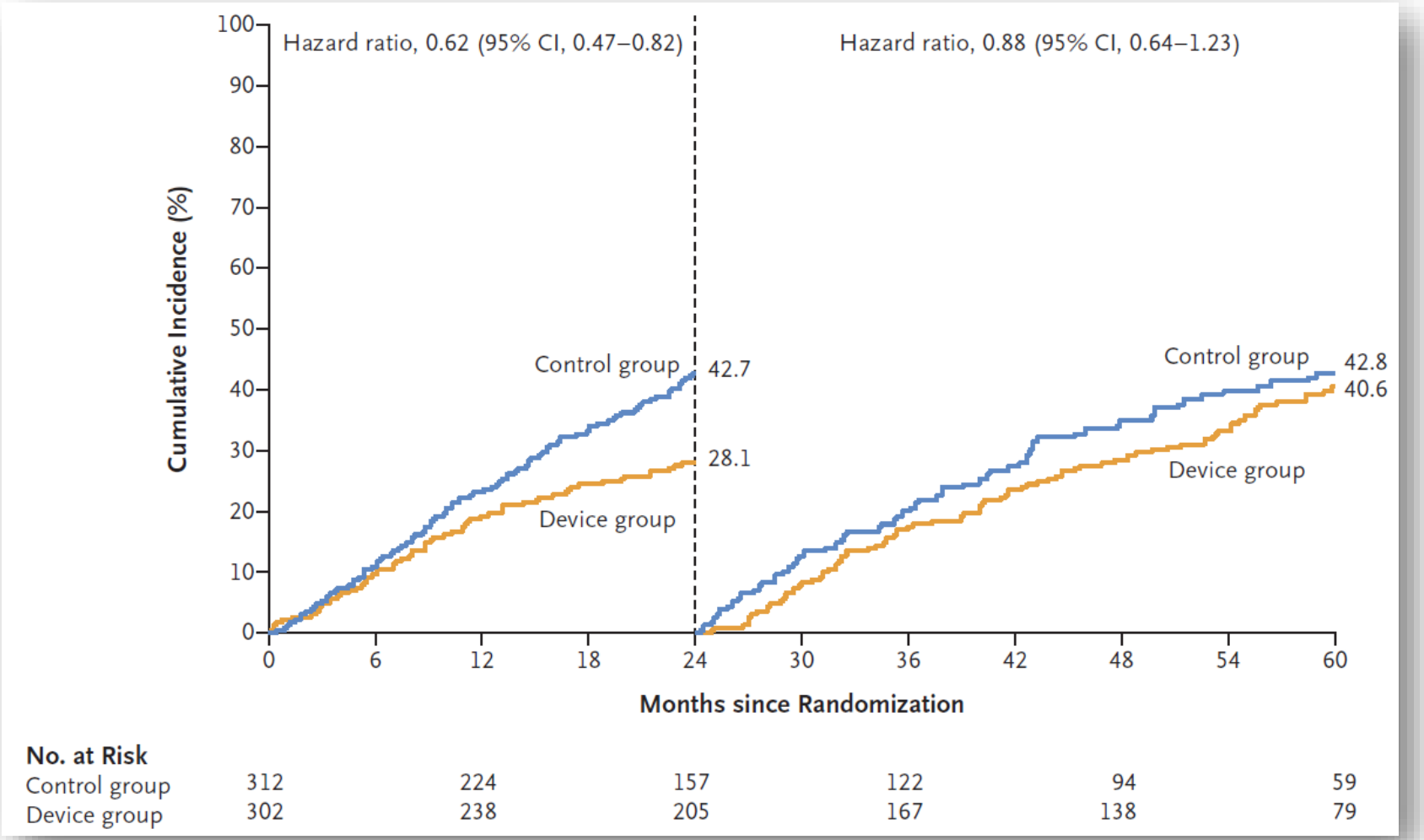


N Engl J Med 2023;389:1949-60.

COAPT 5 year follow up

Transcatheter repair of secondary mitral regurgitation with heart failure

Death, Landmark analysis



N Engl J Med 2023;388:2037-48.