Watchman, Mitral Valve Clip & Structural Heart Disease

James G Jollis MD FACC

Duke University

Disclosures

- None

Watchman, Mitral Clip, New valves

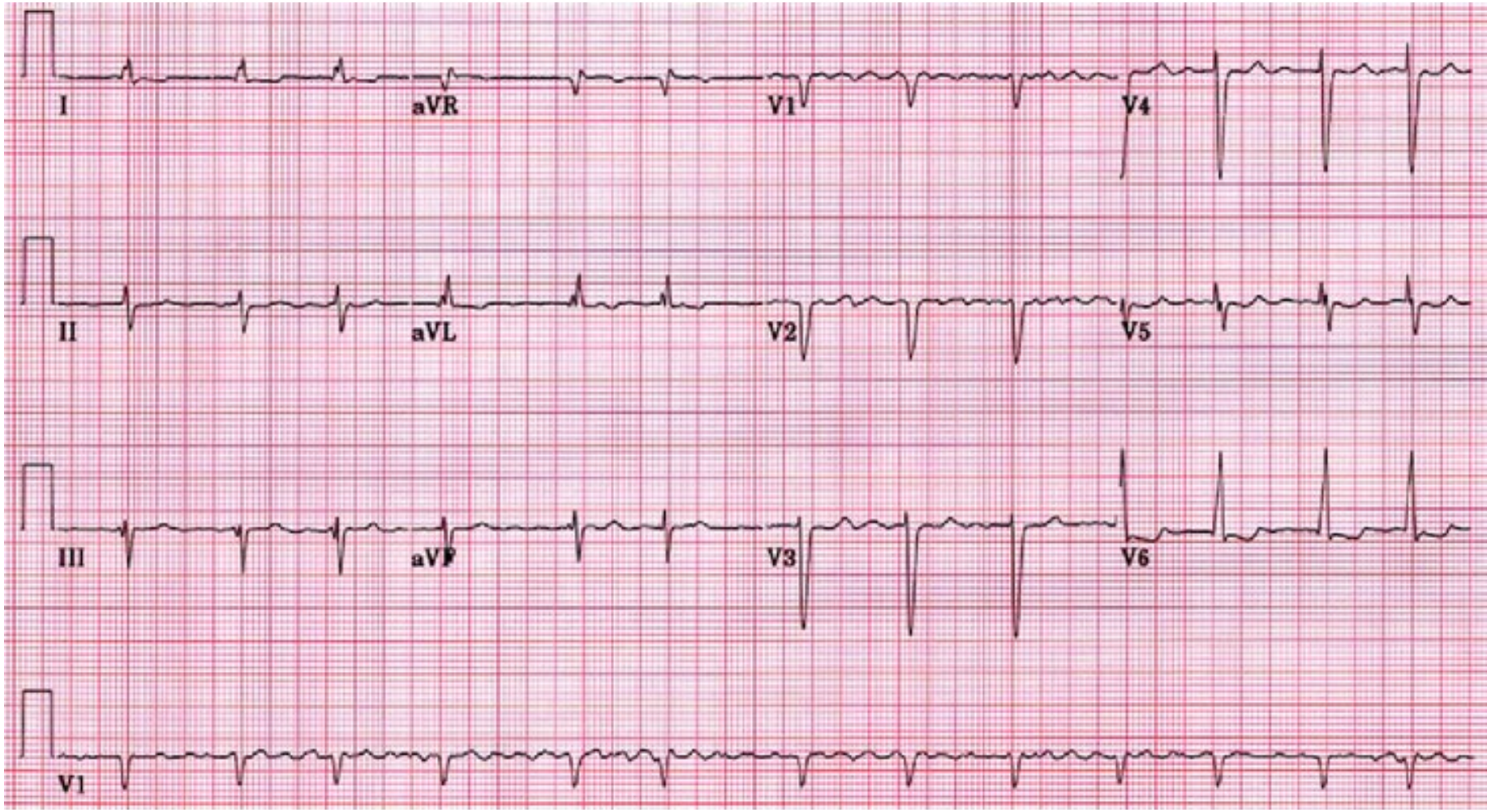
- Left atrial occlusion device
- Mitral valve edge-to-edge clipping
- Promising percutaneous valves

S.R. 75 y.o. man

- Paroxysmal atrial fibrillation
  - BP cuff “irregular heartbeat” symbol
  - 36 hours total on 7-day Holter
- Hypertension
- CHADS Vasc score = 3 for age 75 and hypertension
- Rx. Apixaban 5 mg BID

(If 2 of 3, age>= 80, creatine <= 1.5, weight <=60 kg, reduce dose to 2.5 mg BID)

S.R. 75 y.o. man



CHA2DS2-VASc

Letter	Characteristic	Points (if yes)
C	congestive heart failure*	1
H	hypertension	1
A	age ≥75 years old	2
D	diabetes	1
S	stroke, TIA, or thromboembolism	2
V	vascular disease**	1
A	age 65-74 years	1
S	sex: female	1
		Maximum 9 points

* **Congestive heart failure:** left ventricle ejection fraction ≤40

** **Vascular disease:** myocardial infarction, peripheral vascular disease, or aortic plaque

S.R. 75 y.o. man

Taking care of a small farm, woodworking shop, afraid of bleeding risk.

$600 out of pocket with Medicare Part D.

Table 1. Medicare Part D Use and Spending on Eliquis, Calendar Year (CY) 2022

	Total Enrollees	LIS Enrollees[a]	Non-LIS Enrollees
Number of Part D Enrollees	53,063,000	14,957,000	38,106,000
Number of Enrollees Taking Eliquis	3,505,000	1,013,000	2,492,000
Share of Part D Enrollees Taking Eliquis	6.6%	6.8%	6.5%
Total Spending on Eliquis			
Total Spending	$15,220,750,000	$4,327,661,000	$10,893,089,000
Average per Enrollee taking Eliquis	$4,342	$4,272	$4,371
Enrollee Out-of-Pocket Spending on Eliquis			
Total OOP Spending	$1,546,358,000	$31,396,000	$1,514,962,000
Average OOP per Enrollee taking Eliquis	$441	$31	$608

Notes: [a]For eligible Part D enrollees who meet income and asset requirements, the Low-Income Subsidy (LIS), also known as Extra Help, provides assistance with premiums, deductibles, and co-payments for covered Part D drugs.

https://aspe.hhs.gov/sites/default/files/documents/d1e51e1f27136349e9a48677d14c5198/Eliquis.pdf

Percutaneous left atrial occlusion (Watchman)

COR	LOE
2a	B-NR

AF, a moderate to high risk of stroke (CHA 2 DS 2 -VASc score >=2), and a contraindication to long-term oral anticoagulation, percutaneous LAAO (pLAAO) is reasonable

2b	B-R

AF and a moderate to high risk of stroke and a high risk of major bleeding on oral anticoagulation, pLAAO may be a reasonable alternative to oral anticoagulation based on patient preference, *with careful consideration of procedural risk and with the understanding that the evidence for oral anticoagulation is more extensive*

Joglar, J. A. et al., 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation. JACC

Long-Term Anticoagulation

Contraindicated

- Severe bleeding due to a nonreversible cause involving the gastrointestinal, pulmonary, or genitourinary systems
- Spontaneous intracranial / intraspinal bleeding due to a nonreversible cause
- Serious bleeding related to recurrent falls when cause of falls is not felt to be treatable

Reasonable

- Bleeding involving the gastrointestinal, pulmonary, or genitourinary systems that is treatable
- Bleeding related to isolated trauma
- Bleeding related to procedural complications

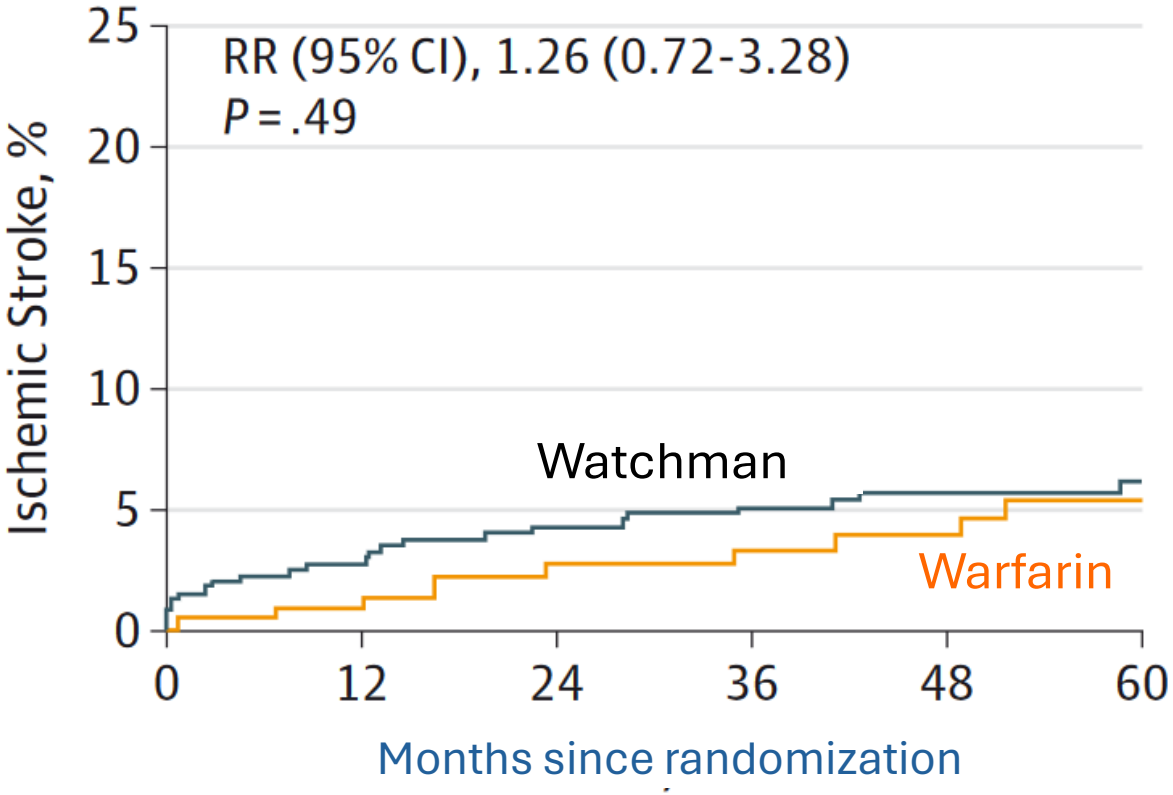
Joglar, J. A. et al., 2023 ACC/AHA/ACCP/HRS Guideline for the Diagnosis and Management of Atrial Fibrillation. JACC

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation PROTECT AF

- 707 pts.
- Nonvalvular A. fib including paroxysmal
- 1 or more CHADS risk factors
- Eligible for long term warfarin
- 2:1 Watchman / Warfarin

- Age 72, BMI 32, CHADS 2.2

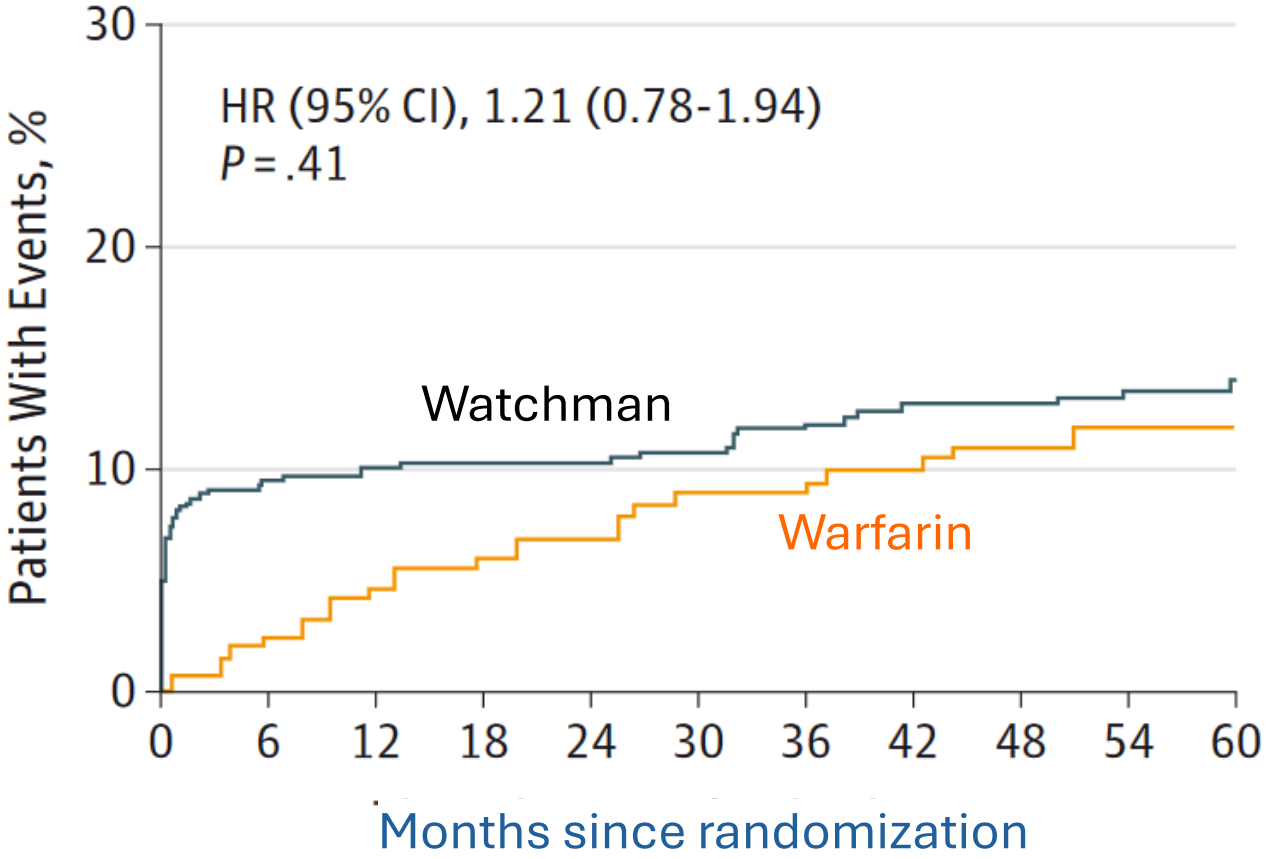
Ischemic stroke



JAMA. 2014;312:1988-1998.

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation PROTECT AF

Major bleeding events and procedure-related complications



JAMA. 2014;312:1988-1998.

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation PROTECT AF

	Device Group, No. (%) (n = 463)			Warfarin Group, No. (%) (n = 244)
	Total Events	Early Events[a]	Late Events	Events
Serious pericardial effusion	22 (4.8)	22 (4.8)	0	
Major bleeding	22 (4.8)	3 (0.6)	19 (4.1)	18 (7.4)
Procedure-related ischemic stroke	6 (1.3)	5 (1.1)	1 (0.2)	
Device embolization	3 (0.6)	3 (0.6)	0	
Hemorrhagic stroke	3 (0.6)	0	3 (0.6)	9 (3.7)
Other	4 (0.9)	4 (0.9)	0	

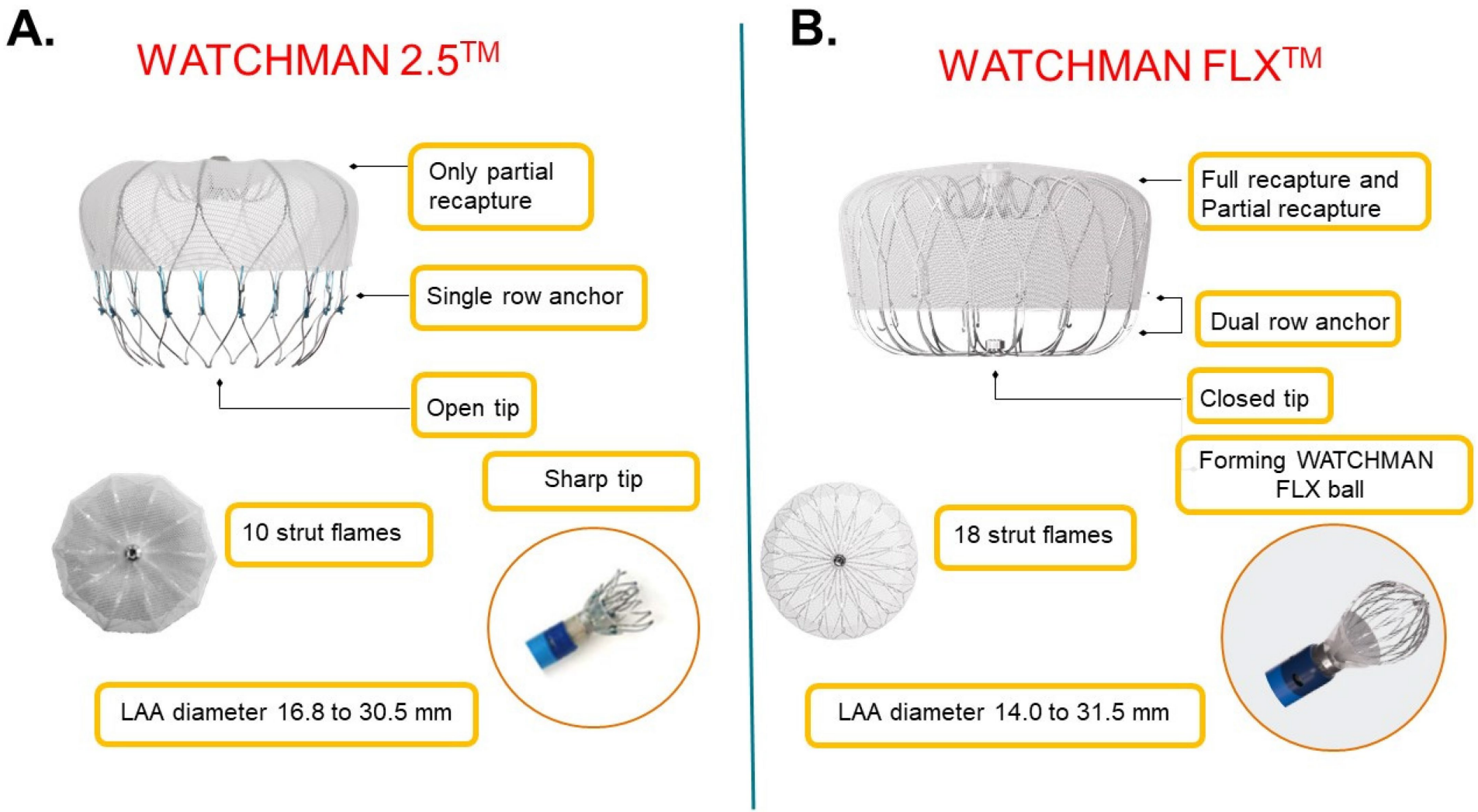
JAMA. 2014;312:1988-1998.

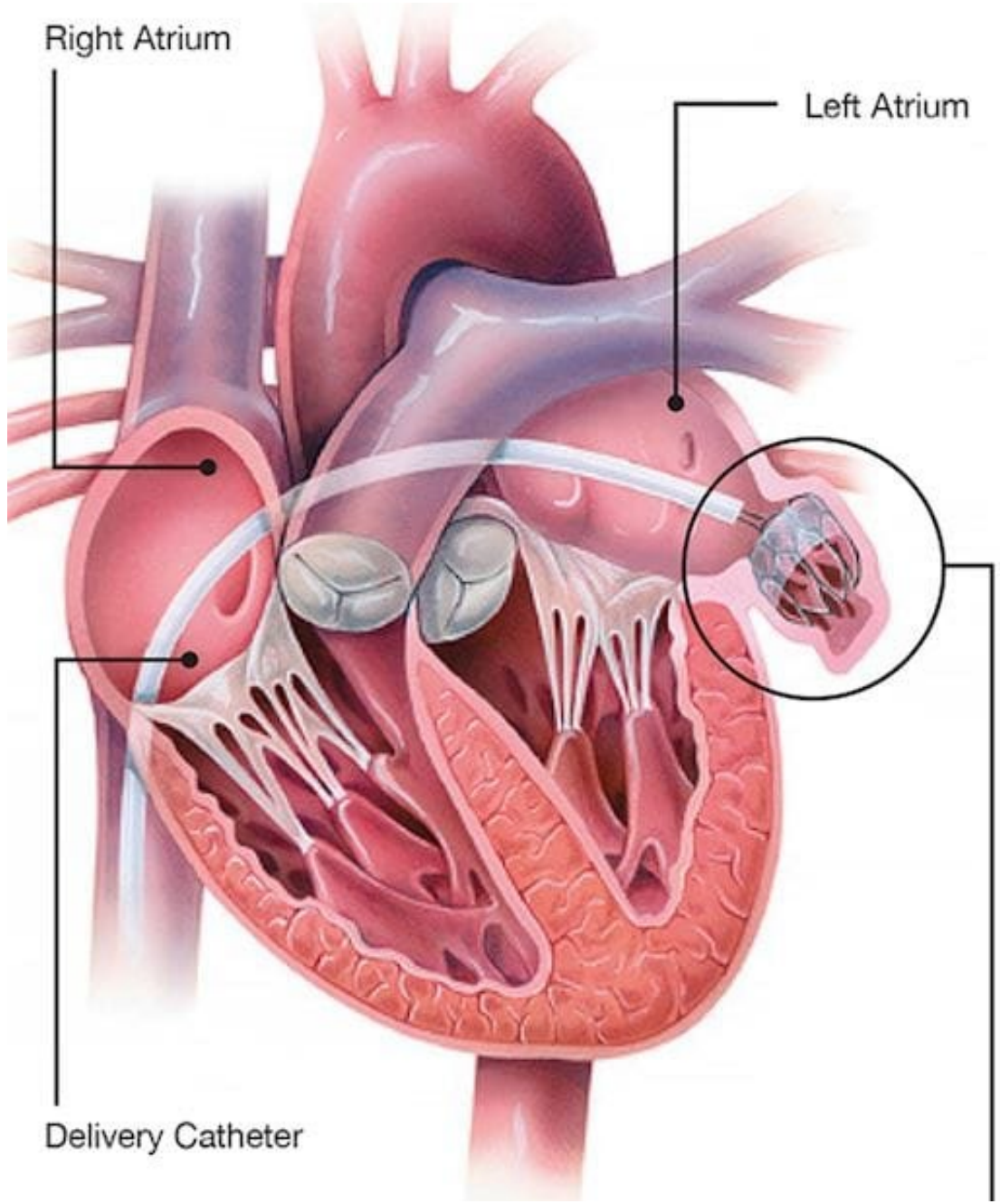
Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation PROTCT AF

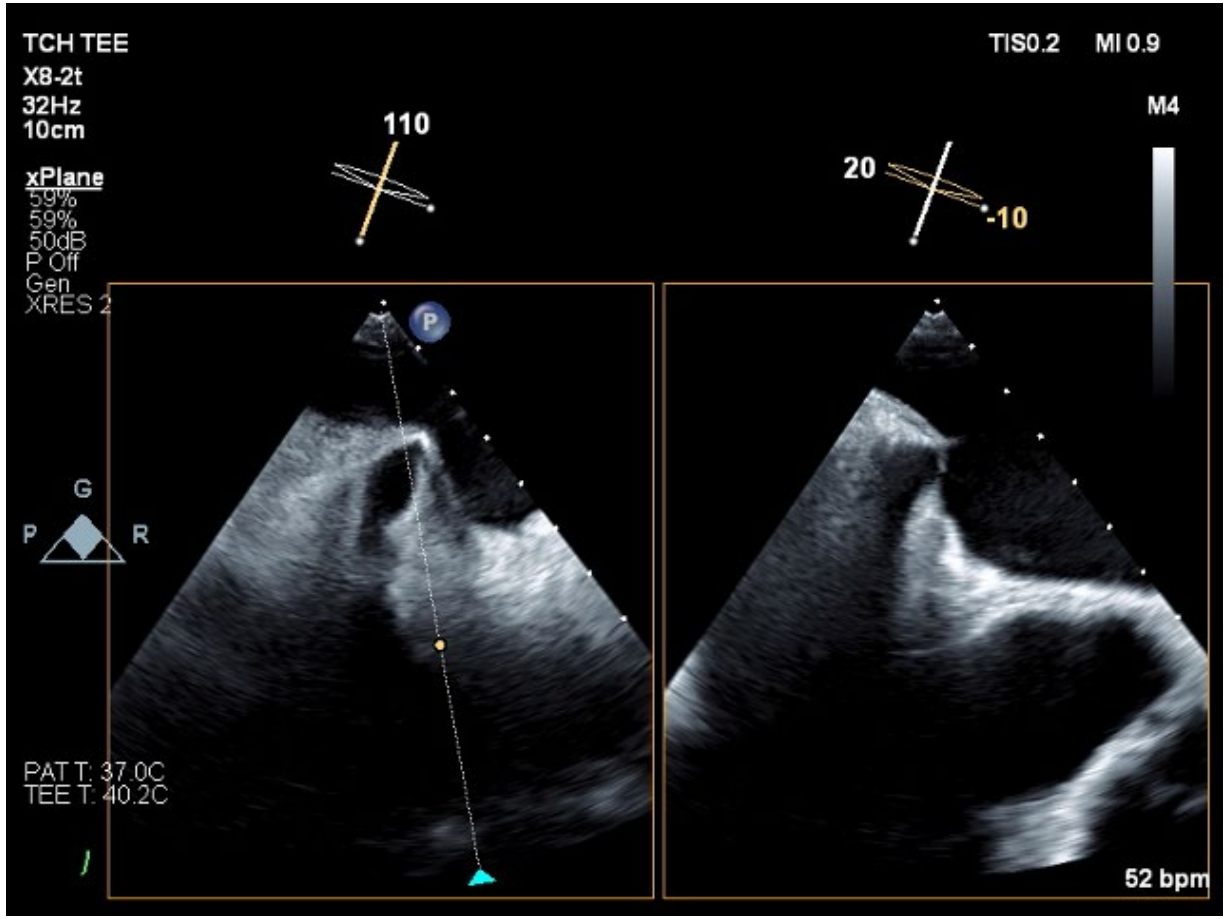
	Device Group, No. (%) (n = 463)			Warfarin Group, No. (%) (n = 244)
	Total Events	Early Events[a]	Late Events	Events
Serious pericardial effusion	22 (4.8)	22 (4.8)	0	
Major bleeding	22 (4.8)	3 (0.6)	19 (4.1)	18 (7.4)
Procedure-related ischemic stroke	6 (1.3)	5 (1.1)	1 (0.2)	
Device embolization	3 (0.6)	3 (0.6)	0	
Hemorrhagic stroke	3 (0.6)	0	3 (0.6)	9 (3.7)
Other	4 (0.9)	4 (0.9)	0	

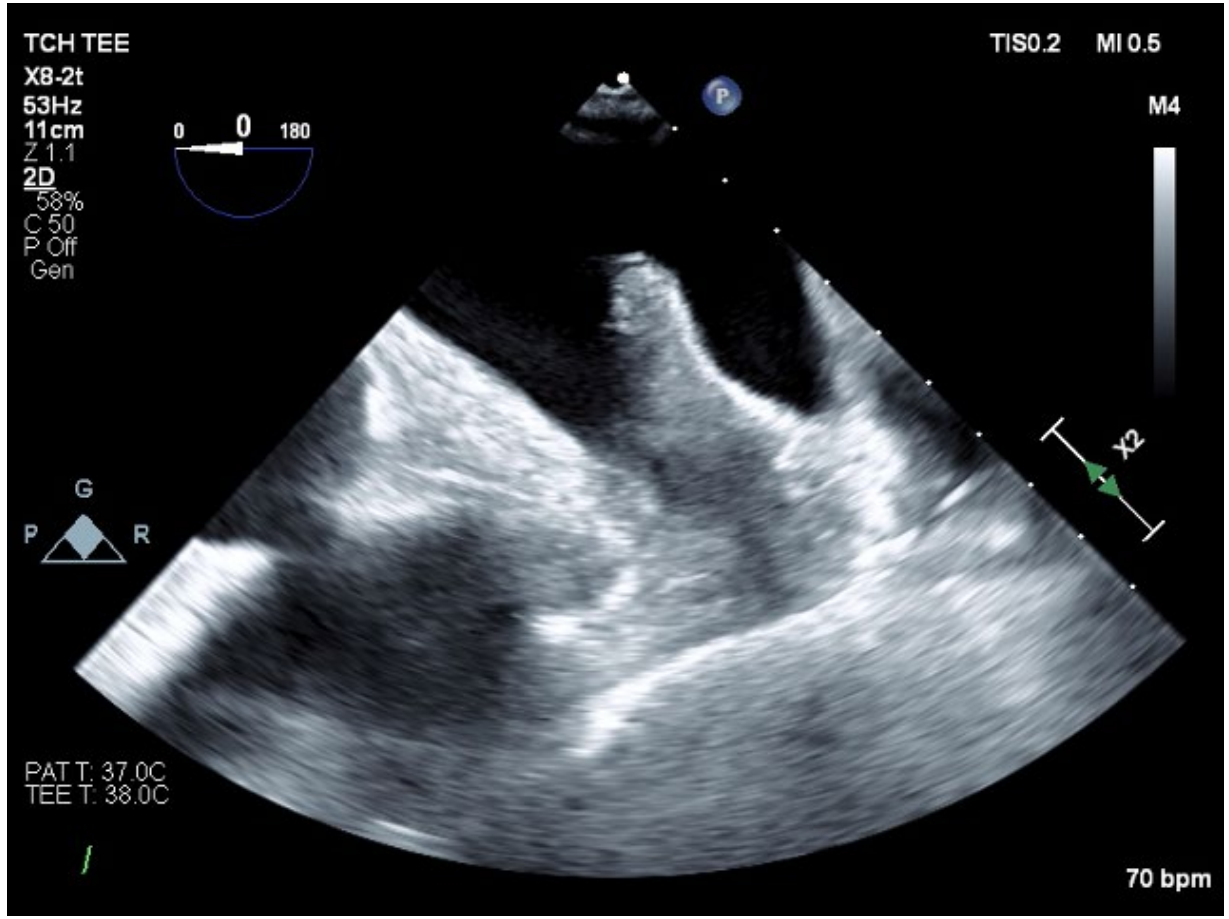
JAMA. 2014;312:1988-1998.

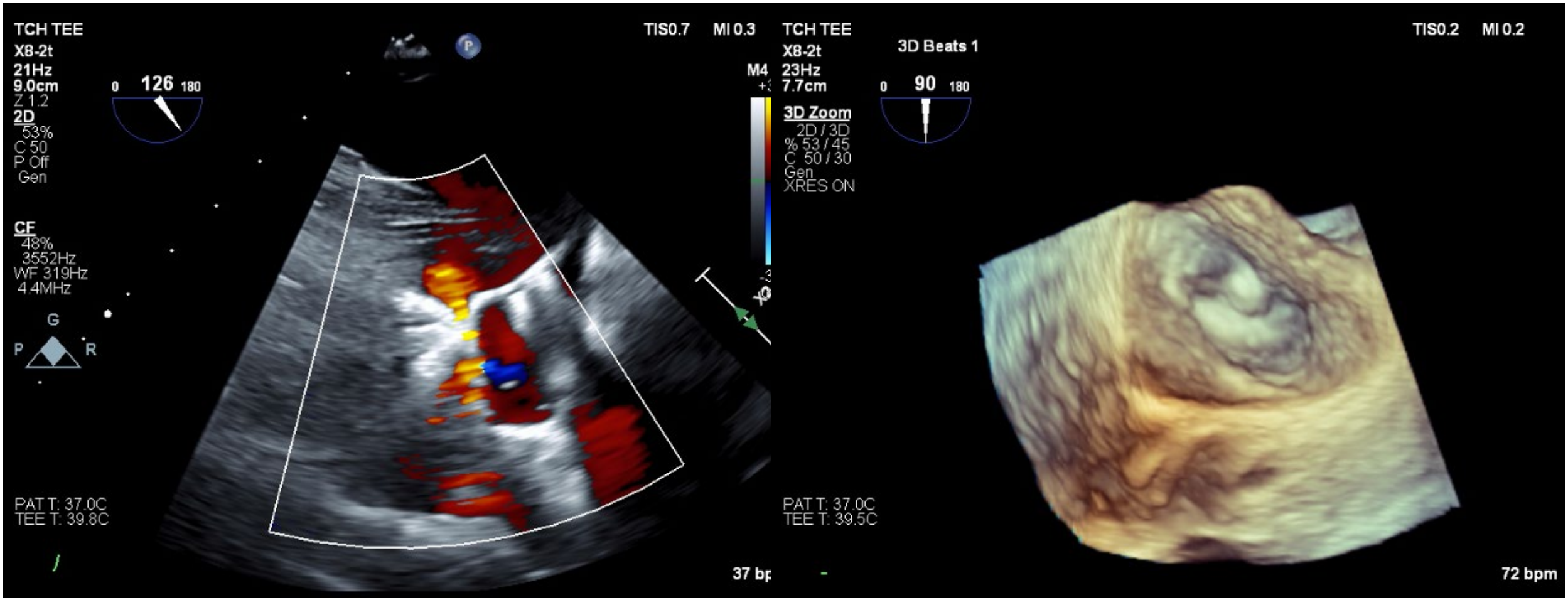
Watchman FLX



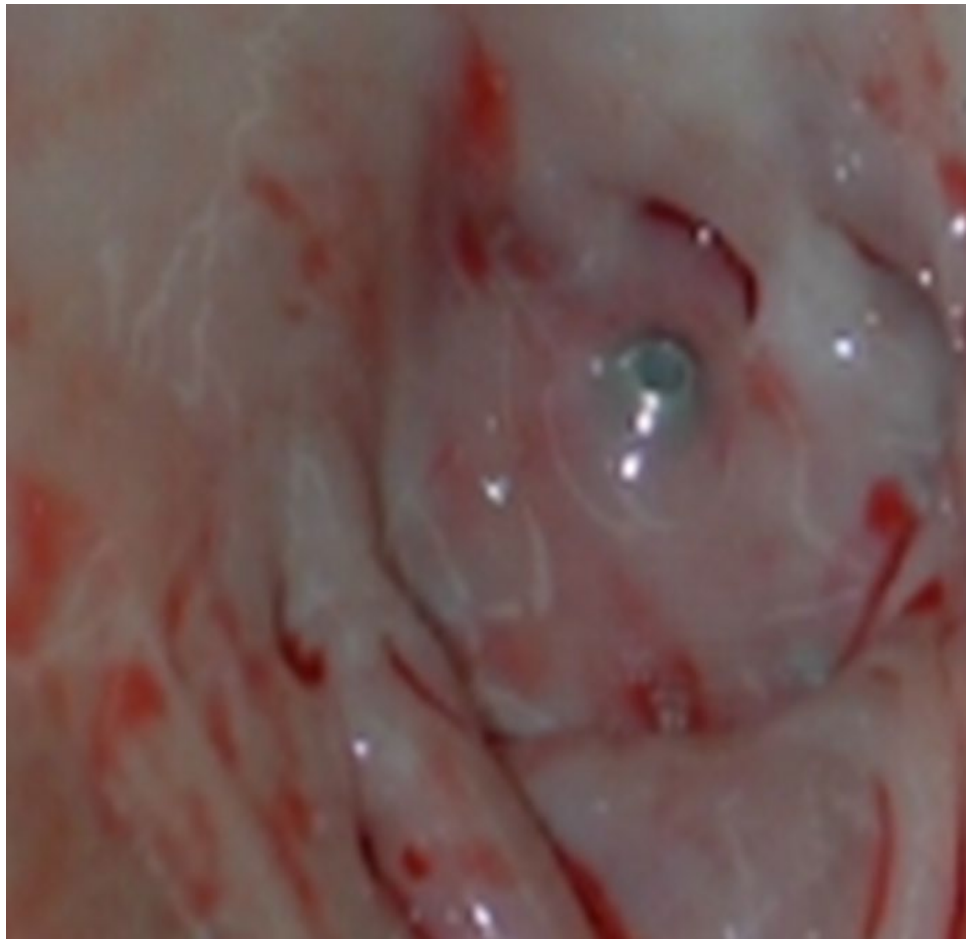

Right Atrium
Left Atrium
Delivery Catheter


TCH TEE
X8-2t
32Hz
10cm
xPlane
59%
59%
50dB
P Off
Gen
XRES 2
TIS0.2 MI 0.9
M4
110
20
-10
G
P
R
PAT T: 37.0C
TEE T: 40.2C
52 bpm


TCH TEE
X8-2t
53Hz
11cm
Z 1.1
2D
58%
C 50
P Off
Gen
TIS0.2 MI 0.5
M4
0 0 180
X2
G
P
R
PAT T: 37.0C
TEE T: 38.0C
70 bpm


TCH TEE
X8-2t
21Hz
9.0cm
Z 1.2
2D
53%
C 50
P Off
Gen
0 126 180
CF
48%
3552Hz
WF 319Hz
4.4MHz
G
P
R
PAT T: 37.0C
TEE T: 39.8C
TIS0.7 MI 0.3
M4
37 bp
TCH TEE
X8-2t
23Hz
7.7cm
3D Zoom
2D / 3D
% 53 / 45
C 50 / 30
Gen
XRES ON
3D Beats 1
0 90 180
PAT T: 37.0C
TEE T: 39.5C
TIS0.2 MI 0.2
72 bpm

9-months post implant



Percutaneous left atrial occlusion (Watchman)

- Alternative to Warfarin
- Alternative to NOAC?
  - CHAMPION AF trial, 3000 patients, estimated completion 2027
- CHADS = 2 or CHADSVAC= 3, participate in shared decision making
- 2016-2020 – 85,190 implanted, mean hospital charge $122,504

Circulation. 2023;148:A11705


WATCHMAN

S.R. 75 y. o. man

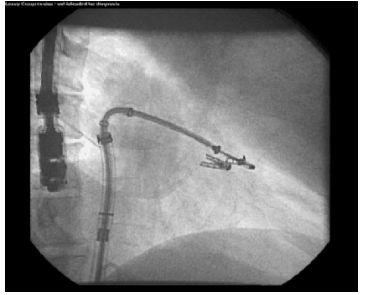
- Watchman FLX 27 mm placed without complication

Apixaban 5 mg BID for 6 weeks

TEE confirming absence of device leak >5mm / thrombus

ASA 81 mg for 1 year post device

Conclusions



- Patients with a moderate risk of stroke and higher risk of bleeding on oral anticoagulation may be treated with a left atrial appendage occlusion device.

- Ongoing trials are comparing the latest Watchman FLX device to NOACs.

Watchman, Mitral Clip, New valves

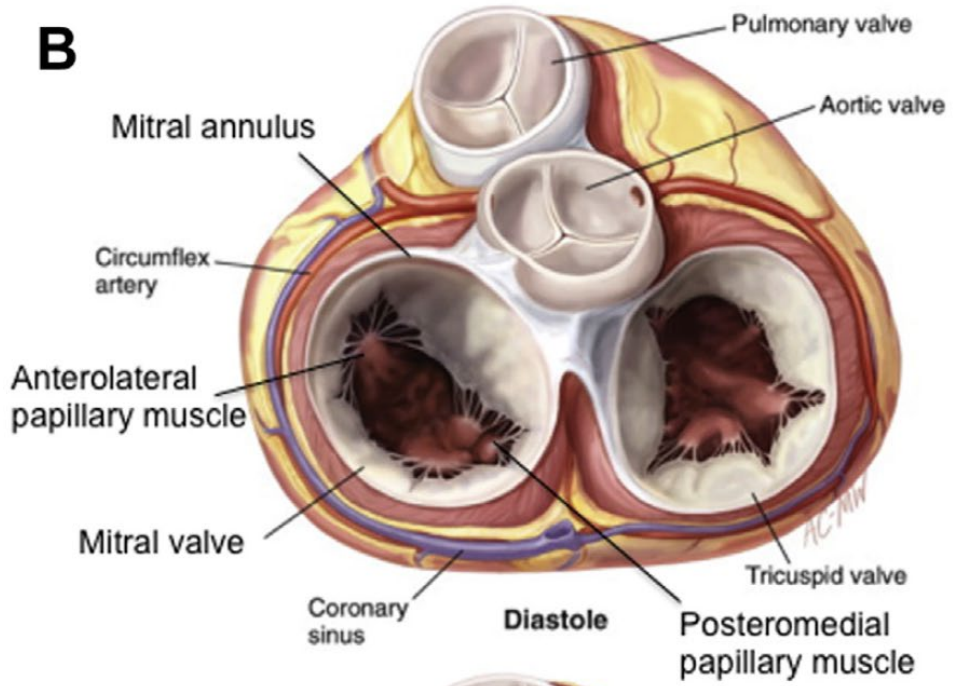
- Left atrial occlusion device
- **Mitral valve edge-to-edge clipping**
- Promising percutaneous valves

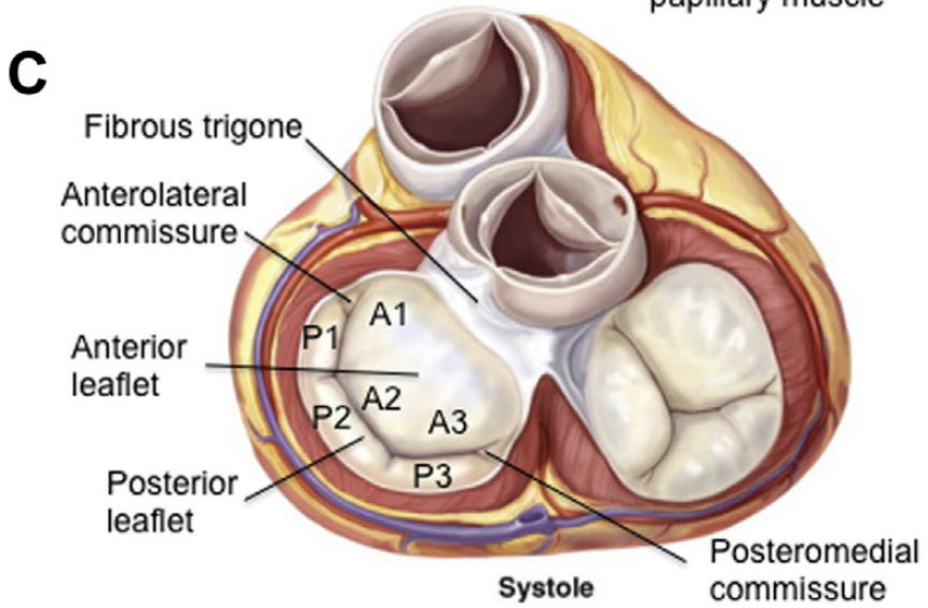
MC 78 y.o. woman

- 78 y.o. woman in wheelchair
- Prior CABG 20 years earlier, LIMA still patent, VG – RCA occluded, no targets
- DM, carotid artery disease, prior stroke with residual left sided weakness
- LVEF 35%, severe MR
- QRS complex 110 msec duration
- ACE, spironolactone
- Severe dyspnea with minimal exertion
- Orthopnea, difficulty sleeping
- Multiple hospitalization with pulmonary edema

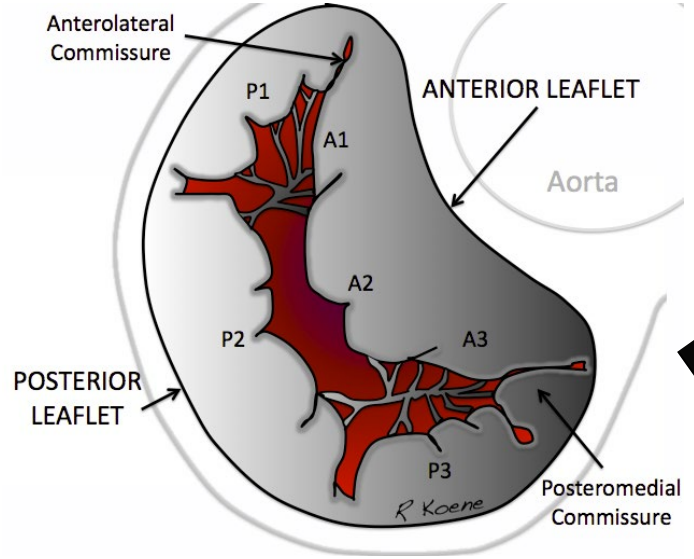
MC 7

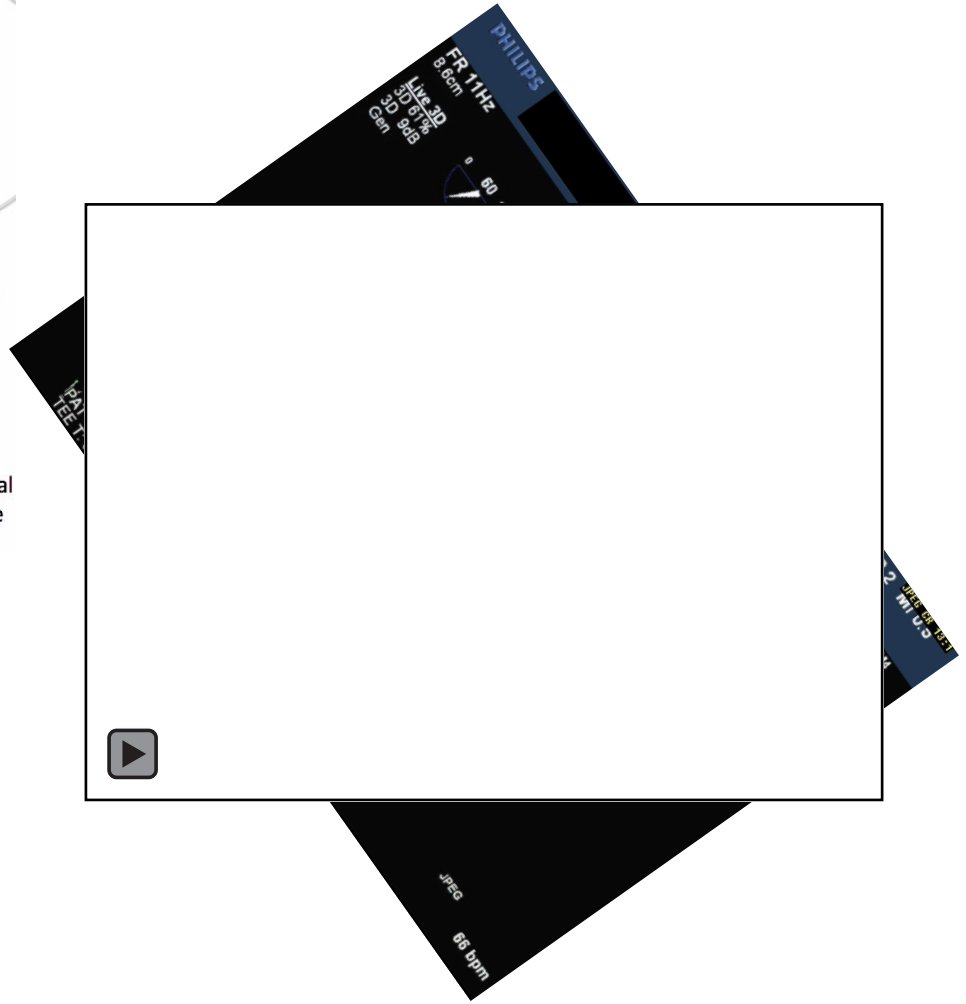
Mitral valve



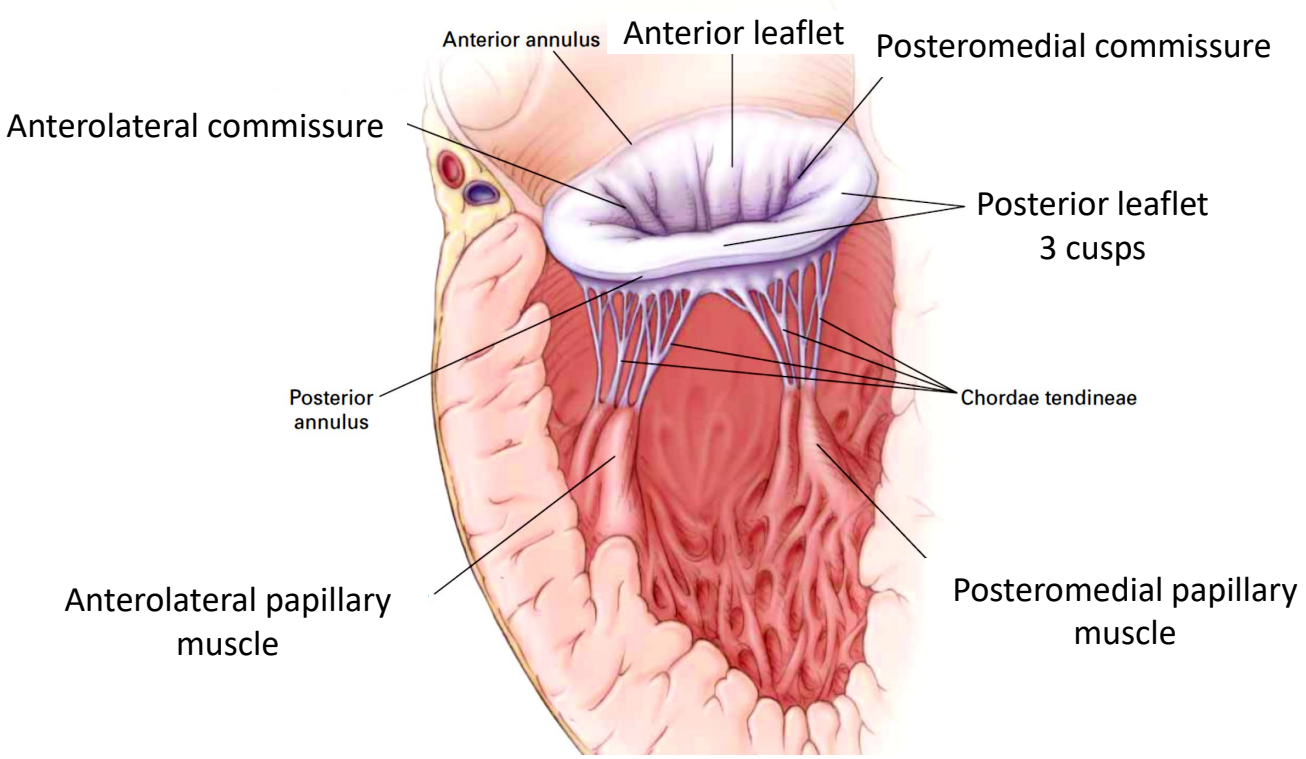


Mitral valve





Mitral valve



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

Degenerative vs Functional Mitral regurgitation

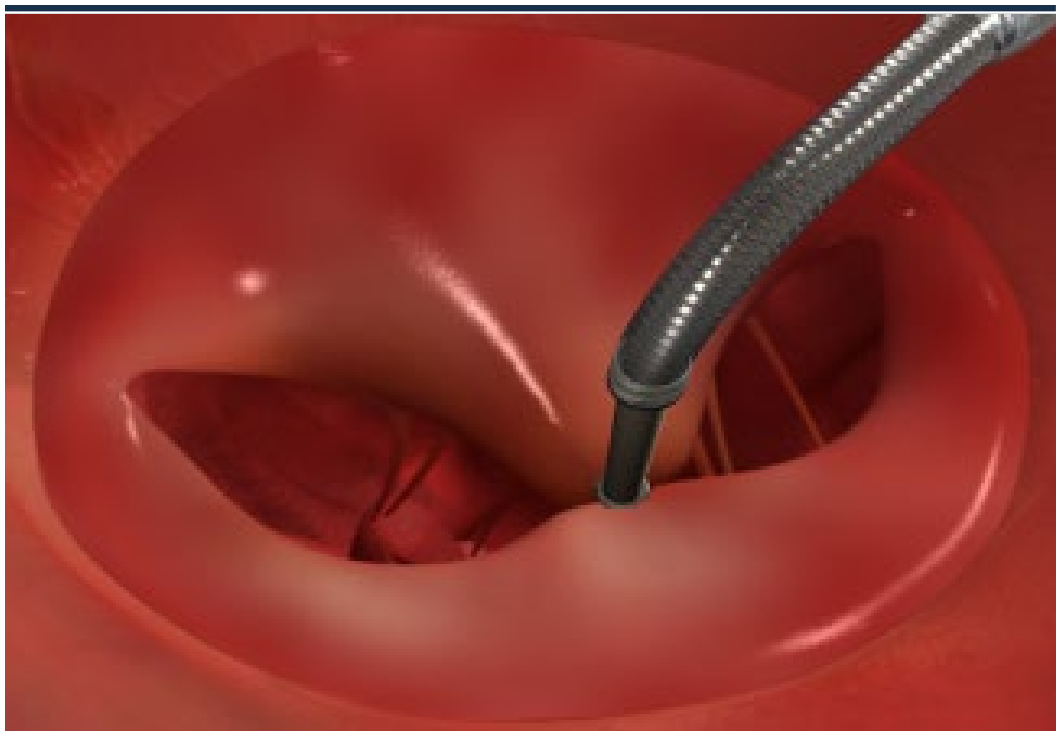
Degenerative / Primary

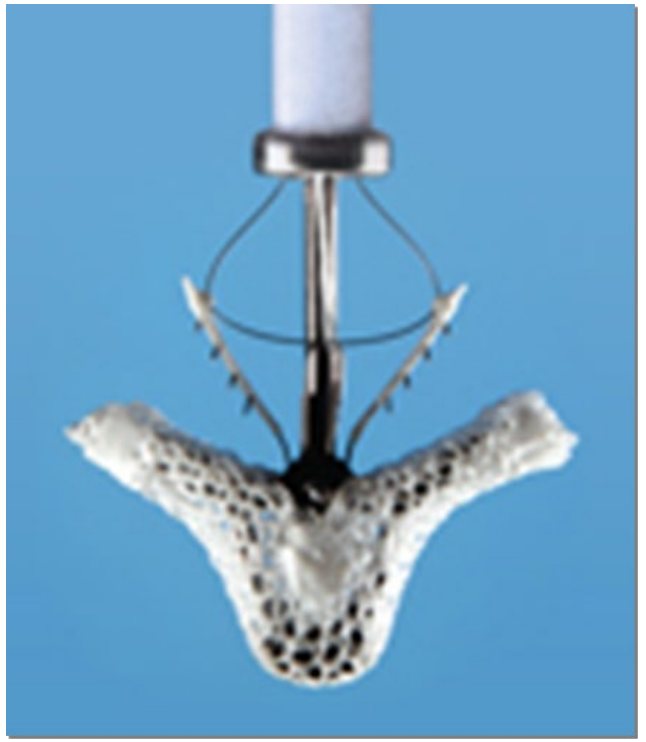
- i.e. flail leaflet, prolapse, rheumatic

Functional / Secondary

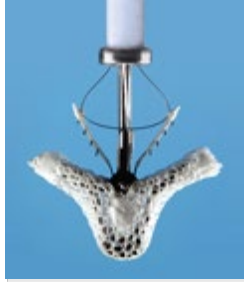
- i.e. dilated LV with failure of leaflets to coapt due to inadequate support apparatus

Mitral transcatheter edge-to-edge repair (TEER)





Mitral transcatheter edge-to-edge repair (TEER)



COR	LOE
2a	B-NR

Severely symptomatic patients (NYHA class III or IV) with secondary severe MR and high or prohibitive surgical risk, transcatheter edge-to-edge repair (TEER) is reasonable if mitral valve anatomy is favorable for the repair procedure and patient life expectancy is at least 1 year

Otto, CM et al. 2020 ACC/AHA. Guideline for the Management of Patients With Valvular Heart Disease . JACC

Two trials : COAPT and MITRA-FR

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 DECEMBER 13, 2018 VOL. 379 NO. 24

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

oun, G. Leurent, B. Iung, G. Bonnet, N. Piriou, T. Lefèvre, C. Piot, F. Rouleau, ıann, F. Leclercq, C. Saint Etienne, E. Teiger, L. Leroux, N. Karam, N. Michel, Trochu, B. Cormier, X. Armoiry, F. Boutitie, D. Maucort-Boulch, C. Barnel, rin, A. Vahanian, and N. Mewton, for the MITRA-FR Investigators*

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

G.W. Stone, J.A. Lindenfeld, W.T. Abraham, S. Kar, D.S. Lim, J.M. Mishell, B. Whisenant, P.A. Grayburn, M. Rinaldi, S.R. Kapadia, V. Rajagopal, I.J. Sarembock, A. Brieke, S.O. Marx, D.J. Cohen, N.J. Weissman, and M.J. Mack, for the COAPT Investigators*

COAPT

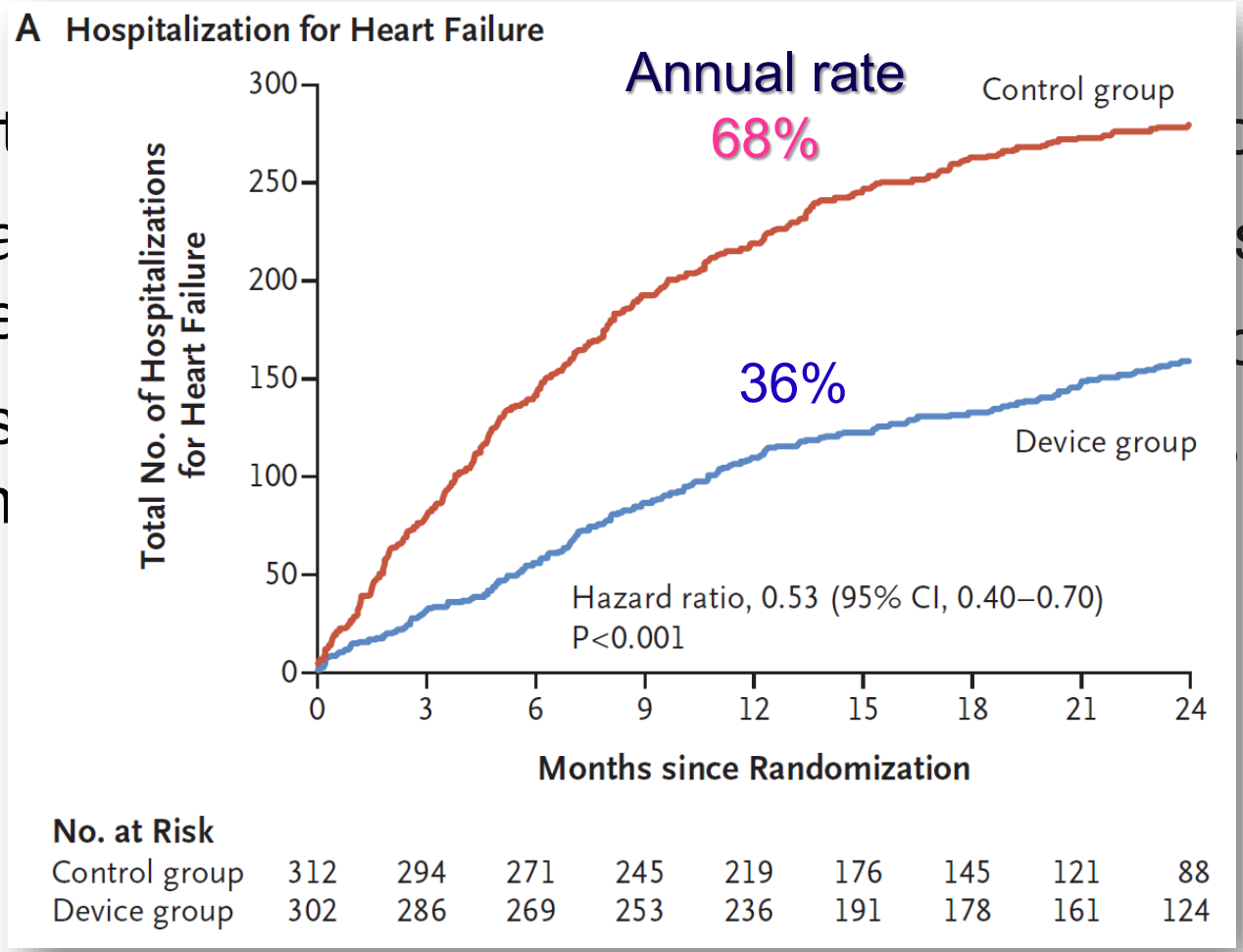
- 614 patients
- Class II-IVa heart failure and 3-4+ mitral regurgitation
- EF 20 to 50%
- Remained symptomatic despite maximal medical rx.

- 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 2018;379:2307-18. N Engl J Med 2023;388:2037-48.

COAPT – Hospitalization for heart failure

- 614 patient… …omen
- Class II-IVa… …synch
  4+ mitral re… …cardiomyopathy
- remained s… …9%, III 52
  maximal m…



N Engl J Med 2018;379:2307-18. N Engl J Med 2023;388:2037-48.

COAPT - Death

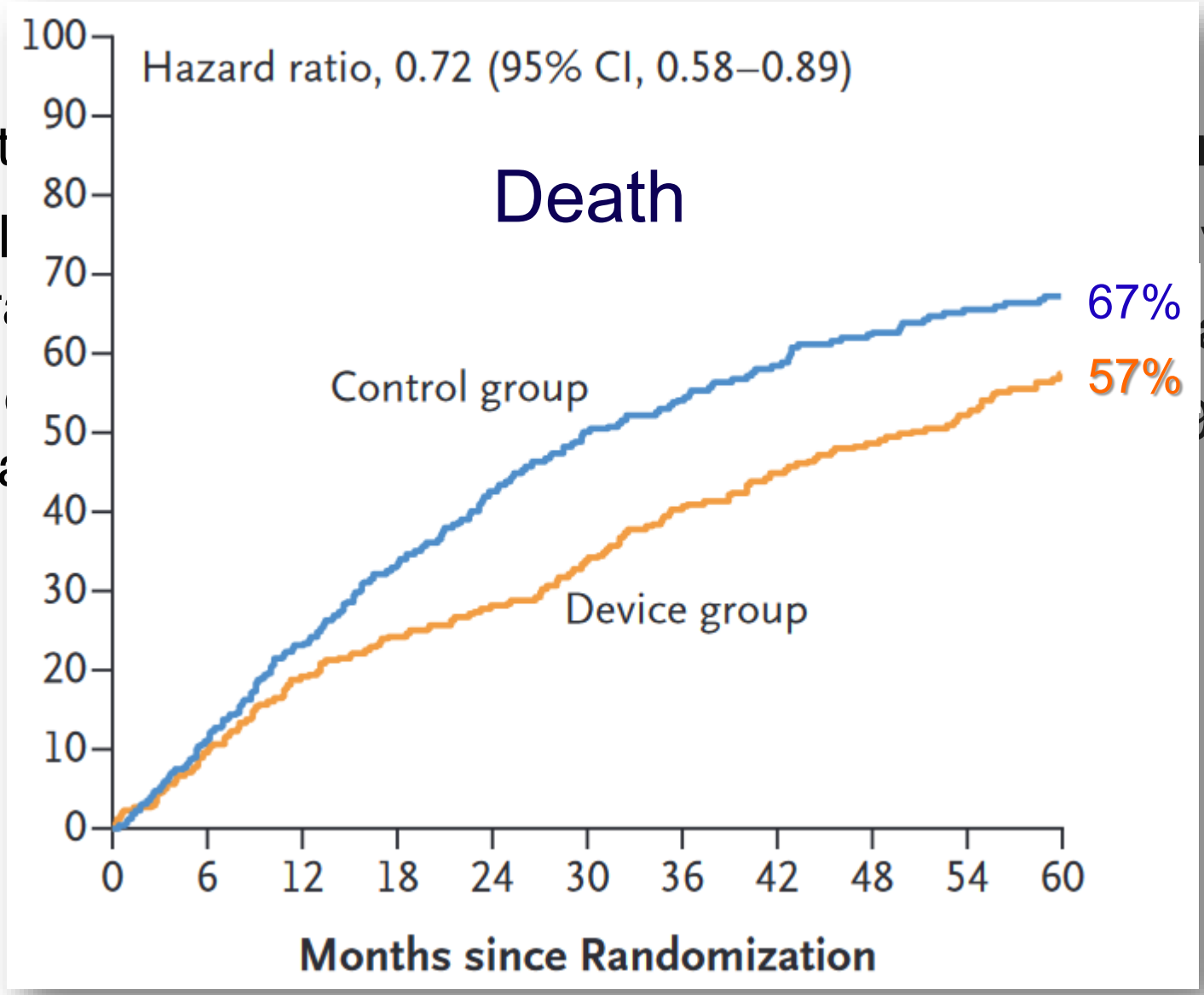
- 614 pat
- Class II
  4+ mitr
- remain
  maxima

men

ynch

ardiomyopathy

%, III 52



Engl J Med 2023;388:2037-48.

MC

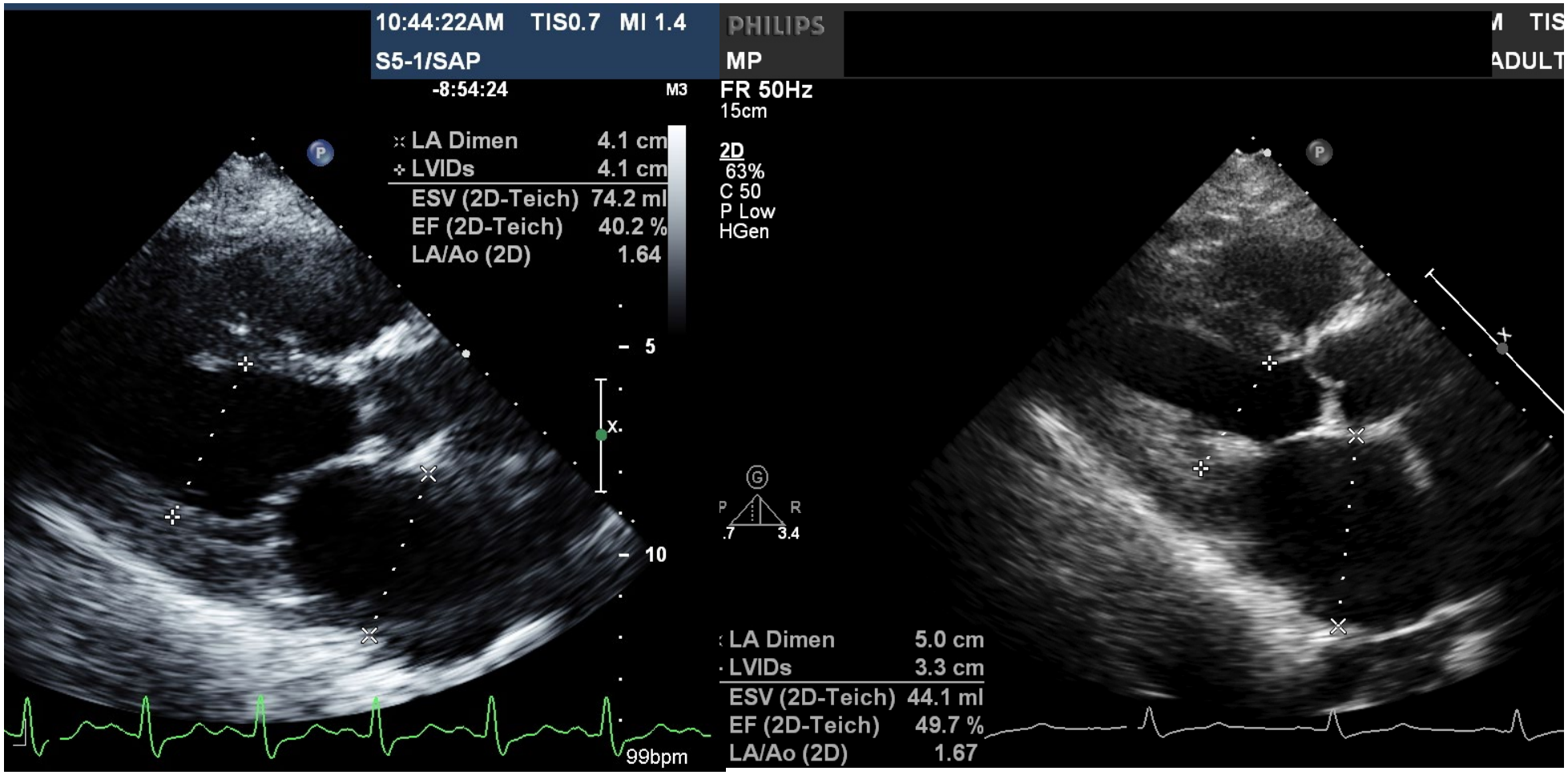
MC

MC 7

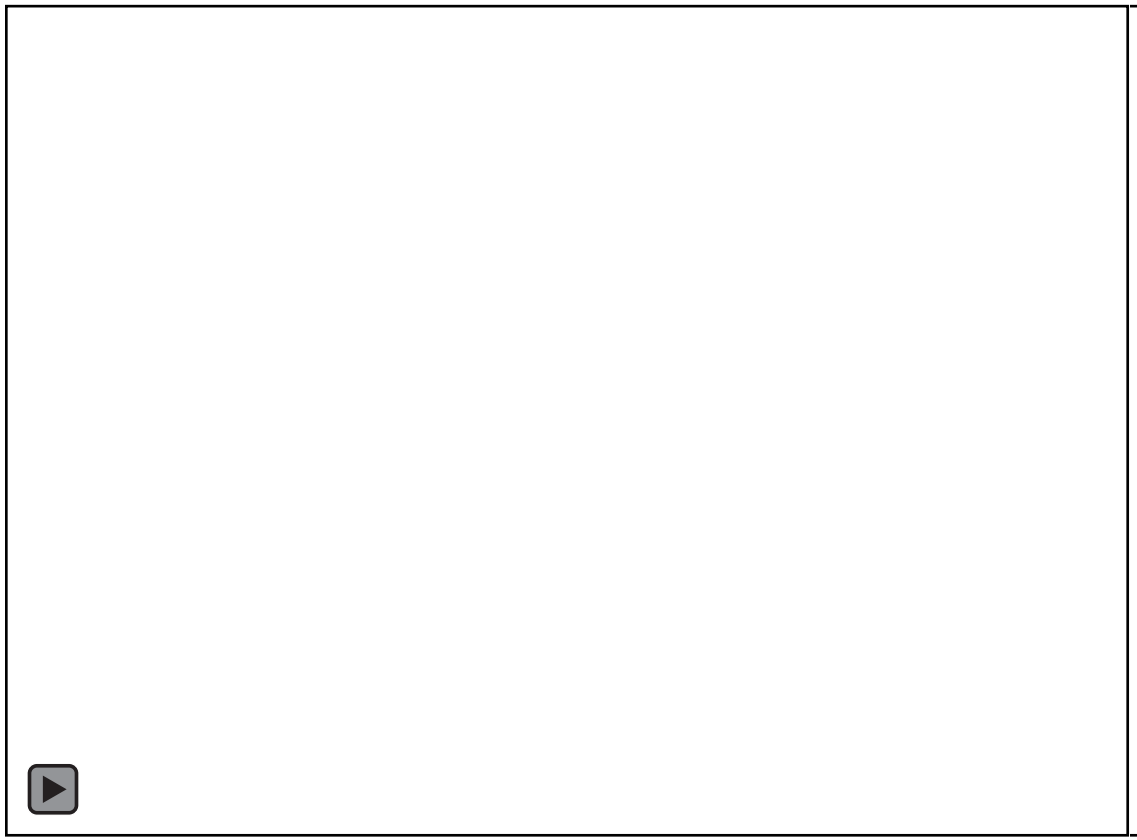
MC 78 y.o. woman

Left ventricular internal diameter Systole

Pre 4.1 Post 3.3 cm



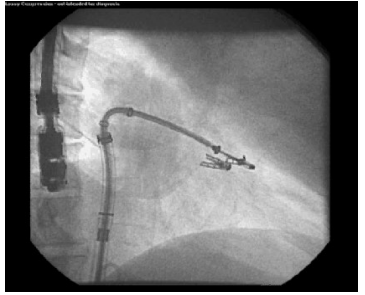
MC 78 y.o. woman



MC 78 y.o. woman

- 1 clip, medial side A2-P2
- MR severe to moderate
- Marked improvement in her shortness of breath
- No hospitalizations for congestive heart failure for 14 months so far

Conclusions



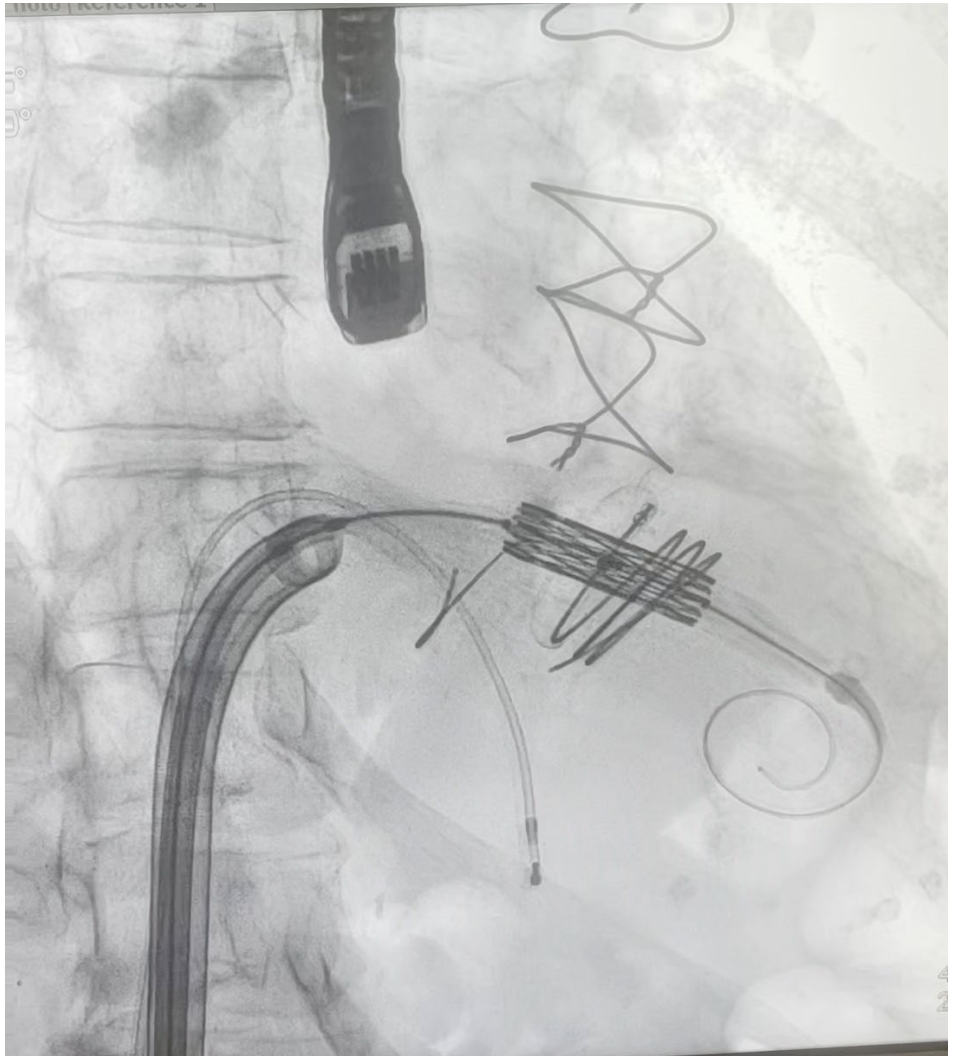
- If severe symptomatic mitral regurgitation persists despite optimal guideline-directed medical therapy, edge-to-edge clipping (COAPT Trial) can be considered.

Watchman, Mitral Clip, New valves

- Left atrial occlusion device
- Mitral valve edge-to-edge clipping
- **Promising percutaneous valves**

Promising percutaneous valves

Sapien TAVR valve in mitral position



EVOQUE tricuspid valve

28-French transfemoral delivery system

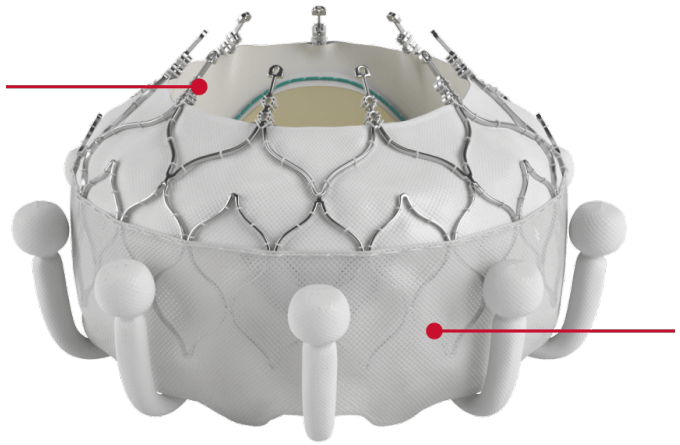
Nitinol expanding frame

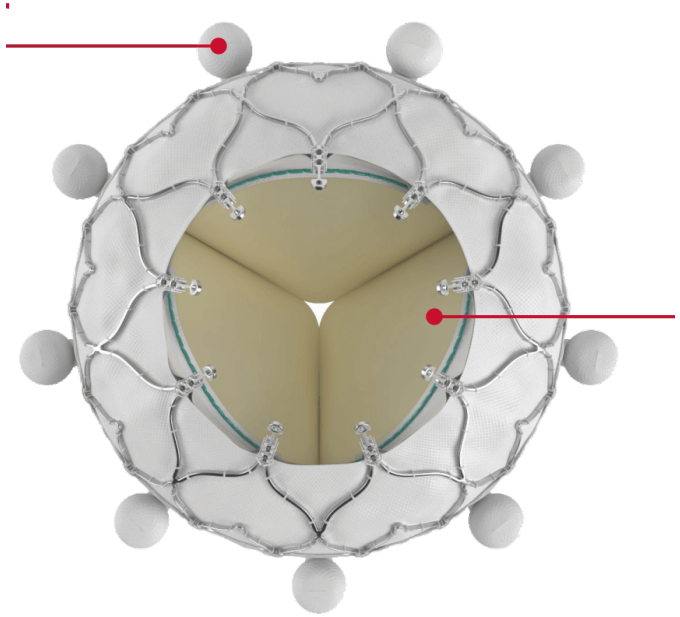
9 ventricular anchors

Bovine pericardial leaflets

Annular sealing skirt

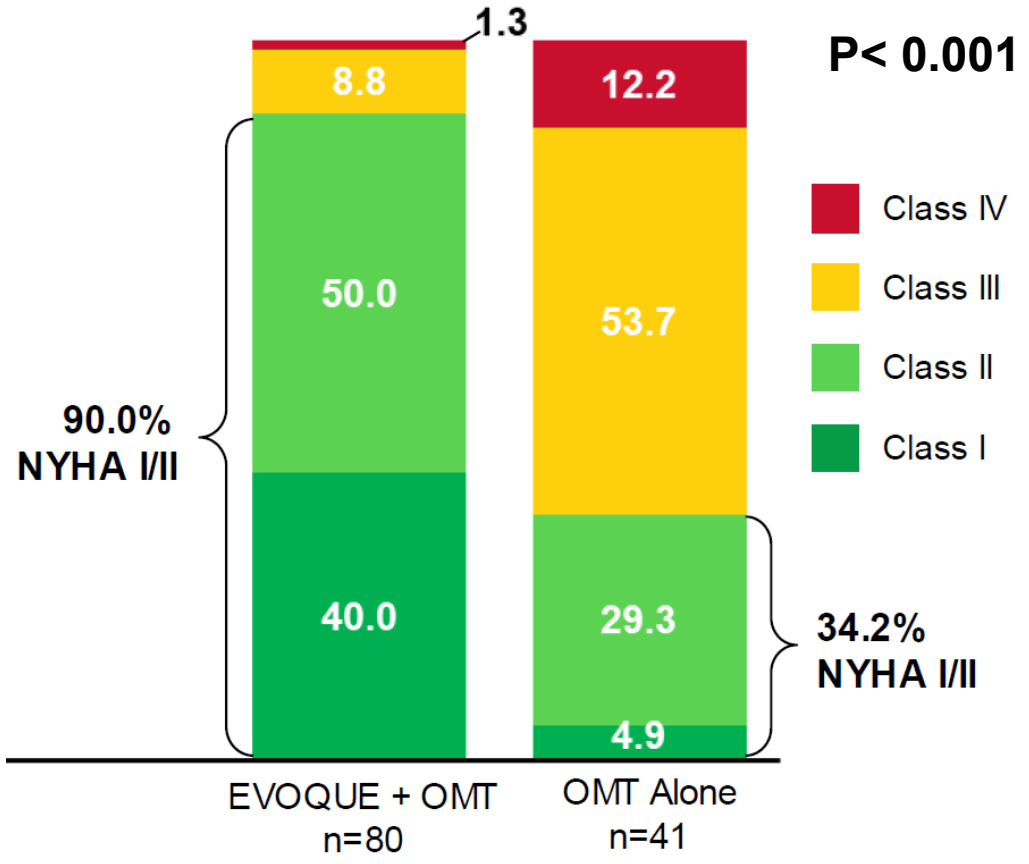
44, 48, 52 mm sizes



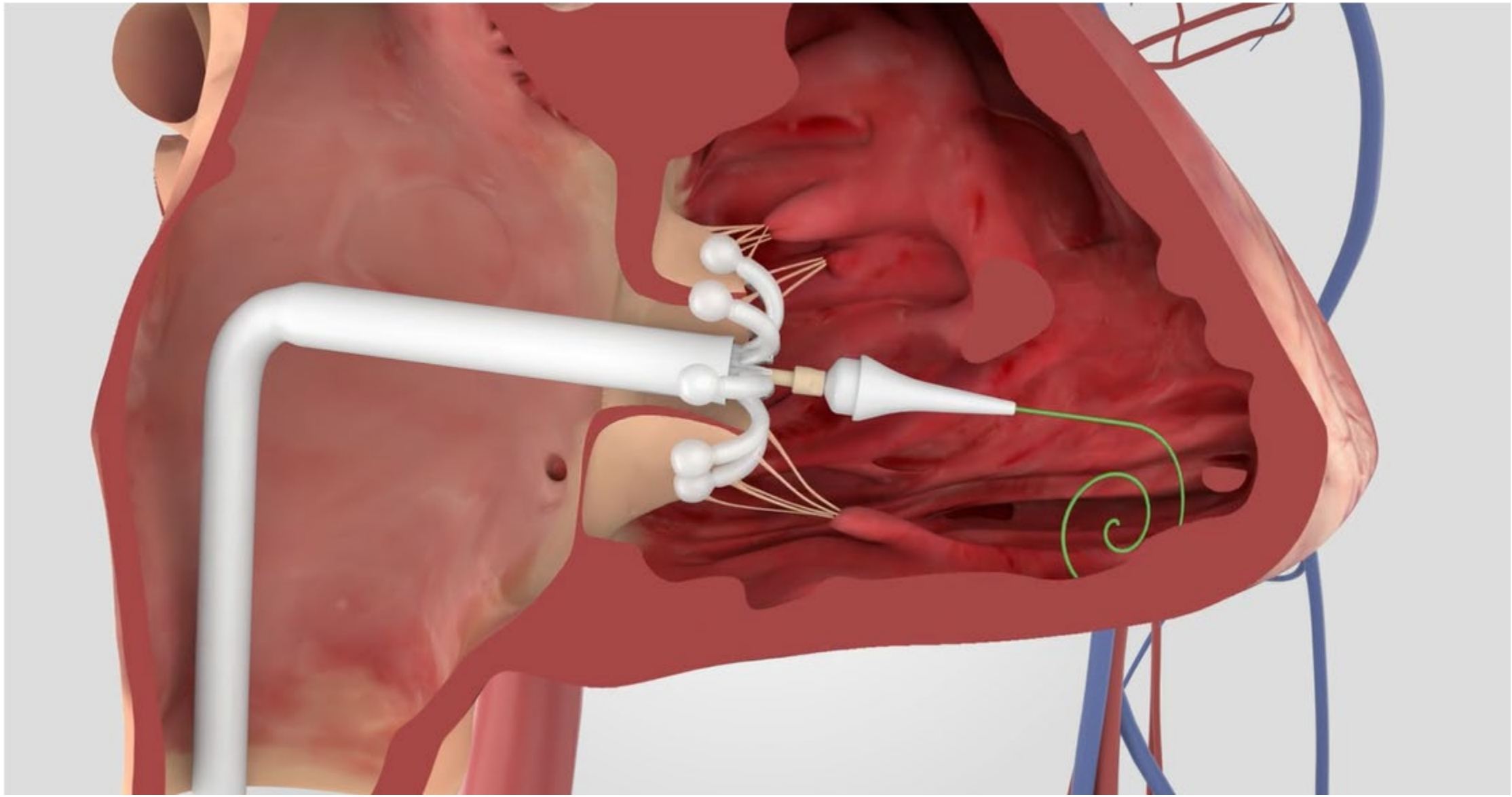


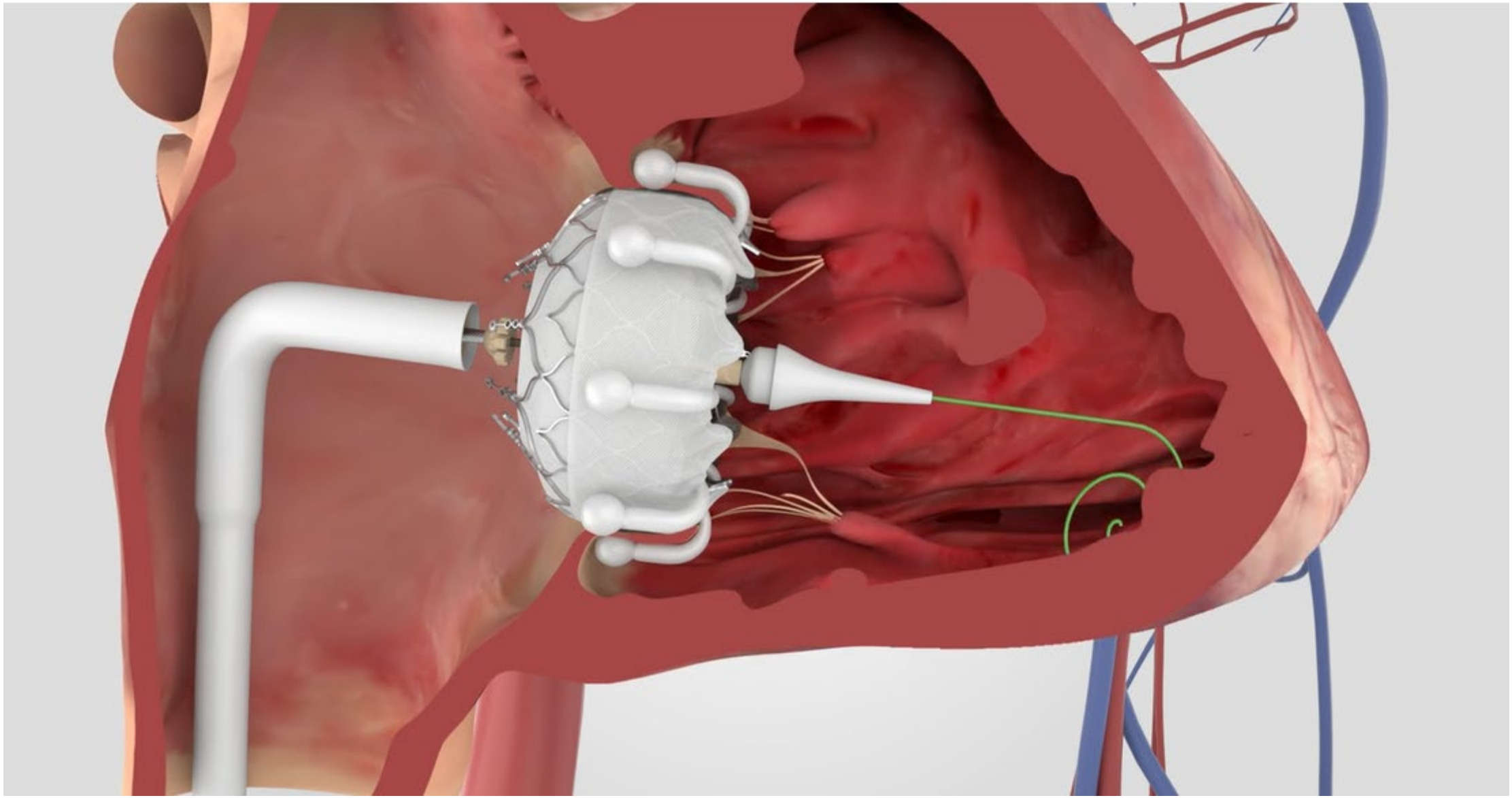
Triscend II 6 months primary effectiveness

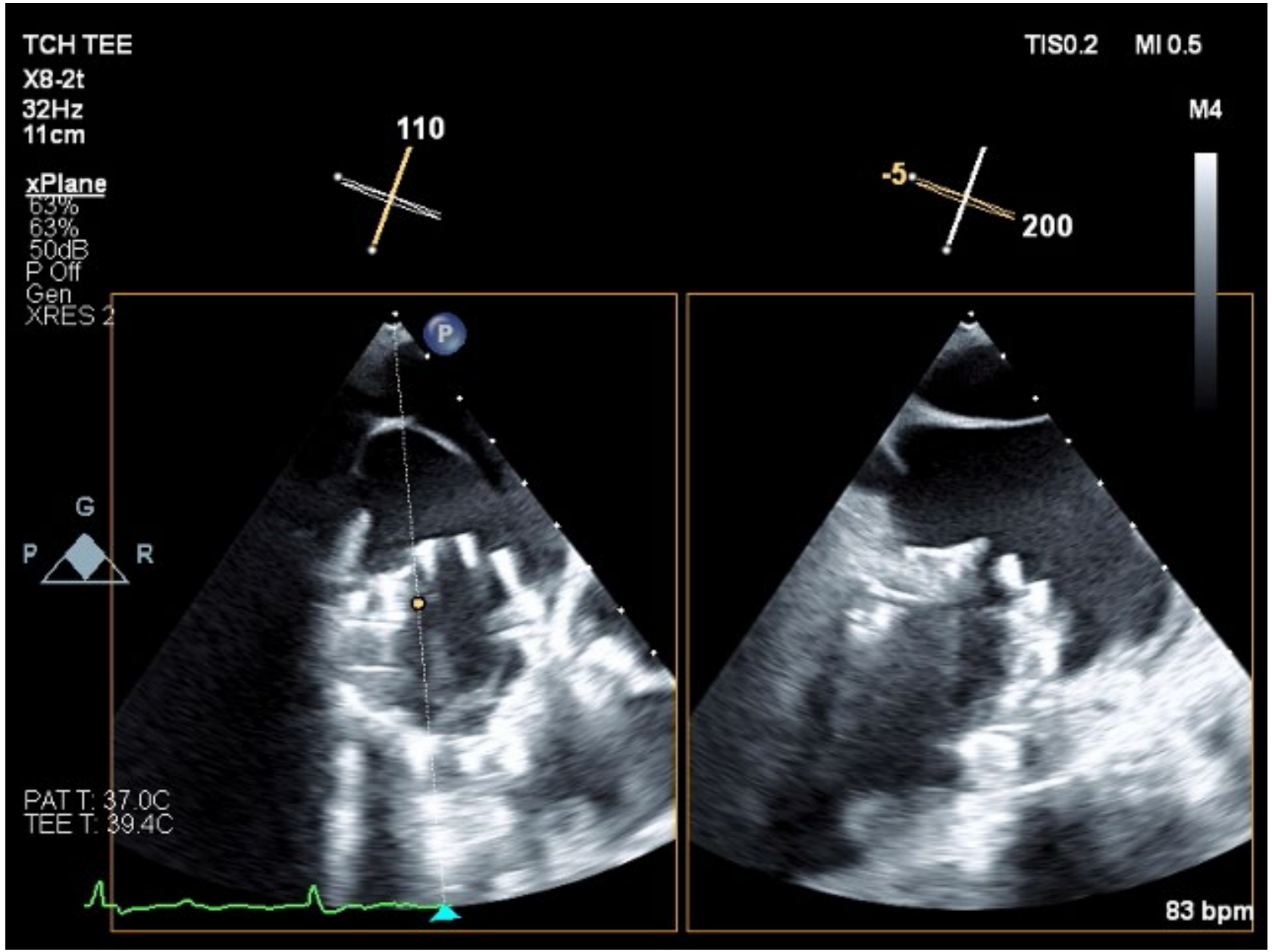
Functional status



3 CV deaths, 14 permanent pacer, 10 severe bleeding






TCH TEE
X8-2t
32Hz
11cm
xPlane
63%
63%
50dB
P Off
Gen
XRES 2
TIS0.2 MI 0.5
M4
110
-5
200
P
G
P
R
PAT T: 37.0C
TEE T: 39.4C
83 bpm


ACURA
NEW ORLEANS JAZZ & HERITAGE FESTIVAL
ACURA
NEW ORLEANS JAZZ & HERITAGE FESTIVAL

Proposed algorithm for antithrombotic treatment after left atrial appendage closure

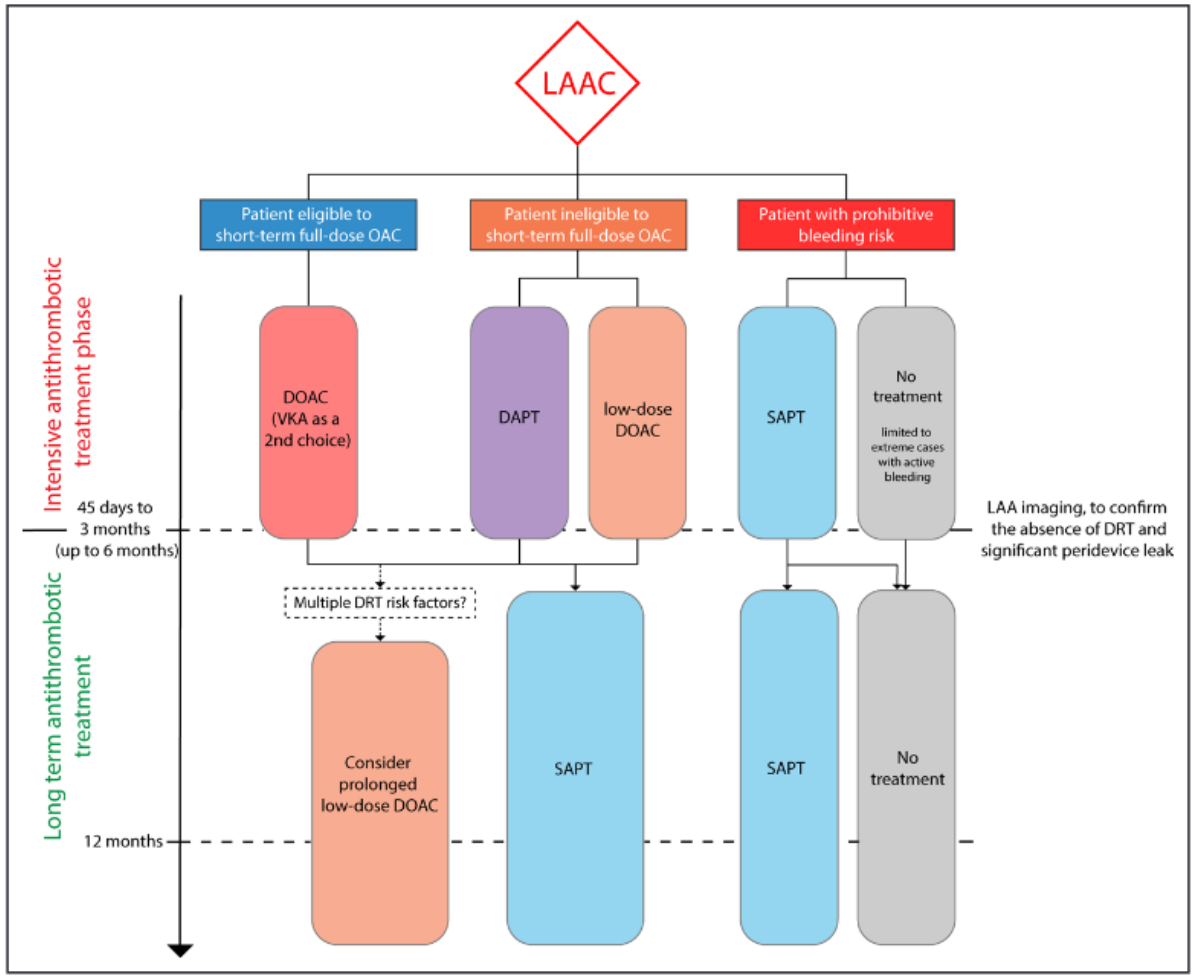


Figure 4. Proposed algorithm for antithrombotic treatment after left atrial appendage closure (LAAC).
Suggested approach for antithrombotic treatment after LAAC. Patients ineligible to short-term oral anticoagulant (OAC) are defined as patients with recent bleeding or high risk of uncontrollable bleeding (ie, patients who were not treated with OAC before the procedure). Patients with prohibitive bleeding risk are those who cannot tolerate dual antiplatelet therapy (DAPT) or low-dose OAC because of active bleeding or high risk of recurrence of uncontrollable bleeding. DOAC indicates direct oral anticoagulant; DRT, device-related thrombus; LAA, left atrial appendage; SAPT, single antiplatelet therapy; and VKA, vitamin K agonist.

Circ Cardiovasc Interv. 2023;16:e012812.

CHADS-VASC

Congestive heart failure	1
Hypertension	1
Age >74	2
Age 65-74	1
Diabetes Mellitus	1
Stroke/TIA	2
Vascular disease	1
Female	1

Yearly risk of Stroke, by score

1 (1.3%)	**2**(2.2%)	**3**(3.2%)
4 (4.0%)	**5**(6.7%)	**6**(9.8%)
7(9.6%)	**8**(6.7%)	**9**(15.2%)

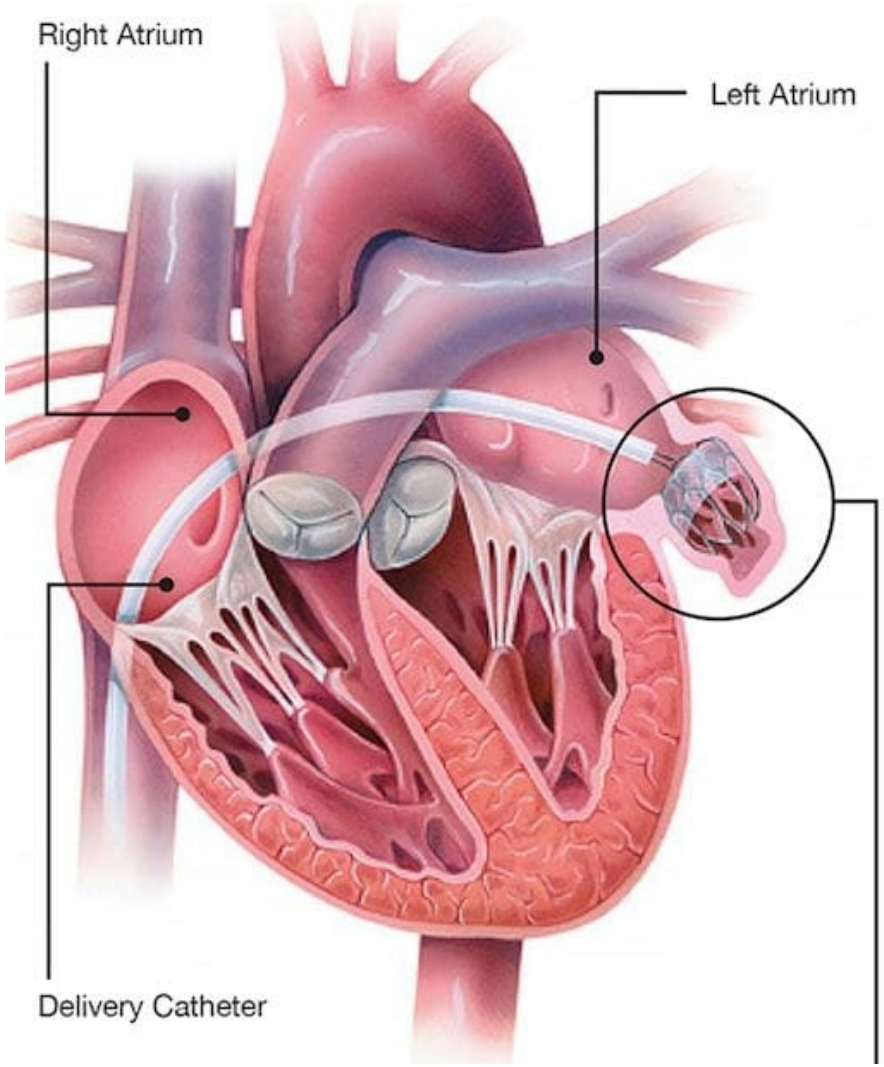
NICE recommend consideration of anticoagulation if score >0

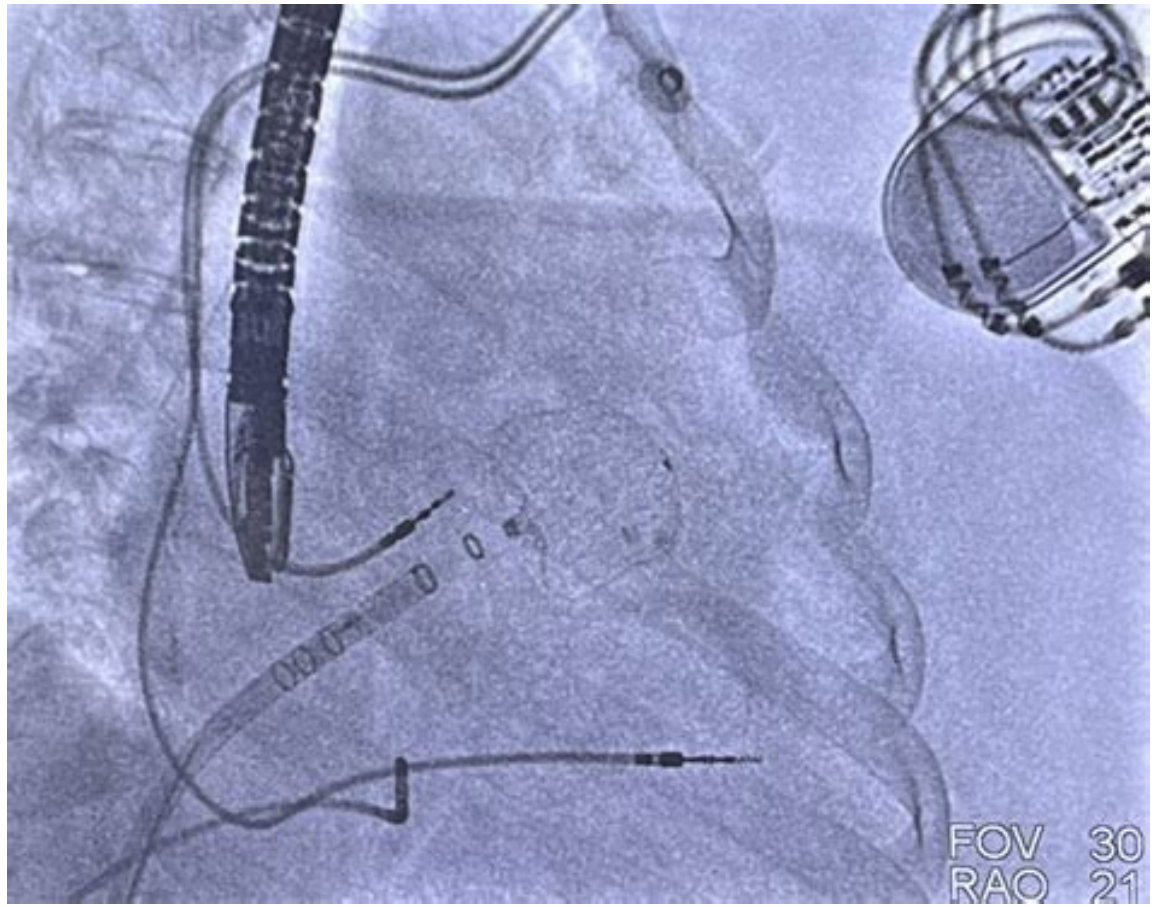
HAS-BLED

Hypertension (>160mmHg)	1
Renal (dialysis, transplant Cr >200)	1
Liver (cirrhosis, LFTs Bili x2 or others x3)	1
Stroke History	1
Prior Major bleed/predisposition	1
High/Unstable INR	1
Age >65 years	1
Medication predisposing to bleed	1
Alcohol/Drugs (≥8 drinks/week)	1

Yearly risk of Major Bleed, by score

0-1	1.02%
2	1.88%
3	3.7%
≥4	>8%


Right Atrium
Left Atrium
Delivery Catheter


FOV 30
RAO 21

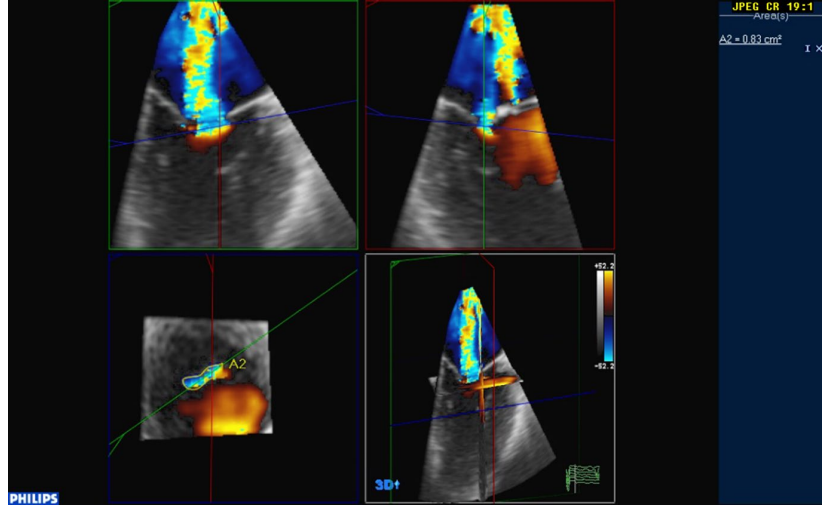
CMS National Coverage Determination

- A CHADS 2 score ≥ 2 (Congestive heart failure, Hypertension, Age >75, Diabetes, Stroke/transient ischemia attack/thrombo-embolism) or
- CHADS 2-VASc score ≥ 3 (Congestive heart failure, Hypertension, Age ≥ 65, Diabetes, Stroke/transient ischemia attack/ thromboembolism, Vascular disease, Sex category)
- A formal shared decision-making interaction with an independent non-interventional physician using an evidence-based decision tool on oral anticoagulation in patients with NVAF prior to LAAC. Additionally, the shared decision-making interaction must be documented in the medical record.

CMS National Coverage Determination

- The patient is enrolled in, and the MDT and hospital must participate in the NCDR LAAO Registry

Severe Mitral regurgitation



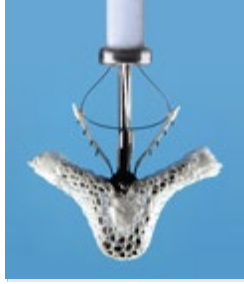
- Jet area > 40% of left atrium
- Vena contracta width >=0.7 cm
- Systolic reversal in pulmonary vein
- Dense, triangular shaped CW Doppler
- Enlarged LV and LA (particularly with normal EF)
- Large flow convergence

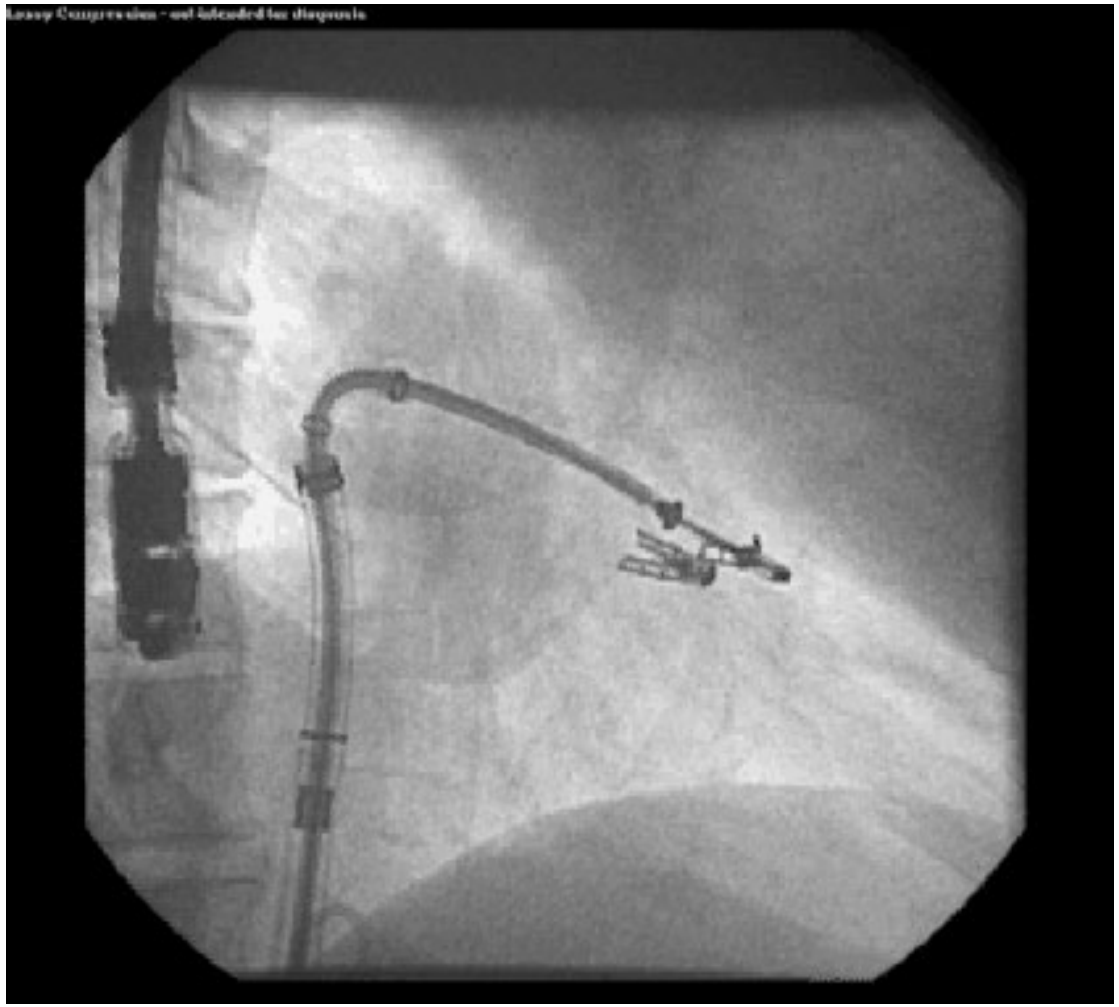
(proximal isovelocity surface area)

  - Effective regurgitant orifice > 0.4 cm^2
  - Regurgitant volume > 60 ml

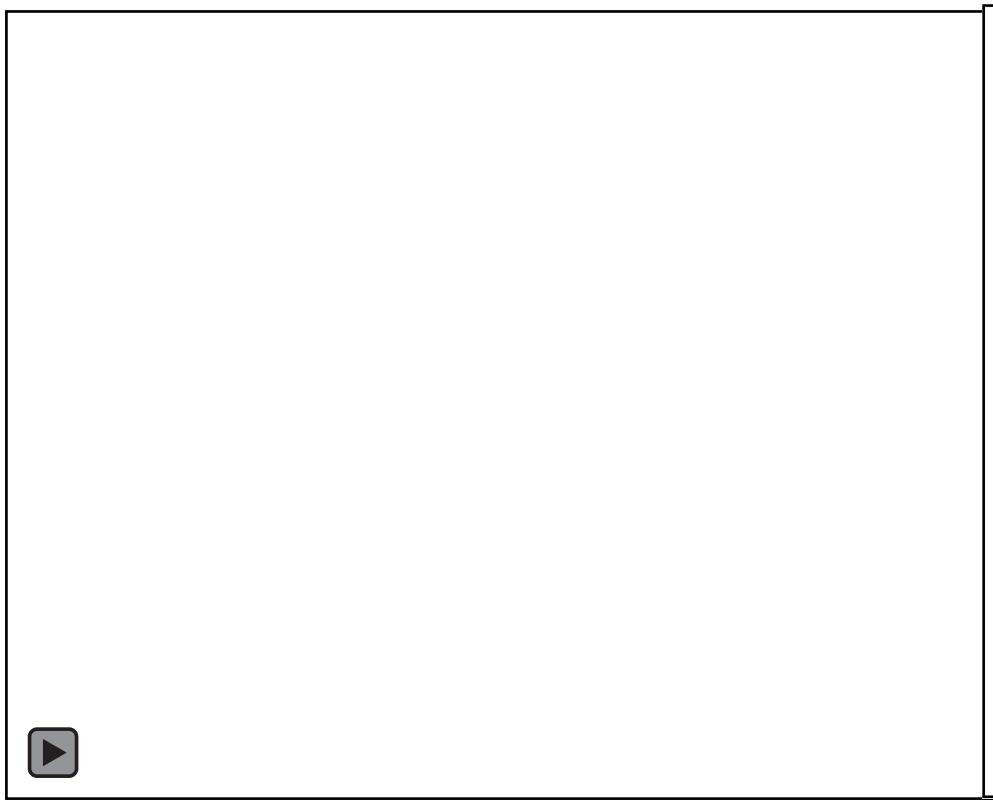
Grayburn PA. How to measure severity of mitral regurgitation Heart 2008;94:376-383

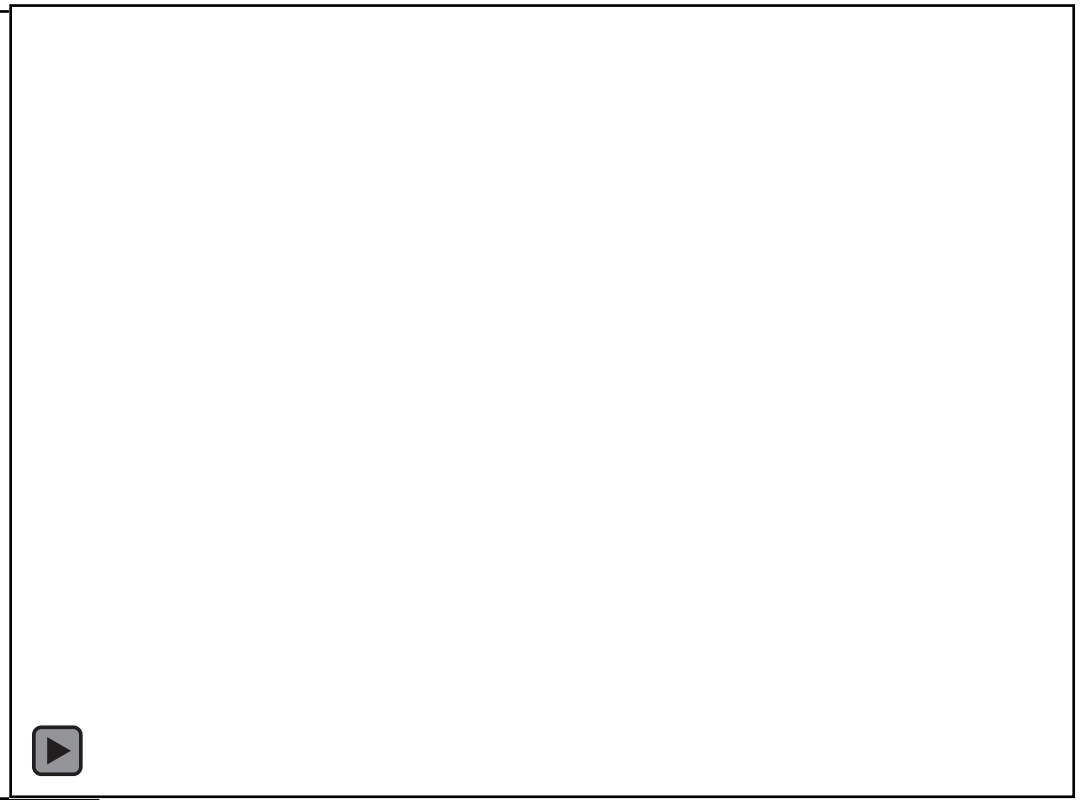
Mitral transcatheter edge-to-edge repair (TEER)

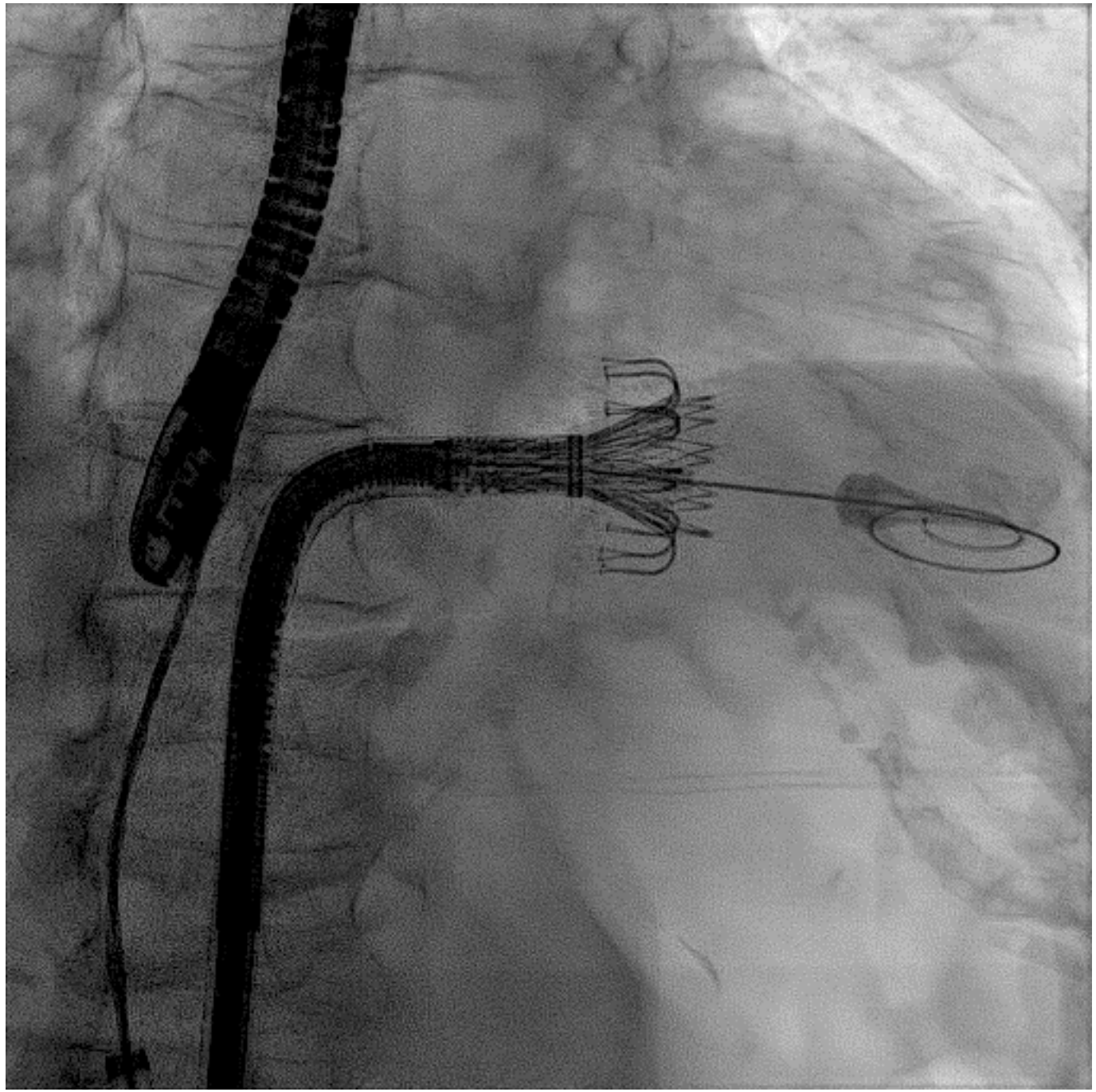


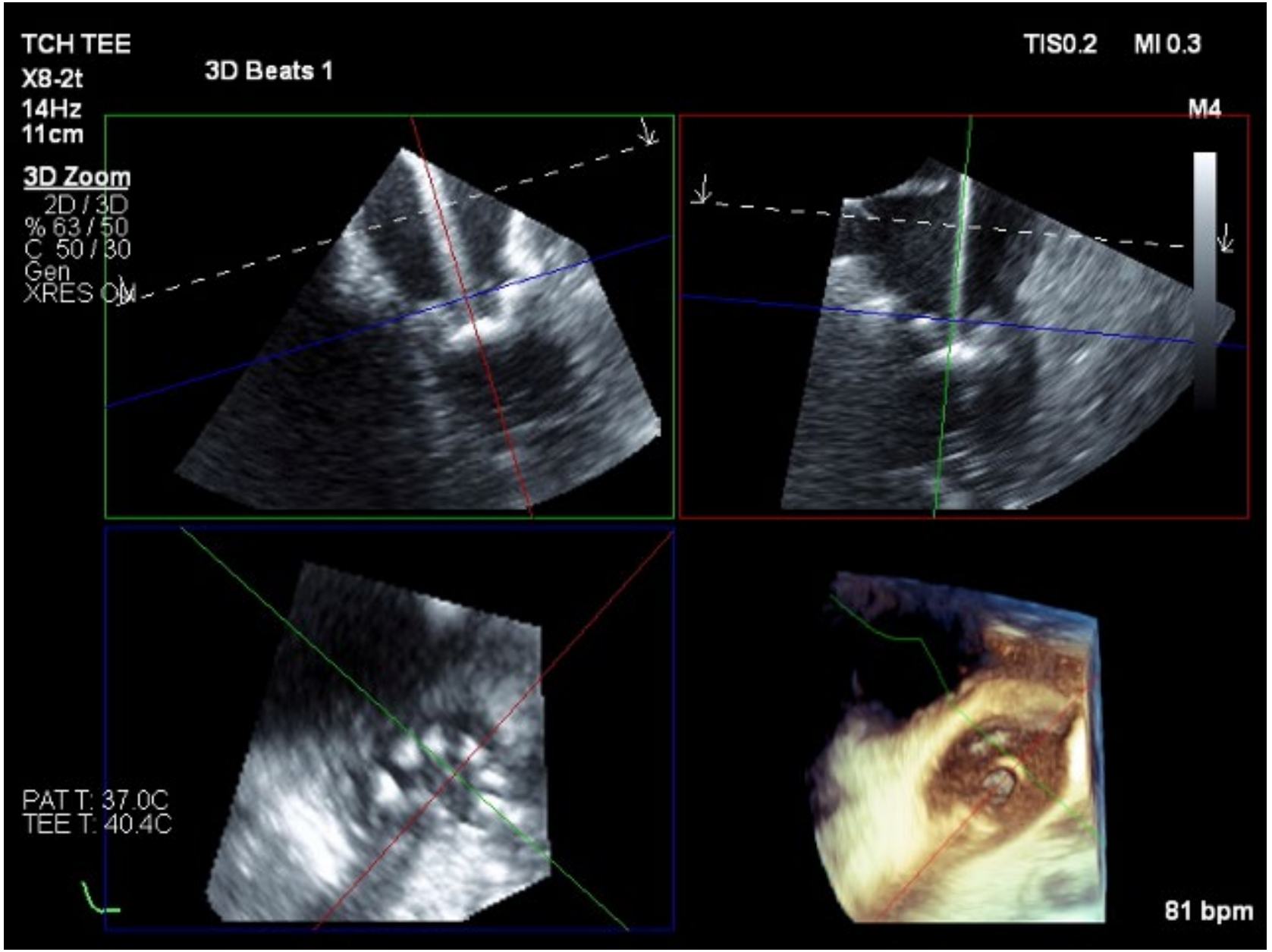


MC 78 y.o. woman





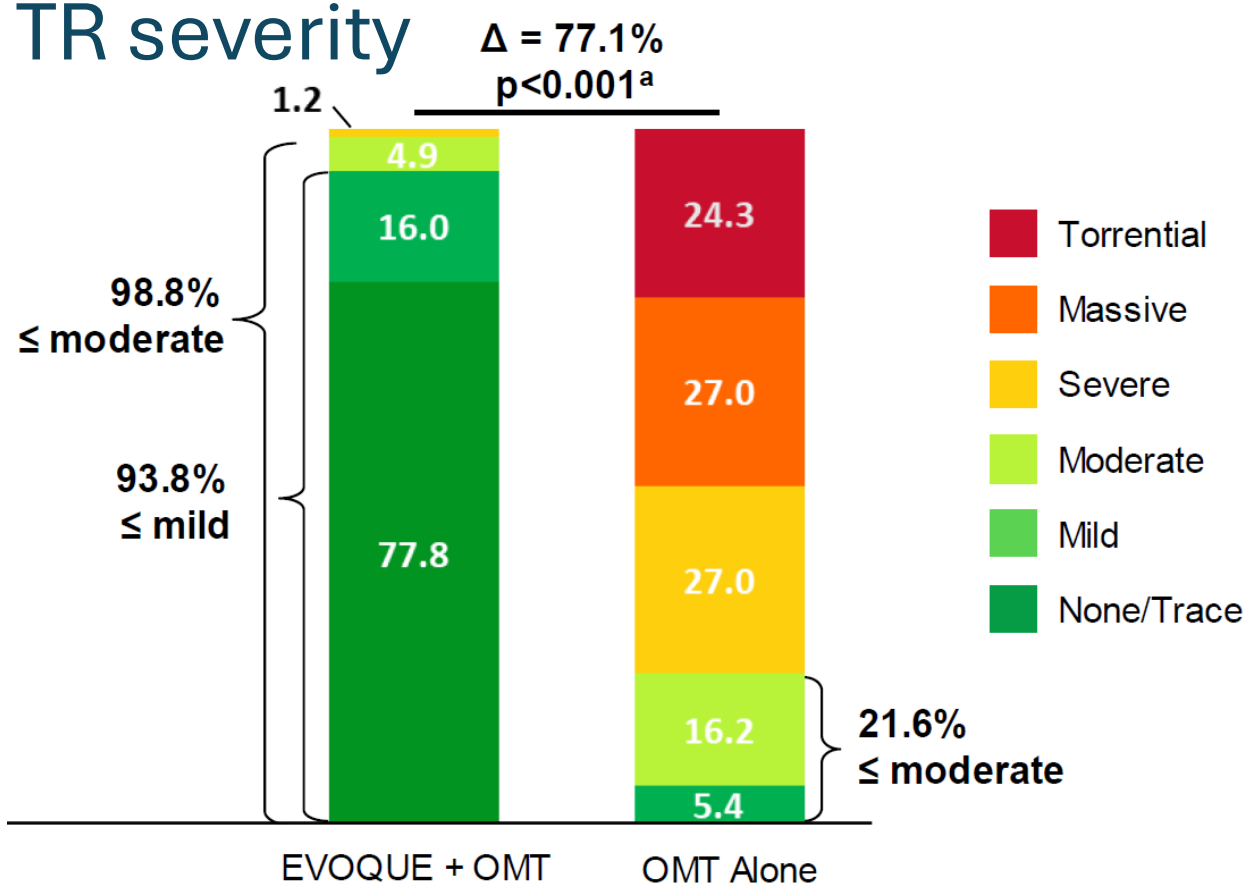



TCH TEE
X8-2t
14Hz
11cm
3D Beats 1
TIS0.2 MI 0.3
M4
3D Zoom
2D / 3D
% 63 / 50
C 50 / 30
Gen
XRES Off
PAT T: 37.0C
TEE T: 40.4C
81 bpm

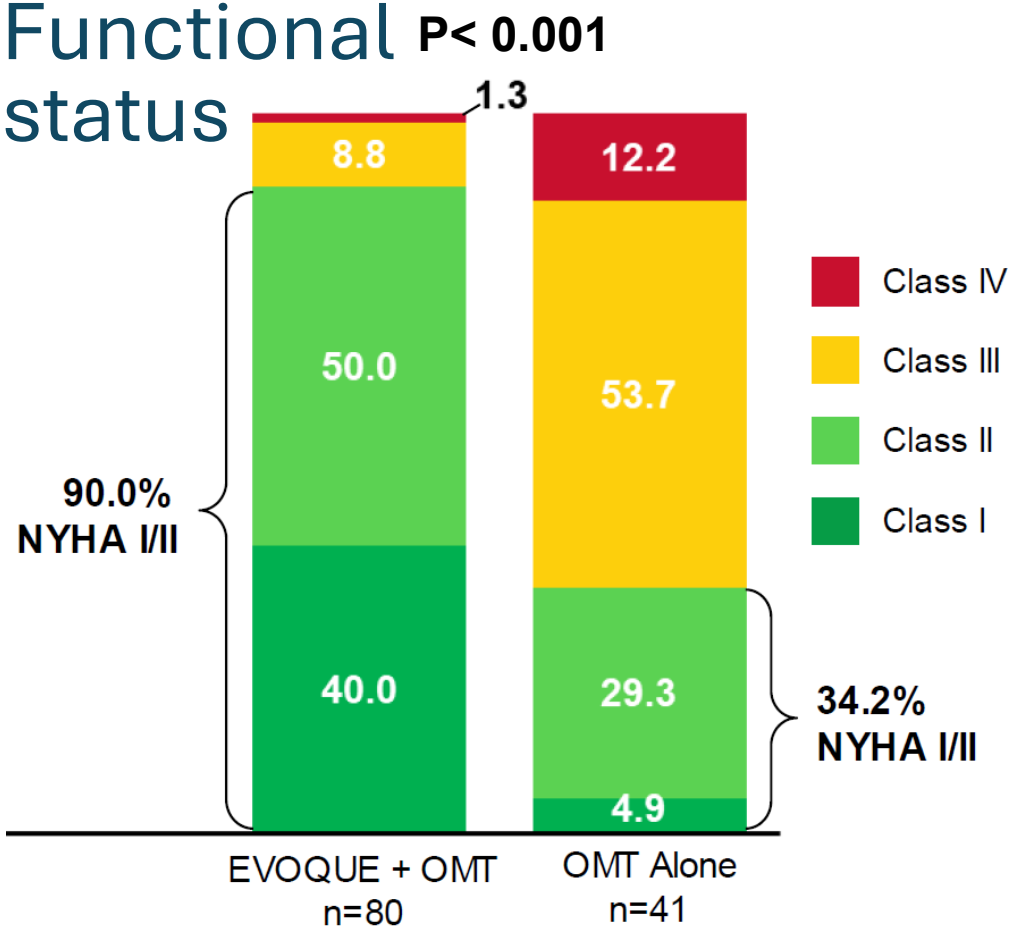
THE TRISCEND II PIVOTAL TRIAL

Triscend II 6 months primary effectiveness

TR severity



Functional status



3 CV deaths, 14 permanent pacer, 10 severe bleeding