Structural Heart Disease Interventions

An Update

Jagadish Khanagavi MD, FACP, FACC
Interventional Cardiologist , Metro Health-University of Michigan

Conflict of Interest Disclosure

- None

Objective

Review the latest updates in diagnosis, work-up and indications for contemporary percutaneous (nonsurgical) management of structural heart conditions:

- Severe aortic stenosis
- Stroke-risk reduction nonvalvular atrial fibrillation
- Stroke and presence of patent foramen ovale
- Severe mitral valve regurgitation

AORTIC STENOSIS

Aortic Stenosis: Which patients are at elevated risk?

- Aortic sclerosis (<2% of cases progress to clinical aortic stenosis each year)
- Atherosclerotic disease
- Smoking
- Hypertension, hyperlipidemia
- Advanced age
- Congenital aortic valves abnormalities
- Genetic factors may predispose to abnormal tissue calcification
- Rheumatic fever
- Rare causes: Williams syndrome, SLE, radiation therapy

Should clinicians image patients who have elevated risk?

- Most asymptomatic patients don't need to be screened
- Study patients with a heart murmur or ejection click if
  - Valvular or structural heart disease is suspected
  - Such patients experience changes in clinical status
  - They have a new murmur and conditions that increase risk
  - There is any doubt about symptom status
- Women with suspected aortic stenosis should be evaluated before pregnancy

How should clinicians evaluate patients for aortic stenosis?

- Transthoracic echocardiography
  - Noninvasive
  - Relatively inexpensive
- Provides information about
  - Stenosis severity
  - Cardiac function
  - Presence and severity of valve abnormalities

CLINICAL BOTTOM LINE: Screening...

- **Risk factors**
  - **Advanced age**
  - **Atherosclerotic disease**
  - **History of rheumatic heart disease**
- **Screen only if symptoms or signs suggest valvular heart disease**
  - **Cardiac murmur**
  - **Ejection click**
- **Use transthoracic echocardiography**

What symptoms or conditions should prompt clinicians to consider aortic stenosis?

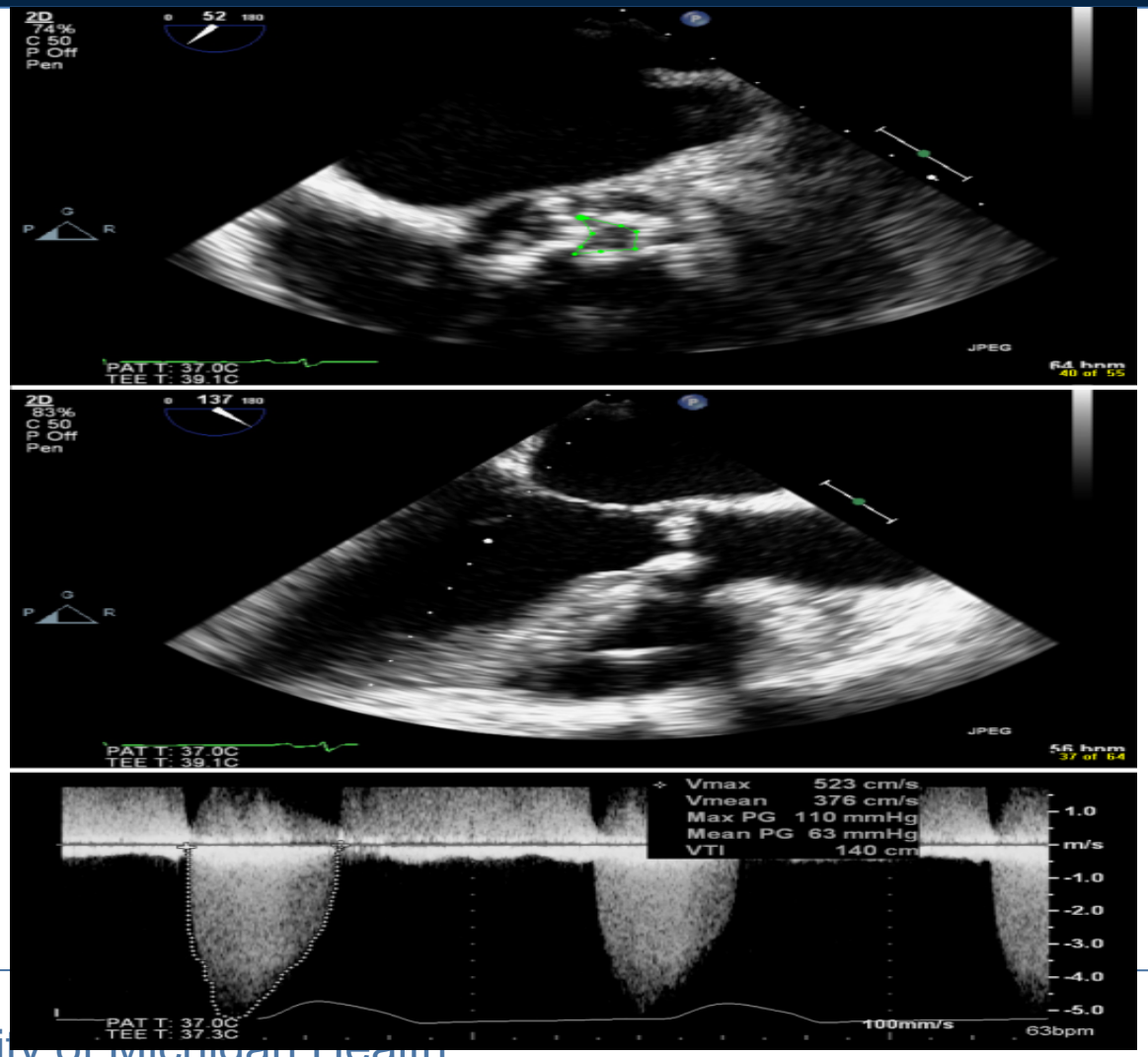
- 3 cardinal symptoms
  - Angina
  - Dyspnea
  - Presyncope or syncope
- Once these occur, risk of death increases
  - From <1% per year to 2% per month
  - 75% of symptomatic patients die within 3 years unless they receive a valve replacement

What laboratory tests and imaging studies should clinicians use to evaluate patients with suspected aortic stenosis?

- Echocardiography
- Retrograde catheterization of the heart to image the aortic valve and measure left ventricular pressure
  - Not recommended if noninvasive methods are adequate
- Hemodynamic criteria that indicate severe stenosis
  - Doppler velocity >4 m/s
  - Aortic valve area <1 cm^2 (<0.6 cm^2/m^2 indexed to BSA)
  - Mean gradient >40 mm Hg

Echocardiography:

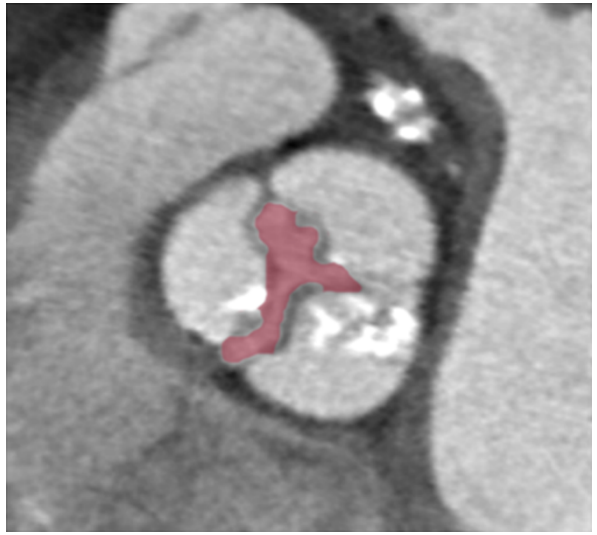
severe aortic stenosis, heavily calcified leaflets, restricted valve opening



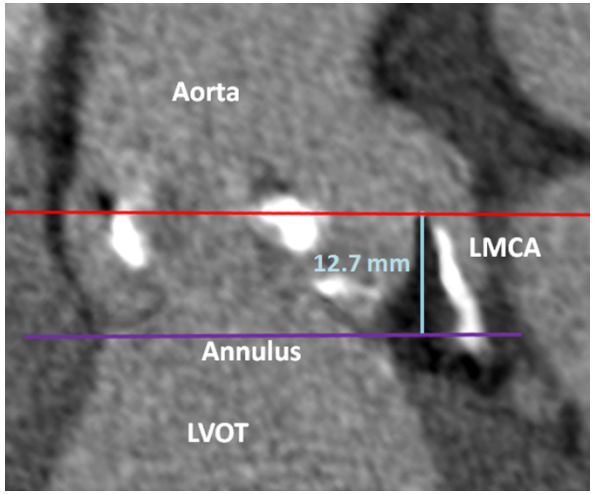
Transcatheter aortic valve replacement (TAVR):

Preintervention cardiac CT and valve deployment

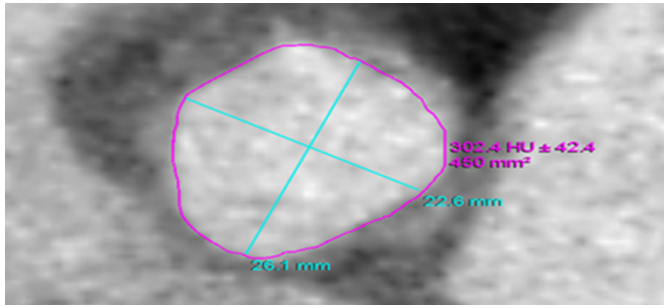
A.



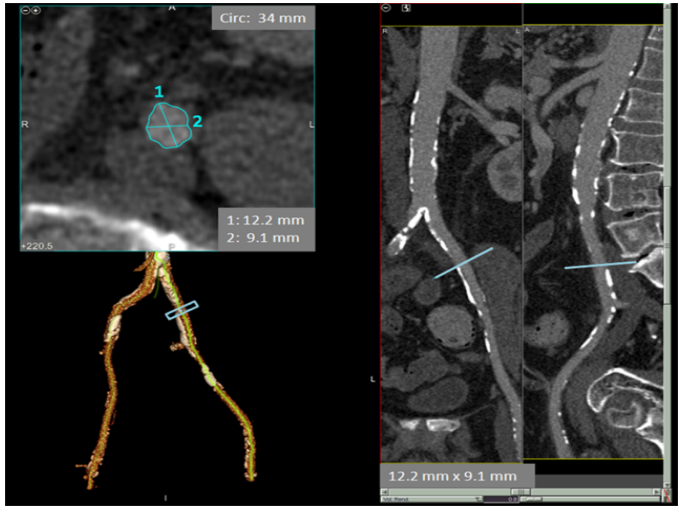
B.



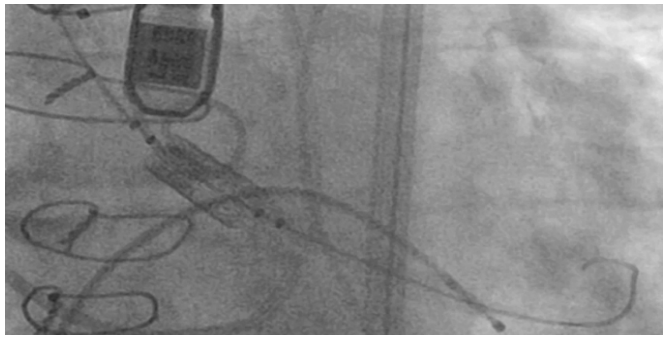
C.



D.



E.



What nondrug therapies should clinicians recommend?

- Moderate-to-severe or severe aortic stenosis
  - Avoid strenuous physical activity
  - Avoid sports that demand high muscular effort

What medications should clinicians use for treatment?

- Definitive management requires mechanical intervention
- No drug reverses aortic stenosis
- Prescribe appropriate medical therapy for associated risk factors or concurrent disease
  - Coronary artery disease
  - Atrial fibrillation
  - Diabetes mellitus
  - Heart failure
  - Hypertension (start at low dose and gradually titrate up)
  - Hyperlipidemia

When should patients be considered for valve replacement?

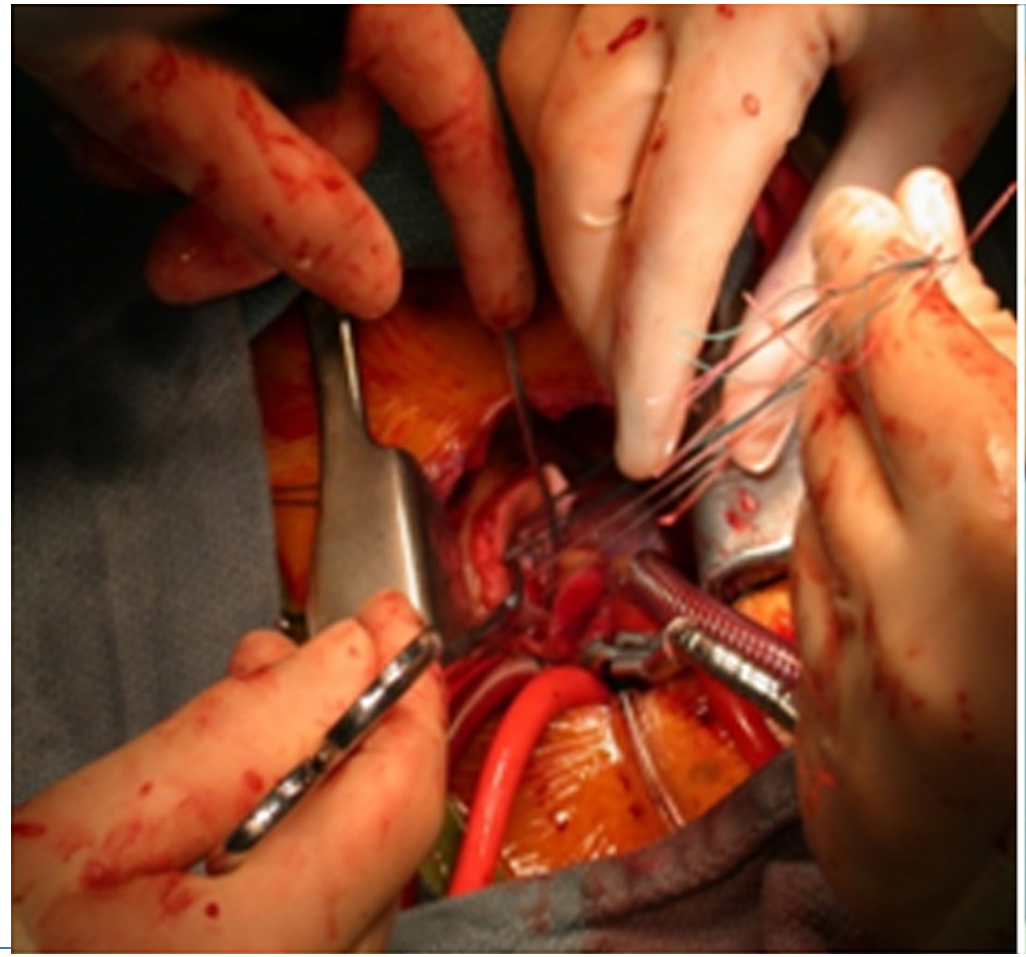
- When symptoms develop
  - Death rate after symptoms start is ≥2%/month
  - Delay risks sudden death

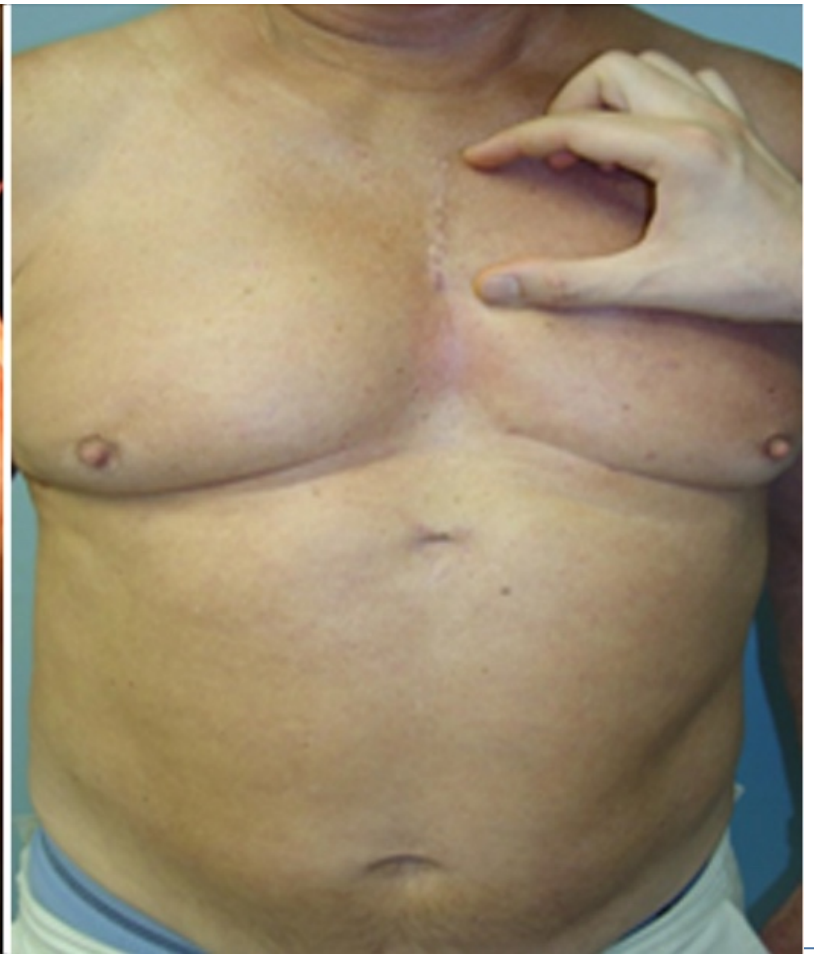
- When asymptomatic patients have severe stenosis
  - Risk for watchful waiting usually outweighs the risk for intervention
  - ACC/AHA guidelines recommend valve replacement for patients with very severe stenosis and low surgical risk
  - ACC/AHA guidelines recommend valve replacement for all patients with severe stenosis and LV dysfunction

Which patients should have surgical aortic valve replacement (SAVR) ?

- **Traditional, definitive, time-tested therapy**
- **Increasing use of bioprosthetic valves instead of mechanical valves**
- **Full sternotomy is the most common approach**
- **Partial sternotomy and mini-thoracotomy approaches are increasingly popular**
- **Surgical mortality is <3% overall; <2% in low-risk patients**
- **Common reasons for wanting to avoid SAVR: advanced age; severe comorbidities; frailty**

Minimally invasive aortic valve replacement via partial upper sternotomy





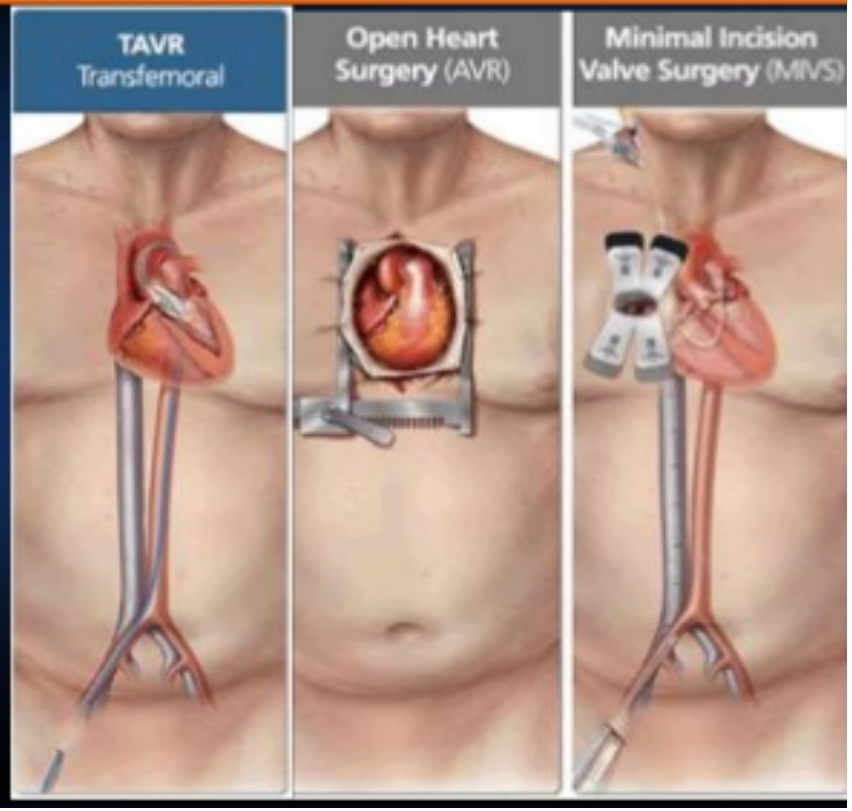
Which patients should have transcatheter aortic valve replacement (TAVR)?

- **Became available in 2011**
- **Equal or superior to SAVR in high-risk and intermediate-risk patients**
- **Usefulness in lower-risk patients proven in recent trials**
- **Well-suited for patient with advanced age, extra-cardiac comorbidities, or anatomical factors that would complicate an open surgical approach**
- **Transfemoral approach is the default**
- **Promising long-term data becoming available**

TAVR

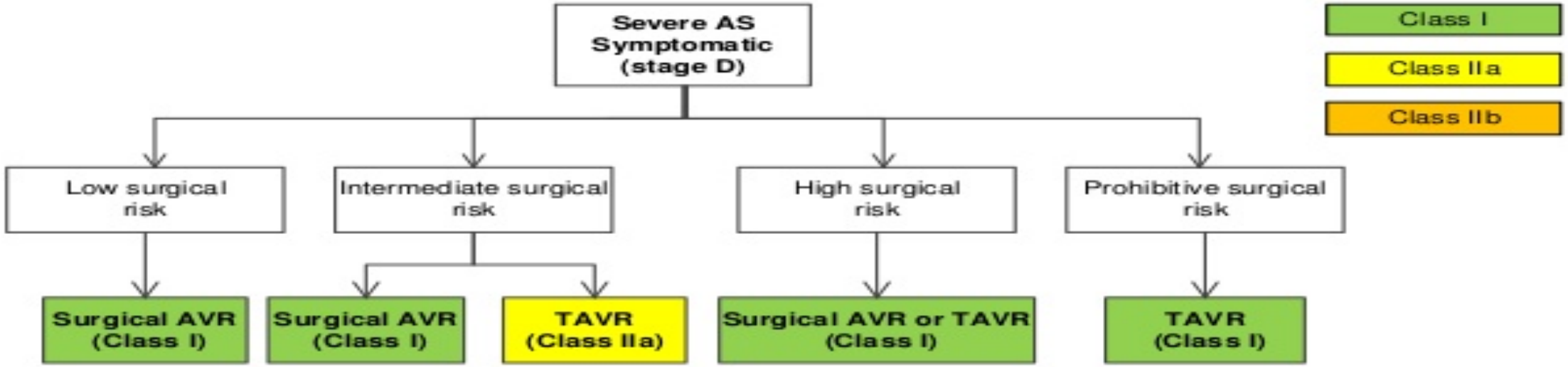
Potential Advantages of TAVR

- Less Invasive, lower risk of bleeding
- Shorter Length of Stay and Recovery
- Similar rates of mortality and stroke (based on High/Intermediate risk trials)



Who Benefits from TAVR in 2019?

Choice of TAVR Versus Surgical AVR in the Patient With Severe Symptomatic AS (Modified)



Helping Cardiovascular Professionals Learn. Advance. Heal.

American Heart Association.

TAVR

Concerns about TAVR in Low Risk Pts

- Paravalvular leak and pacemaker risk
- Valve Performance and Longevity
- Anatomic Considerations (i.e. Bicuspid AoV etc.)
- Young pts likely to need multiple AVRs

Device Evolution

- New generation devices are safer and more effective
- Less pacemaker and paravalvular leak
- Smaller profile and sheath size

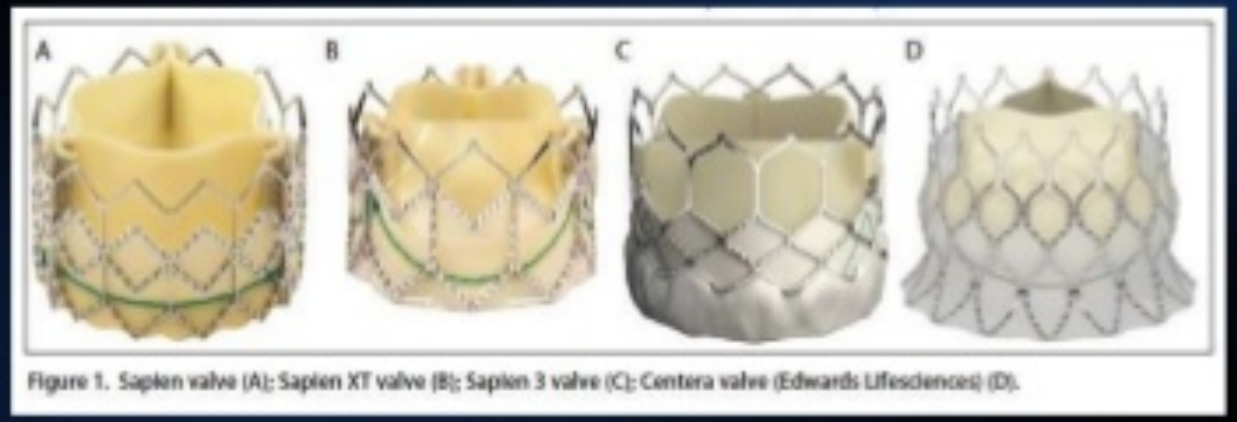
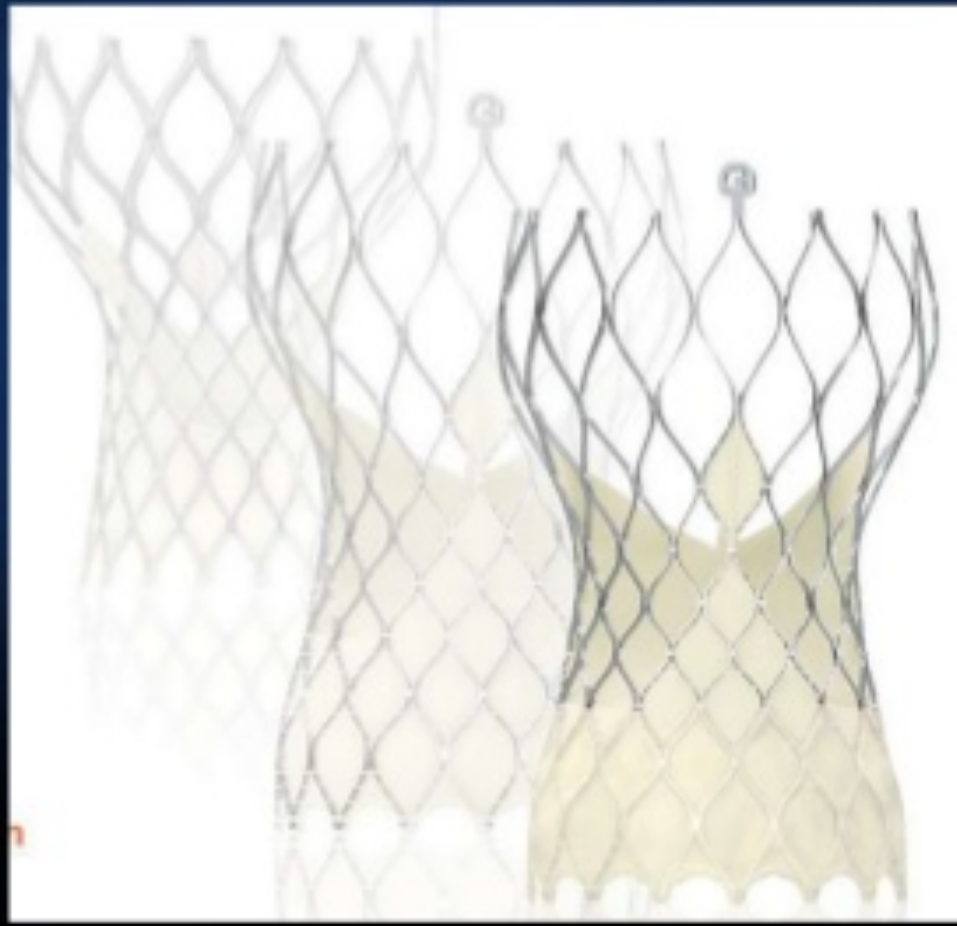


Figure 1. Sapien valve (A); Sapien XT valve (B); Sapien 3 valve (C); Centera valve (Edwards Lifesciences) (D).



Original Article

Transcatheter Aortic-Valve Replacement with a Balloon-Expandable Valve in Low-Risk Patients

N Engl J Med
Volume 380(18):1695-1705
May 2, 2019

The NEW ENGLAND JOURNAL of MEDICINE

Study Overview

- In a randomized trial, 1000 patients with severe aortic stenosis who were at low risk for death with surgery were assigned to undergo transcatheter aortic-valve replacement with a balloon-expandable valve or surgical aortic-valve replacement.
- At 1 year, the rate of death, stroke, or rehospitalization was significantly lower in the TAVR group.

Conclusions

- Among patients with severe aortic stenosis who were at low surgical risk, the rate of the composite of death, stroke, or rehospitalization at 1 year was significantly lower with TAVR than with surgery.

Original Article

Transcatheter Aortic-Valve Replacement with a Self-Expanding Valve in Low-Risk Patients

N Engl J Med
Volume 380(18):1706-1715
May 2, 2019

The NEW ENGLAND JOURNAL of MEDICINE

Study Overview

- In a randomized trial, 1468 patients with severe aortic stenosis who were at low risk for death with surgery were assigned to either transcatheter aortic-valve replacement with a self-expanding valve or surgical aortic-valve replacement.

- At 2 years, TAVR was noninferior to surgery with respect to death or disabling stroke.

The NEW ENGLAND JOURNAL of MEDICINE

FDA NEWS RELEASE

FDA expands indication for several transcatheter heart valves to patients at low risk for death or major complications associated with open-heart surgery

More Press Announcements

Press Announcements

For Immediate Release: August 16, 2019

The U.S. Food and Drug Administration today approved an expanded indication for several transcatheter heart valves to include patients with severe aortic valve stenosis (a narrowing of the heart's aortic valve that restricts blood flow to aorta, the body's main artery) who are at low risk for death or major complications associated with open-heart surgery to replace the damaged valves. These transcatheter valves – Sapien 3, Sapien 3 Ultra, CoreValve Evolut R and CoreValve Evolut PRO – were previously indicated only for

Content current as of:
08/16/2019

Who Should Get Surgery Over TAVR?
2011 to 2019

Who Should Get Surgery Over TAVR?

- Risk stratification for TAVR is becoming obsolete
- Both cardiac surgeons and interventional cardiologists say the question has flipped
- 25 percent of patients will be better suited for surgery for various reasons, but 75 percent of aortic valve replacements will move to TAVR in the next few years

Left Atrial Appendage Occlusion for Stroke Prevention in Atrial Fibrillation

Metro Health - University of Michigan

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

AF

- 15–20% of strokes in the general population and for up to 30% in patients over the age of 80 years.
- prevention of stroke-OAC is the standard treatment in patients with AF with a CHA(2)DS2-(VASc) stroke risk score ≥1.
- LAA occlusion -AF with a high stroke risk and contraindications for OAC.

LAA OCCLUSION FOR STROKE PREVENTION IN AF

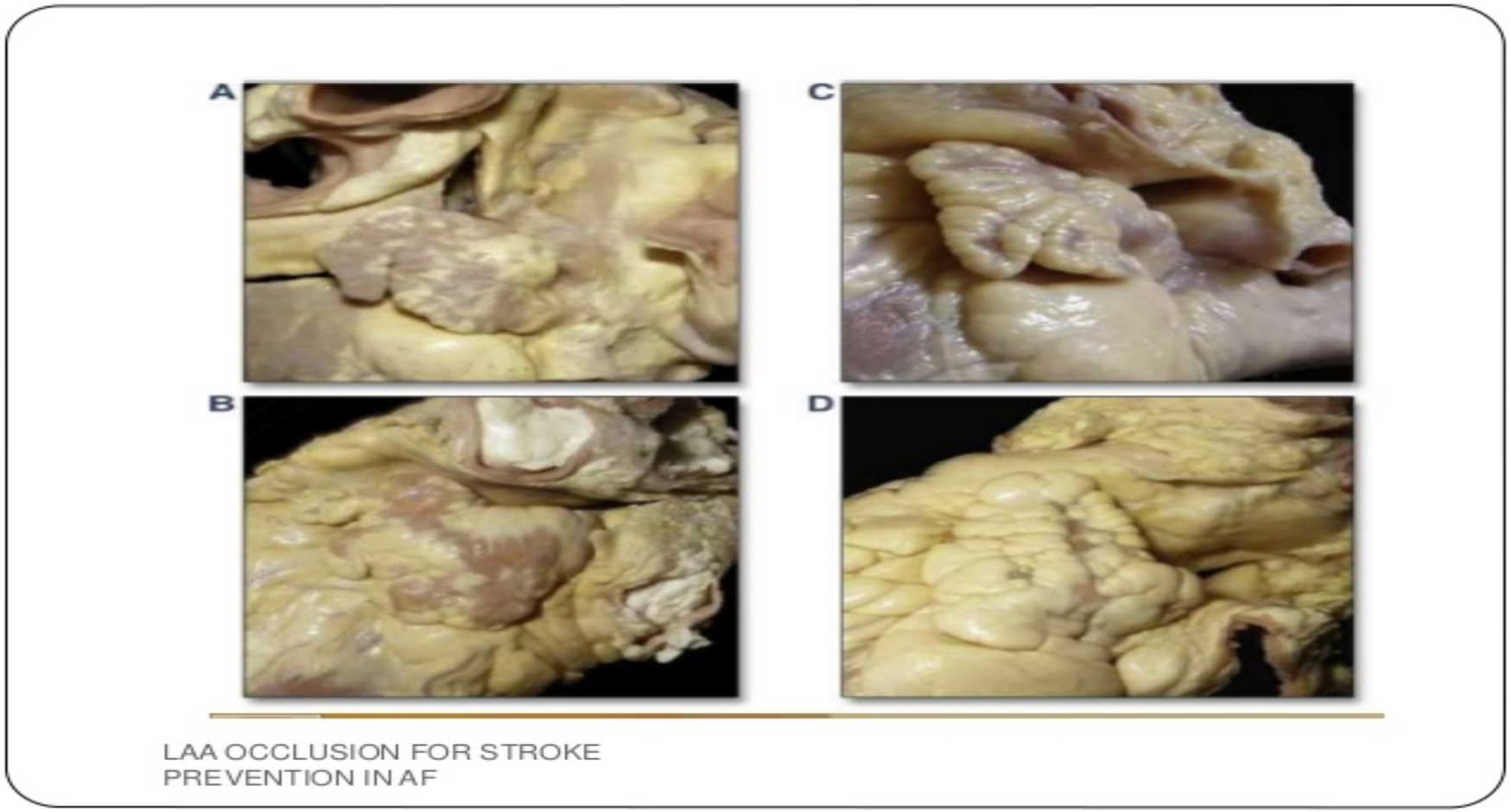
Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

Rationale for LAA occlusion

- 60% of atrial thrombi in valvular AF – LAA
- in NVAF >90% of thrombi were located in the LAA.
- LAA found to be the dominant source of thrombus in patients with NVAF
- reduces the risk of AF-induced stroke in such a range that it outweighs the possible risk on procedural complications.

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation



Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

LAA FUNCTION AND THROMBUS FORMATION

- Normal contraction of the LAA during SR and adequate blood flow within the LAA lower the risk for thrombi
- Thrombus formation - reduced contractility and stasis ensue.
- AF -decrease in LAA contractility and function, manifest as a decrease in Doppler velocities and dilation of the LAA.
- Significant LV dysfunction and elevated LV EDP -LAA thrombus formation in the absence of AF.

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

Indications for percutaneous LAA closure

- Patients with AF at high stroke risk with high risk (or recurrence) of bleeding under (N)OAC due to
- ➢ Uncontrolled, severe hypertension
- ➢ Coagulopathies—low platelet counts, MDS
- ➢ Inherited bleeding disorder— vWD, haemophilia
- ➢ Severe hepatic or renal dysfunction—eg, alcoholic liver disease,cirrhosis

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

- Vascular disease or malformations— eg, intestinal angiodysplasia,Osler-Weber-Rendu disease,previous intracerebral haemorrhage,cerebral microbleeds (~amyloid angiopathy), retinal vasculopathy
- Insufficiently treatable GI disease with bleeding— eg, neoplastic disease, intestinal angiodysplasia
- Recurrent nephrolithiasis
- High probability of frequent and/or severe traumas—eg, epilepsy,in the elderly

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

Contraindications for percutaneous LAA closure

- Low risk for stroke CHA(2)DS2-(VASc)=0
- VHD(eg, MS)
- Other indications for long-term or lifelong OAC—mechanical prosthetic valve, PTE and DVT ,thrombi in the LA or LV
- Contraindications for transseptal LA thrombus or tumour, active infection, uncooperative patient,(presence of ASD/PFO closure device) a thrombus in the LAA

LAA OCCLUSION FOR STROKE PREVENTION IN AF

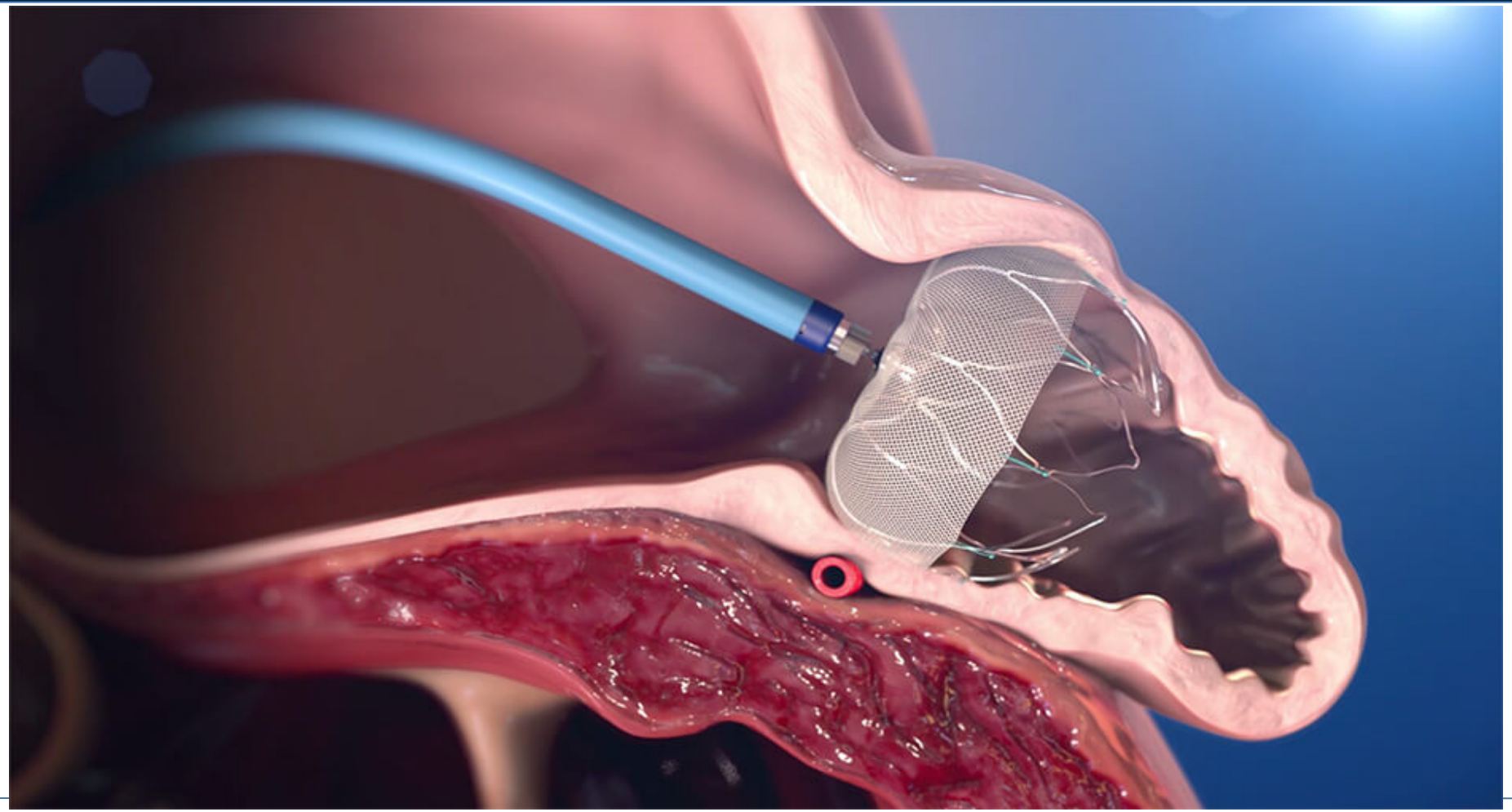
Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

Watchman device

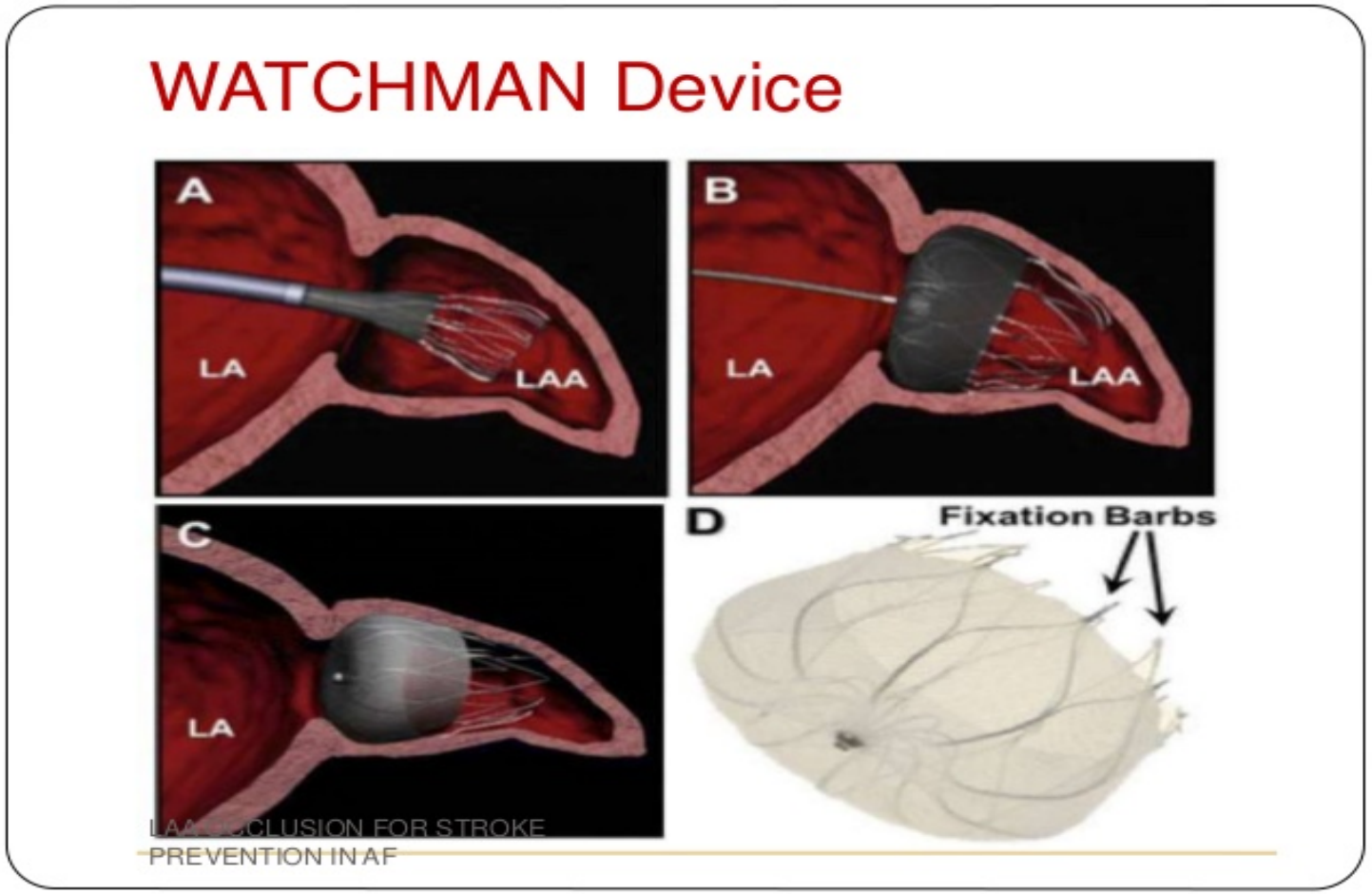
- approved by FDA in 2015 for nonvalvular AF patients at risk for stroke without contraindication to anticoagulation.
- Watchman Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation (PROTECT-AF) trial -trial to examine the efficacy of the Watchman device.
- self-expanding nitinol frame covered with a porous filtering PET (polyethylene terephthalate) membrane.

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Watchman Device

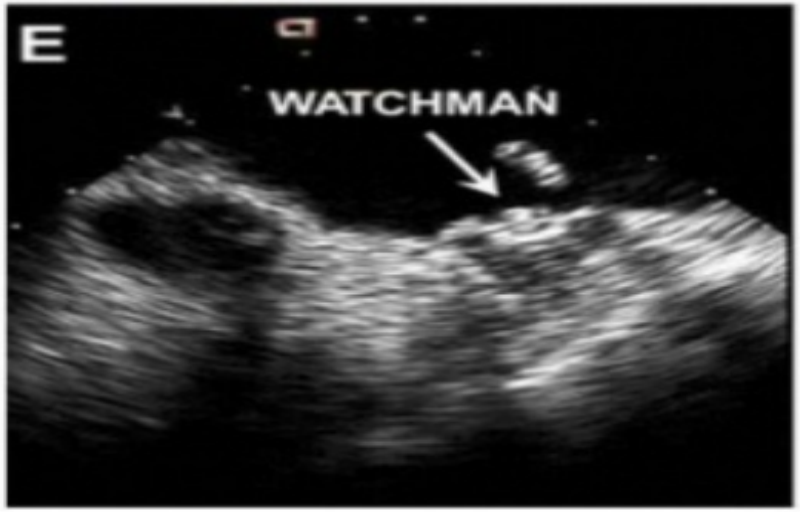


Watchman Device

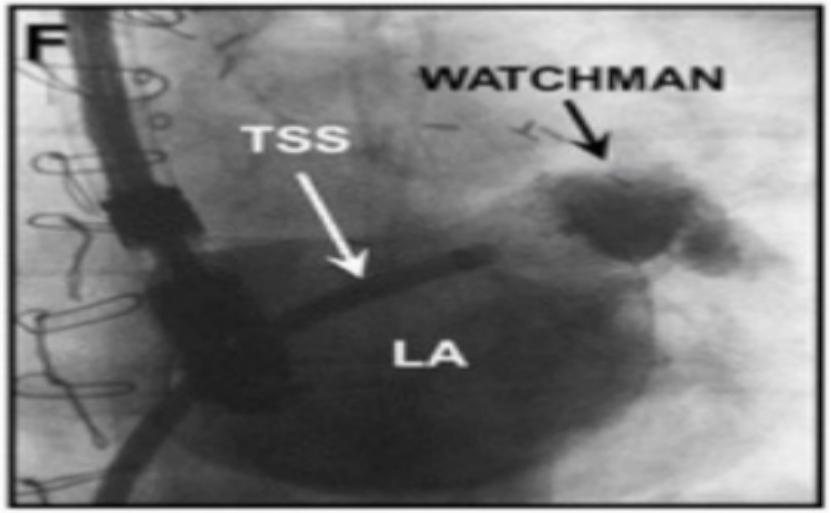


Watchman Device

TEE Image

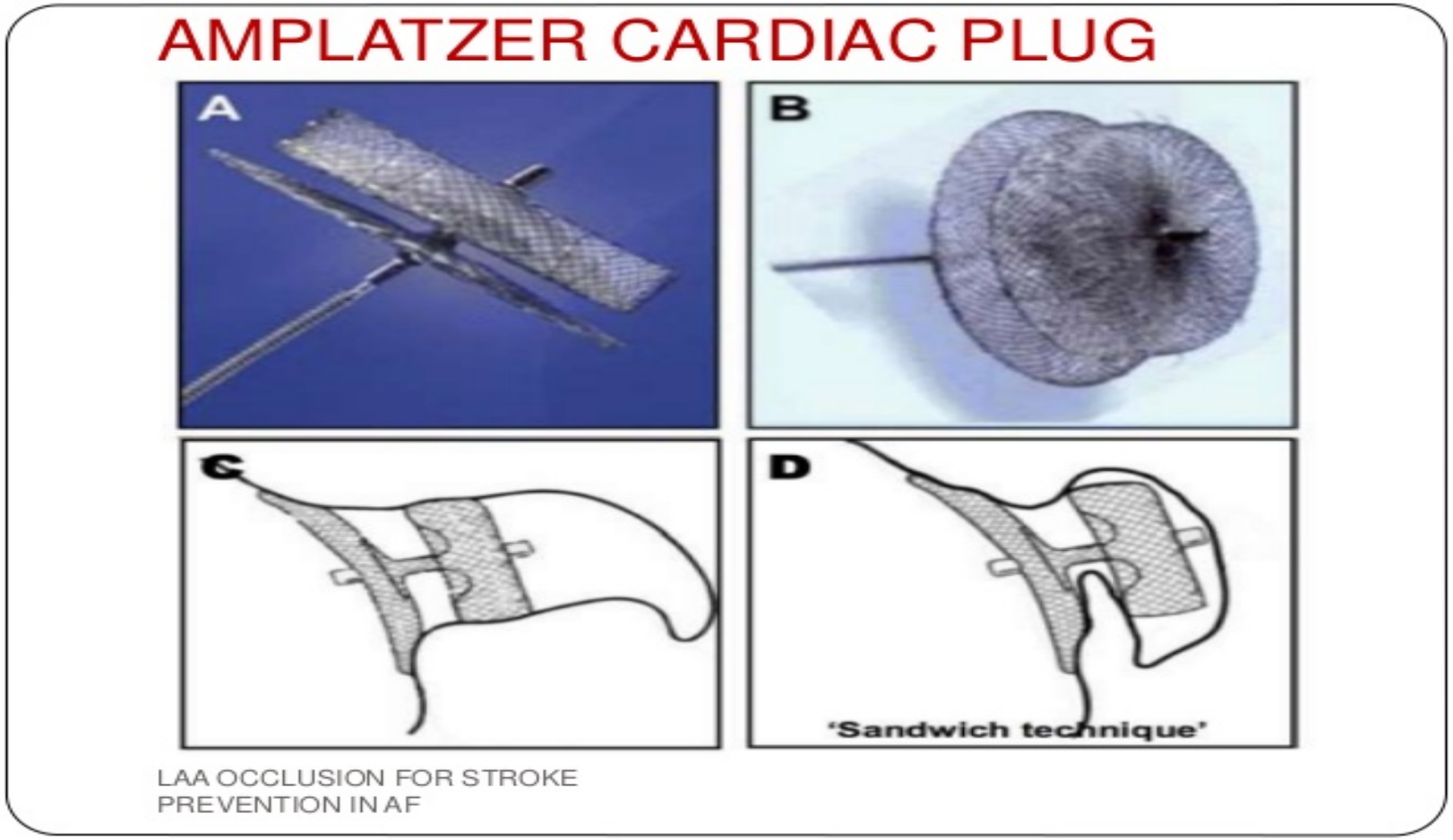


LA Angiogram

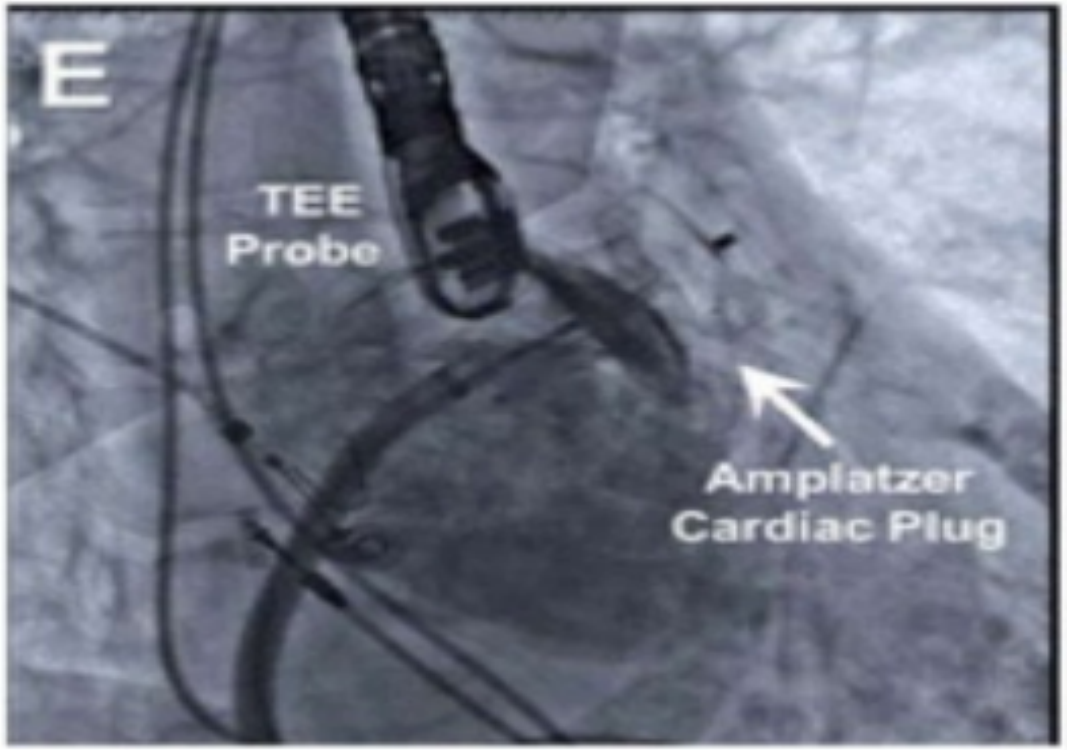


LAA OCCLUSION FOR STROKE PREVENTION IN AF

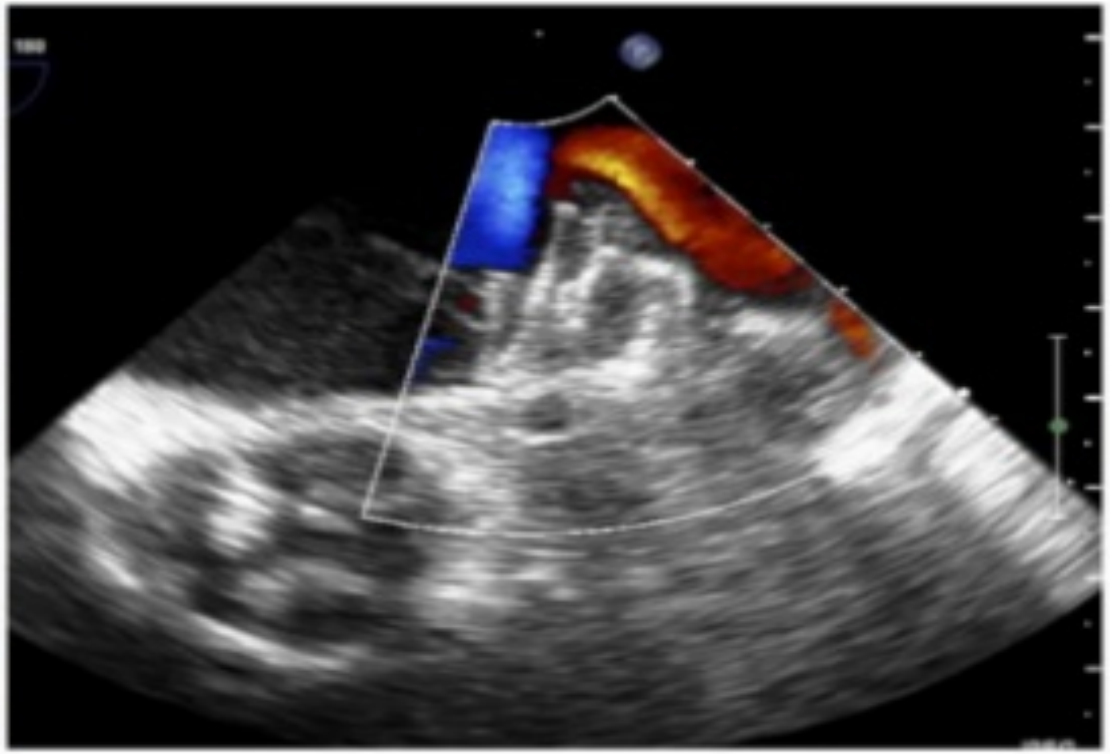
Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation



LA Angiogram

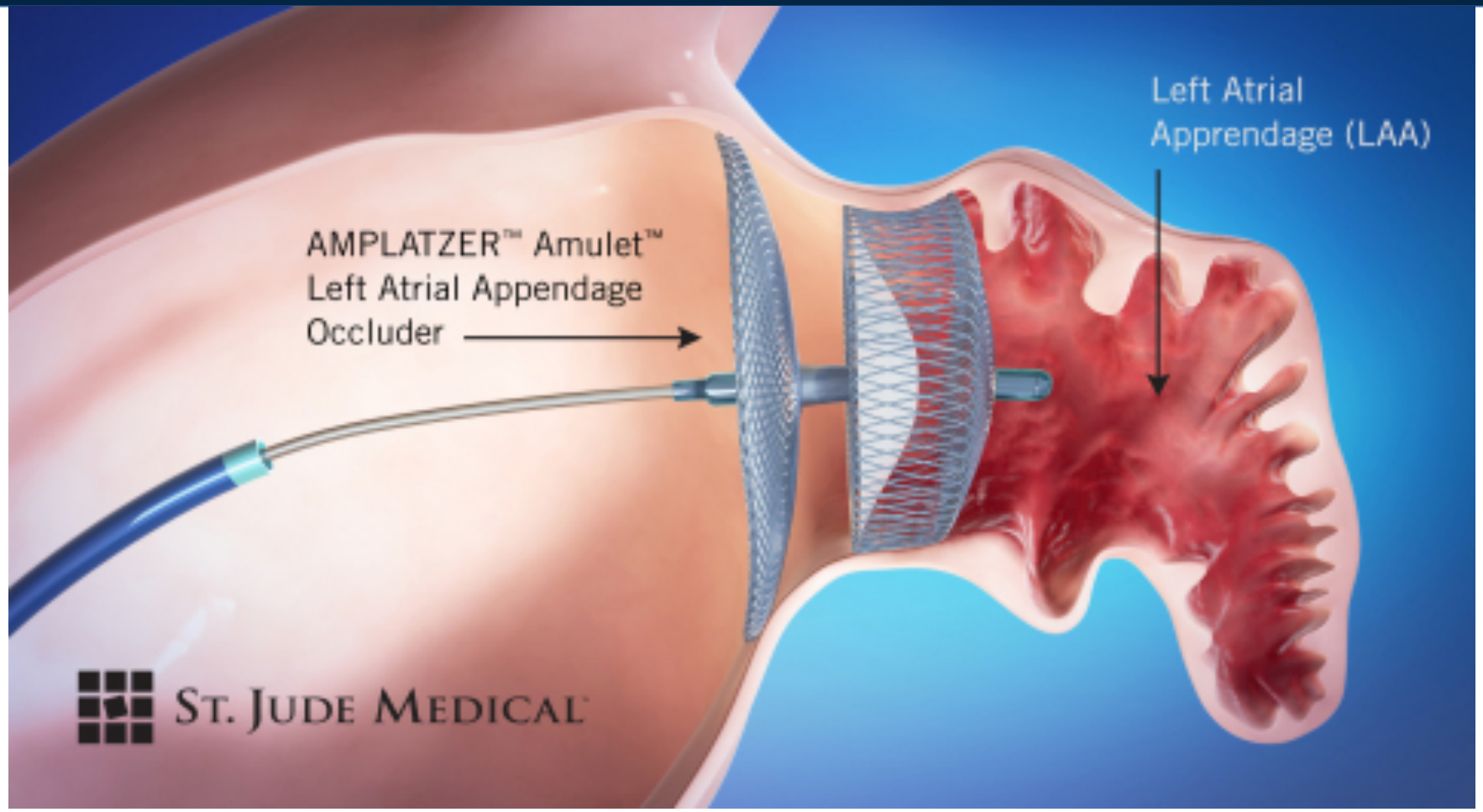


TEE Image



LAA OCCLUSION FOR STROKE PREVENTION IN AF

Amplatzer Amulet Device



Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

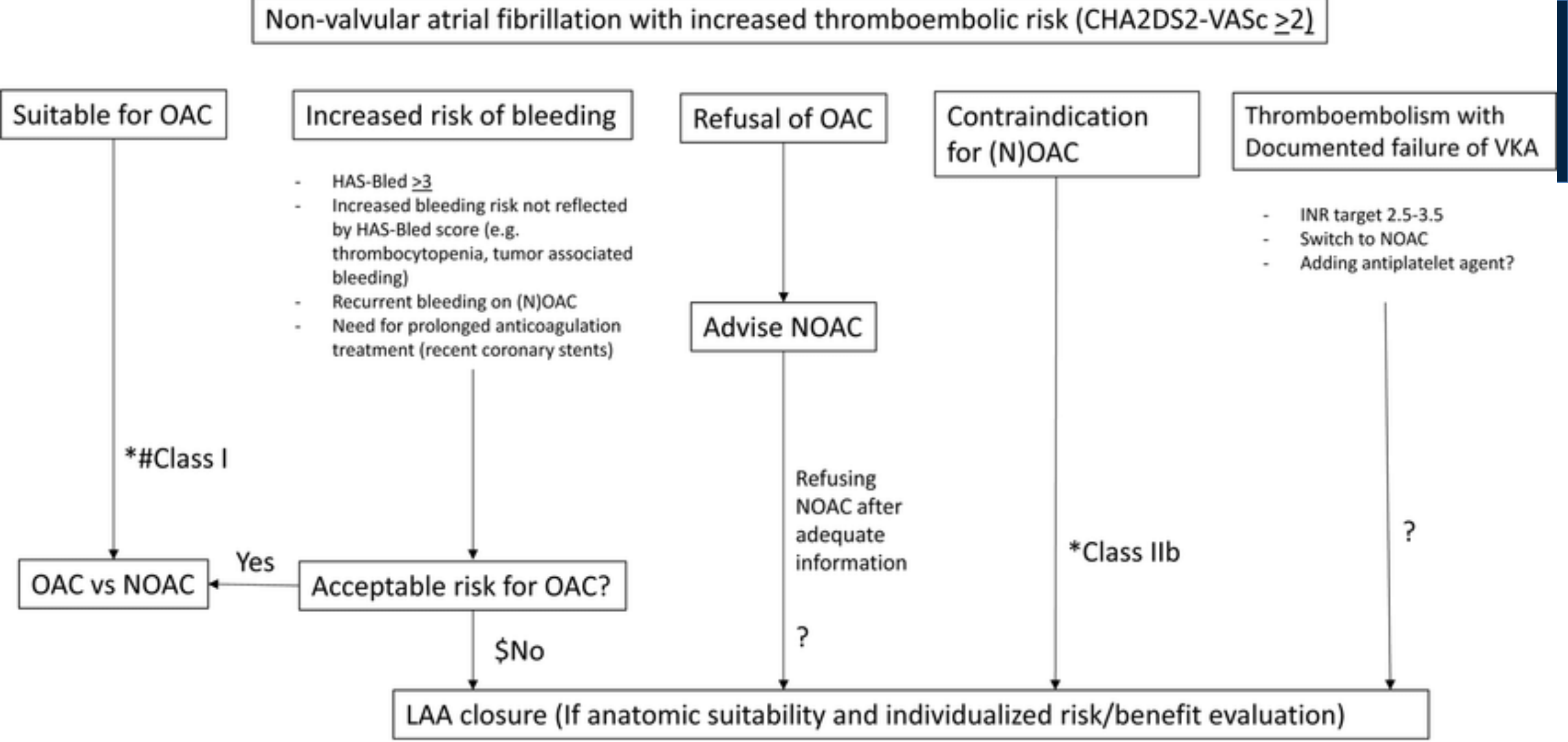
- PROTECT AF (WATCHMAN Left Atrial Appendage System for Embolic Protection in Patients With Atrial Fibrillation) -Watchman device was equivalent to warfarin for preventing stroke in atrial fibrillation, but had a high rate of complications.
- PREVAIL (Evaluation of the WATCHMAN LAA Closure Device in Patients with Atrial Fibrillation Versus Long Term Warfarin Therapy), - complication rate was low.

LAA OCCLUSION FOR STROKE PREVENTION IN AF

Left Atrial Appendage Occlusion of Stroke Prevention in Atrial Fibrillation

- PREVAIL and PROTECT AF are prospective randomized clinical trials with patients randomized 2:1 to LAAC or warfarin; together, they enrolled 1,114 patients for 4,343 patient-years.
- These 5-year outcomes of the PREVAIL trial, combined with the 5-year outcomes of the PROTECT AF trial-Watchman provides stroke prevention in NVAF comparable to warfarin,with additional reductions in major bleeding, particularly hemorrhagic stroke, and mortality.

LAA OCCLUSION FOR STROKE PREVENTION IN AF



* 2012 focused update to the European Society of Cardiology recommendation (8)
# 2014 American Heart Association/American College of Cardiology/Heart Rhythm Society recommendation (7)
$ European Heart Rhythm Association/European Association of Percutaneous Cardiovascular Interventions expert consensus statement on catheter-based left atrial appendage occlusion (13)
? Debated

Summary

- LAA Occlusion is an option for patients with AF and high bleeding risk as well as high stroke risk
- Class IIB indication in 2019 focused update of ACC/AHA/HRS Atrial Fibrillation guidelines
- More centers and better safety in last few years

PATENT FORAMEN OVALE CLOSURE IN 2019

Patent Foramen Ovale Closure in 2019

- PFO is associated with cryptogenic stroke (stroke of unclear etiology)
- PFO is present in 20-25% of the adult population,
- 40% of adults with cryptogenic stroke have a PFO.

Patent Foramen Ovale Closure in 2019

Cryptogenic stroke[1]

- Ca. 25% (10-40%) of patients with ischemic stroke have no probable cause found after standard workup (TTE, 24-hour Holter monitoring, MRI or CT of of the infarct in the brain / neck and brain arteries, blood work).
- Embolic strokes of undetermined source (nonlacunar brain infarcts without substantial proximal arterial stenosis or major cardioembolic sources) represent 80 to 90% of all cryptogenic ischemic strokes.
- Occult, low-burden, paroxysmal atrial fibrillation is increasingly recognized as a source of cryptogenic stroke, especially in older patients (>60 y. of age).
- Low risk of recurrence with aspirine: 1-2% per year.

Patent Foramen Ovale Closure in 2019

Cryptogenic stroke (CS) is a diagnosis of exclusion

Conventional classification:

- Atherosclerotic
- Small arterial occlusion
- Cardioembolic
- Other causes
- **Cryptogenic**

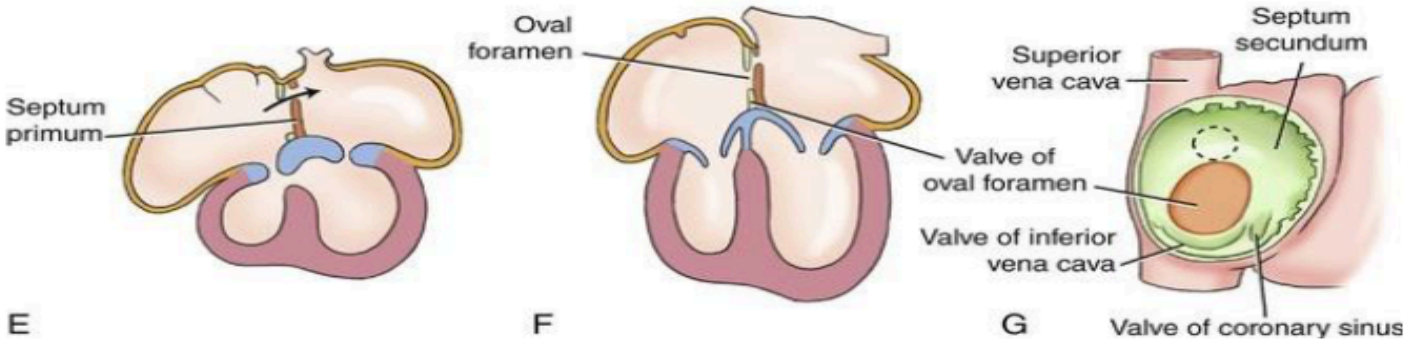
Potential etiologies of CS:

- Paroxysmal atrial fibrillation
- Aortic arch atheromas
- Inherited thrombophilias
- Patent foramen ovale

Patent Foramen Ovale Closure in 2019

Patent foramen ovale (PFO)

- Persistent opening between the atrial septum primum and secundum at the level of the fossa ovalis
- Prevalence: 27.3%[1]
- Mean size ca. 5 mm
- Larger shunt size:
  - atrial septal aneurym
  - prominent valvula Eustachii



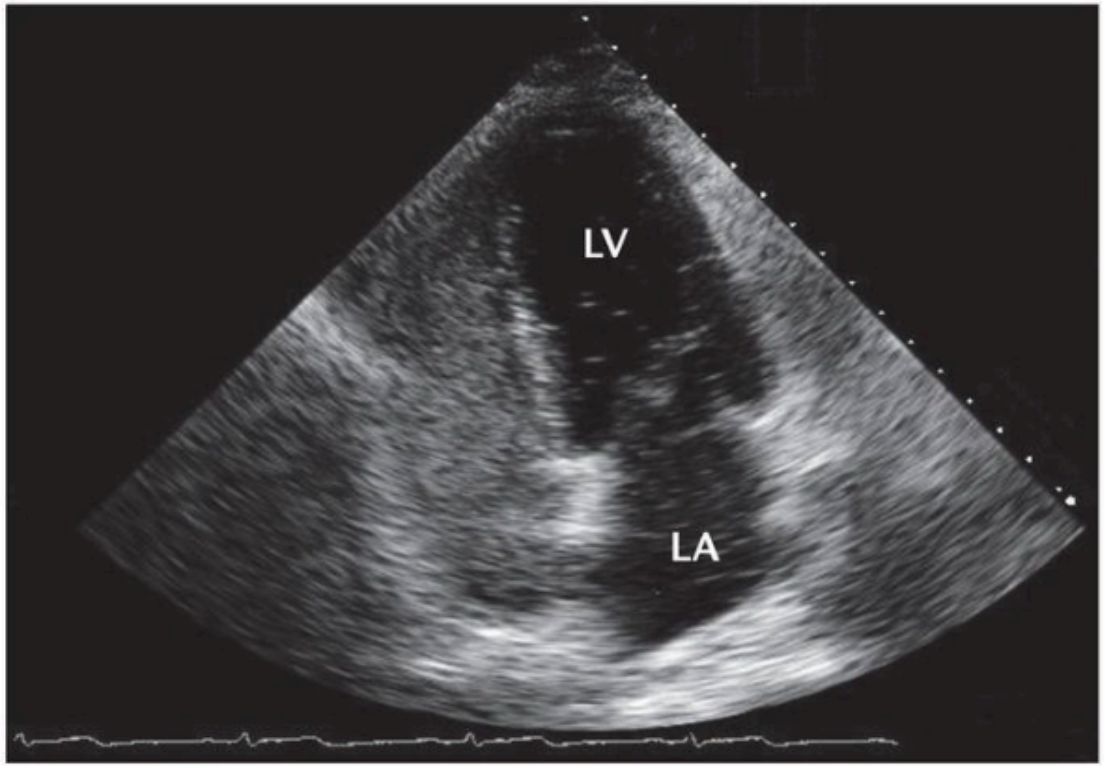
Patent Foramen Ovale Closure in 2019

PFO and stroke

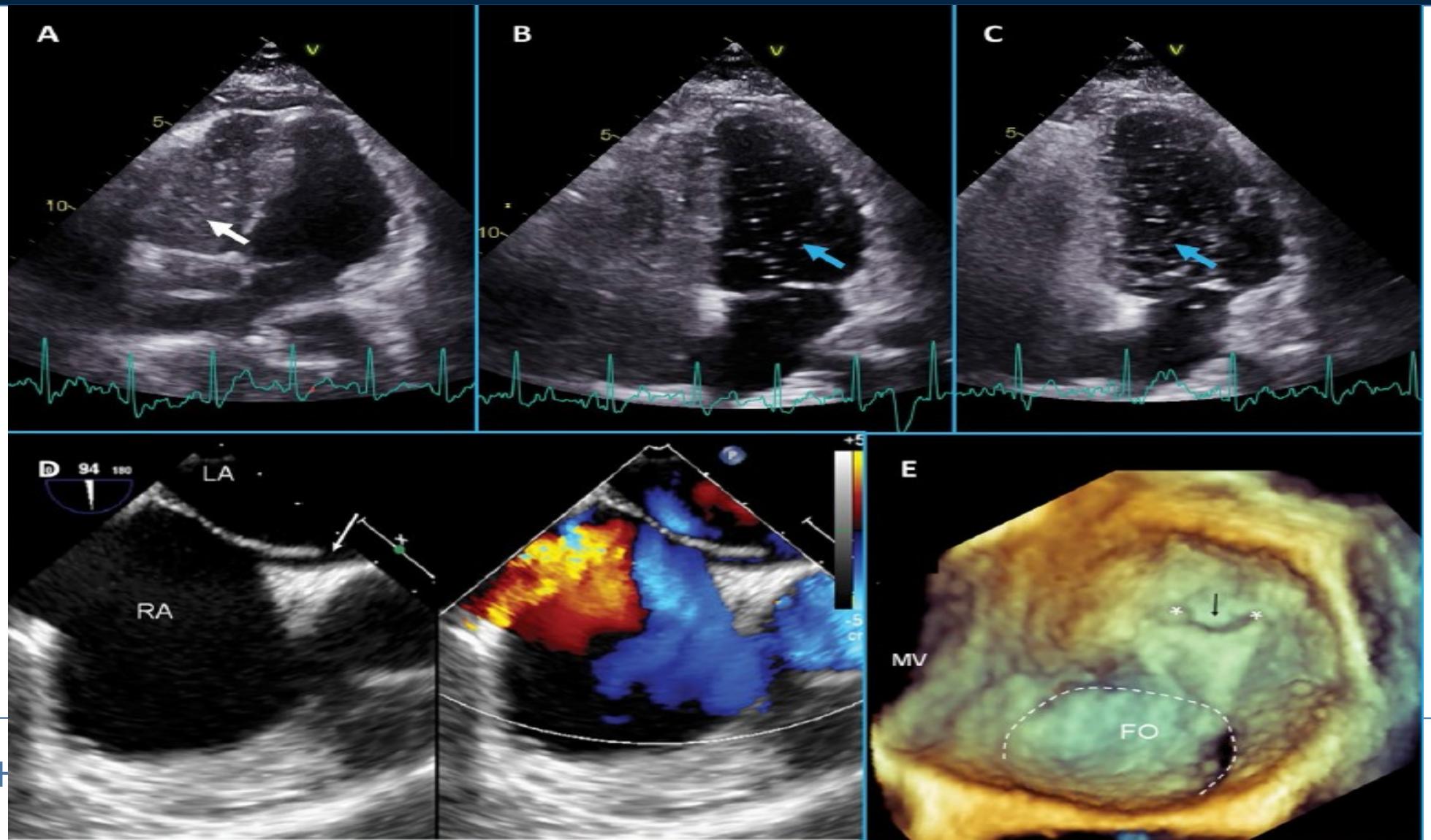
NEJM 1988[1]

- 60 adults < 55 years with ischemic stroke and normal cardiac exam

- PFO prevalence
  - controls: 10%
  - stroke with identif. cause: 21%
  - stroke with risk factor: 40%
  - stroke without identif. cause: 54%



Echocardiographic Assessment of a Patent Foramen Ovale



Patent Foramen Ovale Closure in 2019

PFO closure and stroke: 1992-2016

Circulation 1992[1]

- Case series of 36 patients with presumed paradoxical embolism (strokes, TIAs, systemic arterial emboli, brain abscesses)
- Transcatheter closure can be accomplished with little morbidity

Clinical trials

- **CLOSURE**: N Engl J Med. 2012;366:991-9
- **PC:** N Engl J Med. 2013;368:1083-91
- **RESPECT**: N Engl J Med. 2013;368:1092-10

None of the trials showed superiority of PFO closure vs. medical therapy in the prevention of recurrent vascular events.

Patent Foramen Ovale Closure in 2019

PFO and stroke

RoPE score 2013[1]

- Age, cortical infarct, nonsmoker, first event, no diabetes nor hypertension

- Score 10: 29 y. old with cortical infarction and no CV risk factor
- Score 0: 70 y. old smoker with hypertension, diabetes, prior stroke and no cortical infraction

ROPE Score	PFO %	Attrib. Risk	Recurr. Rate @2y
0-3	23	0	20 (12-28)
4	35	38	12 (6-18)
6	47	62	8 (4-12)
8	67	84	6 (2-10)
9-10	73	88	2 (0-4)

Patent Foramen Ovale Closure in 2019

PFO and stroke – what have learned so far

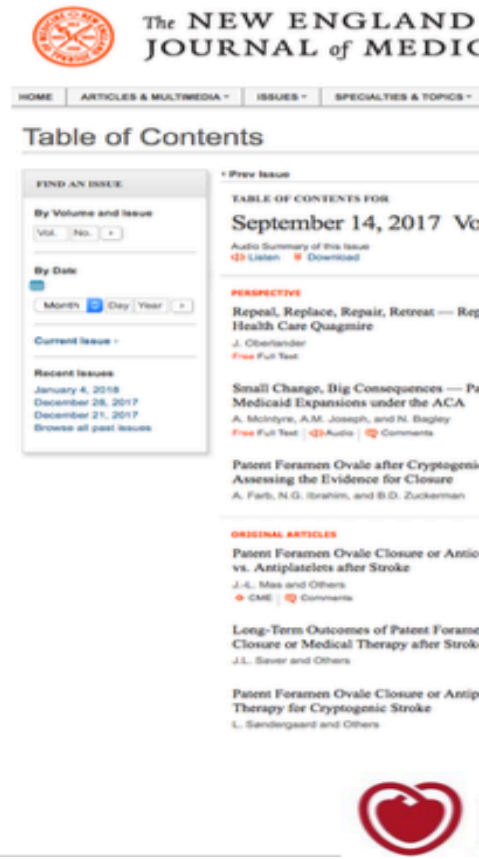
- Paradoxical embolism can lead to stroke but is usually a diagnosis of presumption
- There are „incidental“ PFOs and there are „dangerous“ PFOs

- 2014 AHA stroke prevention guidelines: For patients with a cryptogenic ischemic stroke or TIA and a PFO without evidence for DVT, available data do not support a benefit for PFO closure (Class III; Level of Evidence A).

- Study design matters: identification of „dangerous“ PFOs, length of f/u, not all devices are performing equally well

Patent Foramen Ovale Closure in 2019

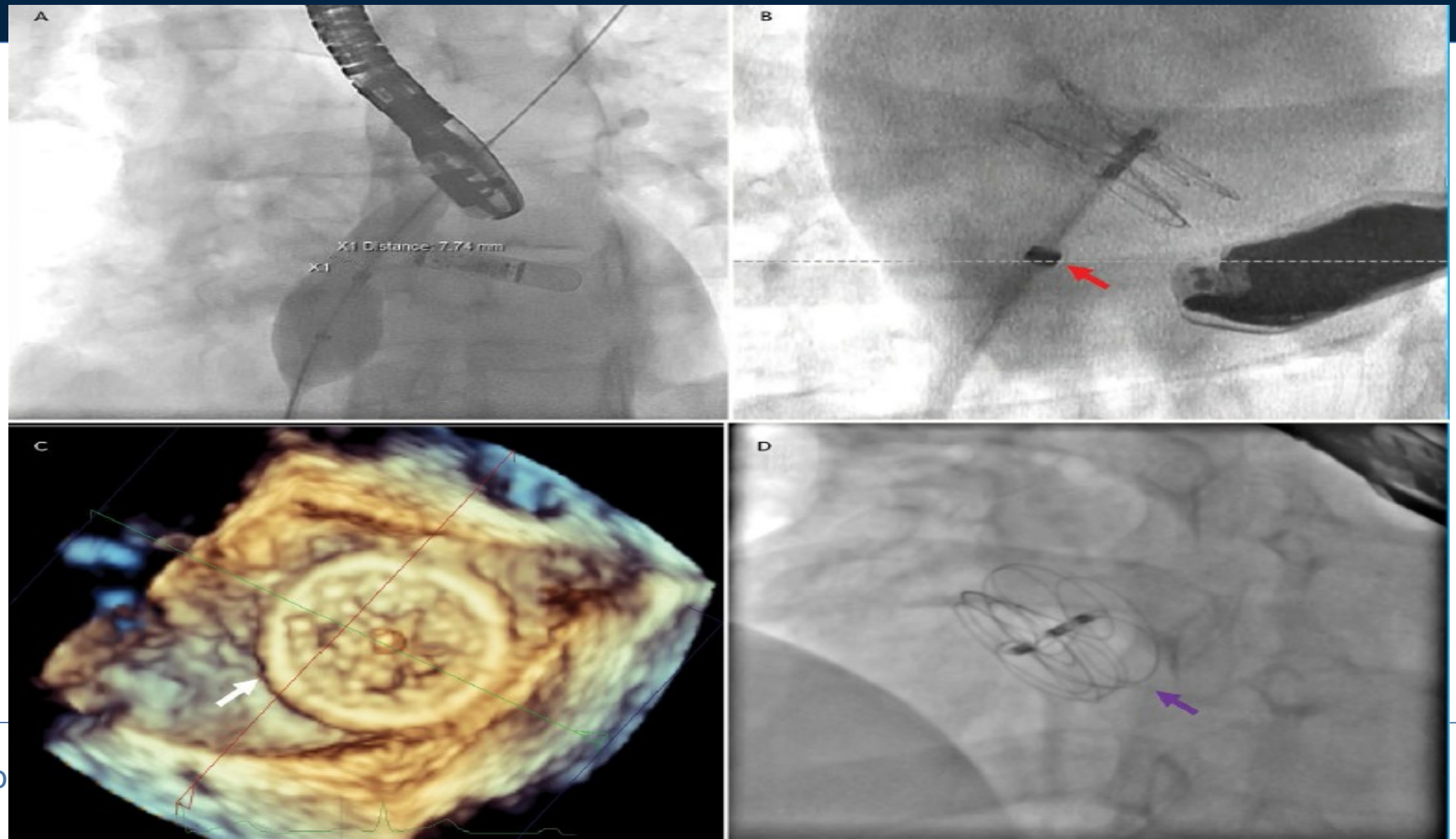
PFO closure and stroke – a new era begins (2017)



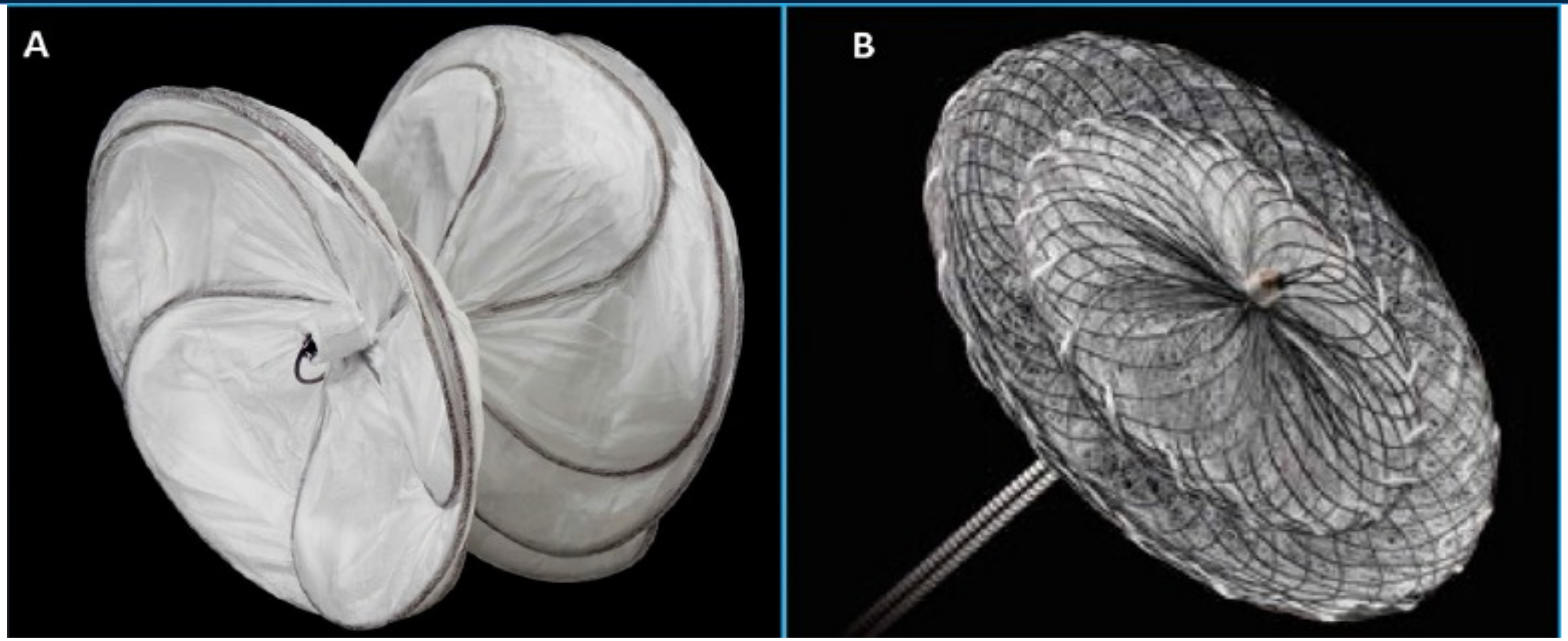
Patent Foramen Ovale Closure in 2019

	RESPECT ext. f/u (n=980; 46 y.)	CLOSE (n=664; 43y.)	REDUCE (n=664; 45 y.)
Design	• Event driven • 1:1 rand. • Device vs. medical therapy	• 900 pts. • 1:1:1 • Antiplatelet vs. OAC vs. device	• N=664 • 2:1 • Device + ASA vs. antiplatelet
Follow-up	• 5.9 y (IQR 4.2-8y)	• 5 +/- 2 y.	• 3.2 y (IQR 2.2-4.8)
Primary endpoint	• Stroke • All-cause mortality	• Stroke	• Stroke • Brain infraction
Device	• Amplatzer • ASA for 6 mo.	• 11 diff. devices	• HELEX or GSO • Plus antiplat. tx.
Inclusion criteria	• 18-60 y. of age • CS* (270 days prior)	• 16-60 y. of age • CS* (6 months prior)	• 18-59 • CS* (180 days prior)
Outcome	• Closure superior • HR 0.55 (0.31-0.999)	• Closure superior to antiplatelet • HR 0.04 (0-0.27)	• Closure superior (stroke prevention) • HR 0.23 (0.09-0.62)

Percutaneous closure of a Patent Foramen Ovale



Patent Foramen Ovale Closure Devices



(A) The Gore Cardioform septal Occluder. (B) The AMPLATZER PFO Occluder

Patent Foramen Ovale Closure in 2019

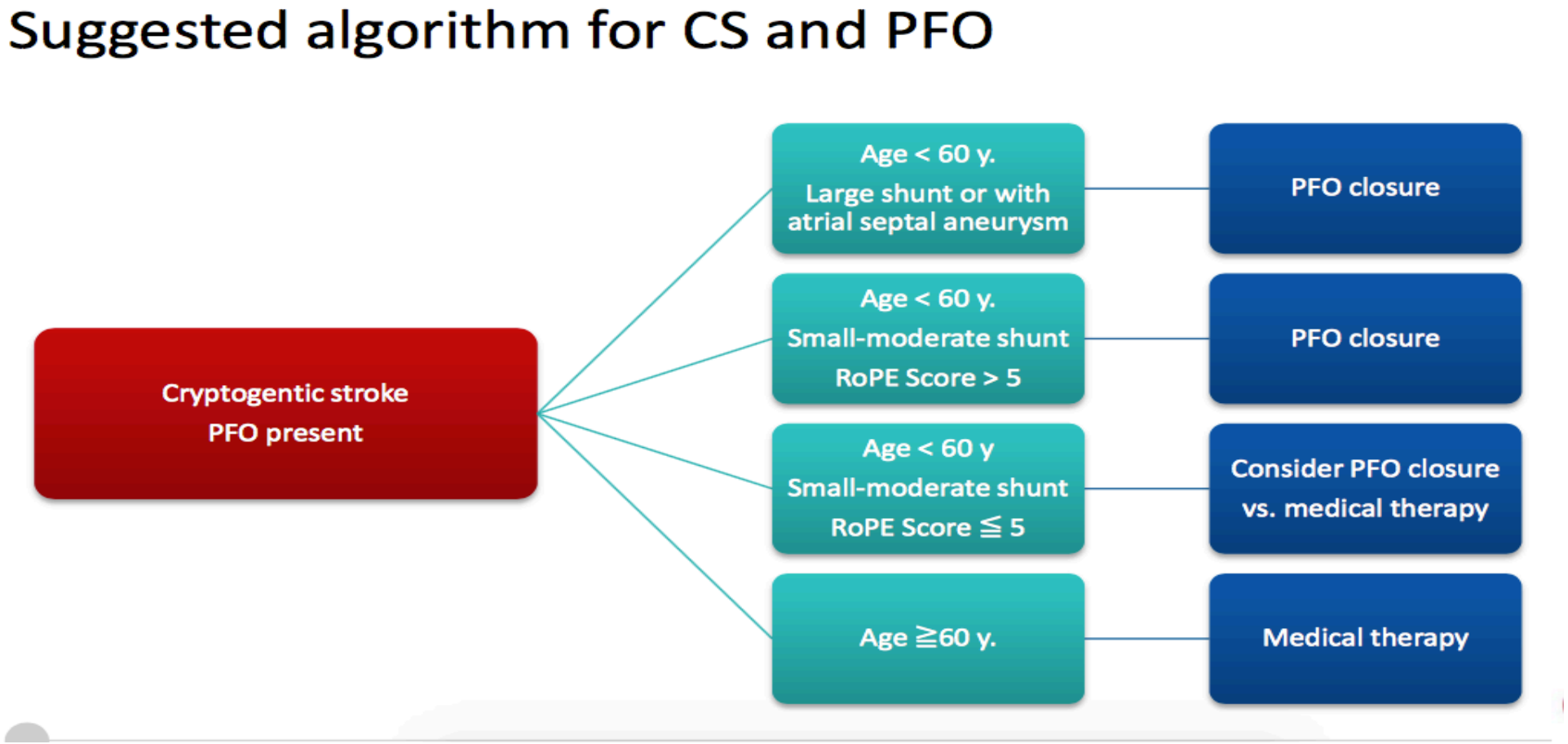
- The data from REDUCE suggests that, for every 28 closed patients, one stroke is avoided at 2 years

- In both REDUCE and CLOSE trials, PFO closure was associated with a higher risk of atrial fibrillation, which was believed to be primarily due to the closure procedure itself (i.e., self-limited).

Patent Foramen Ovale Closure in 2019

- CLOSE and REDUCE were likely positive because of stricter enrollment criteria, leading to the inclusion of subjects whose presenting stroke was secondary to PFO rather than another etiology
- In summary, PFO closure is of moderate benefit compared to antiplatelet therapy alone in the prevention of recurrent ischemic stroke in adults up to 60 years of age.
- It remains unknown how PFO closure compares to systemic anticoagulation (e.g., with novel oral anticoagulants) for the prevention of recurrent ischemic stroke.

Patent Foramen Ovale Closure in 2019

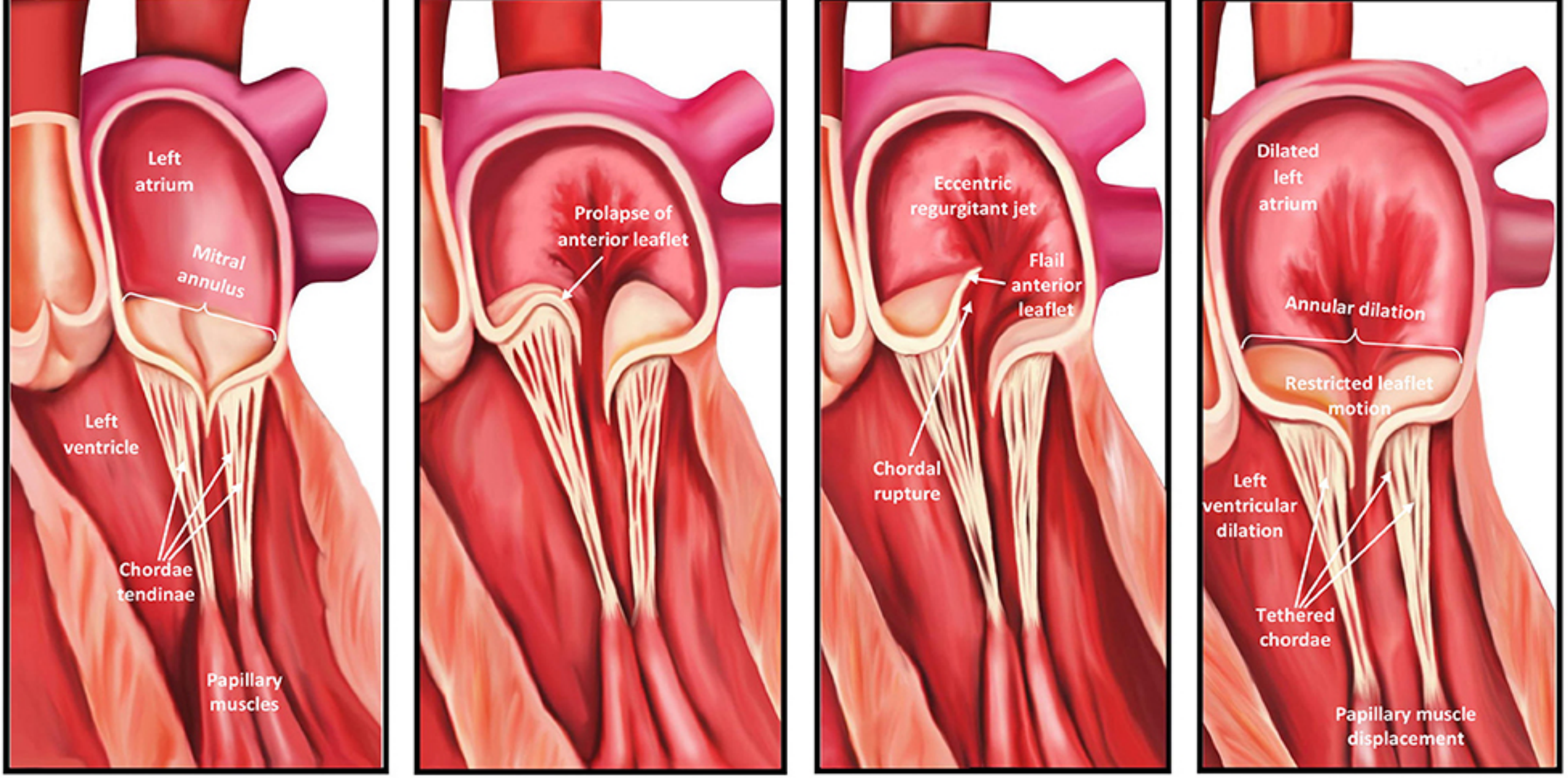


PERCUTANEOUS MITRAL VALVE INTERVENTIONS (REPAIR): CURRENT INDICATIONS AND FUTURE PERSPECTIVES

Metro Health - University of Michigan

Mitral Valve

- Mitral valve regurgitation (MR) is the commonest valvular abnormality encountered among adult patients with cardiac valvular disease and conveys significant morbidity and mortality
- The mitral valve is a complex anatomical structure and etiology for regurgitation is classified as either *primary* or *secondary* MR



Normal mitral valve anatomy

Primary mitral regurgitation due to

Primary mitral regurgitation due to

Functional mitral regurgitation

Primary Mitral Regurgitation

- Medical therapy has a limited to no role
- Surgical therapy is the treatment of choice
- MV repair is the preferred mode of therapy considering the lower operative mortality, superior long-term survival, and fewer valve related complications from bleeding and endocarditis compared to valve replacement

Primary Mitral Regurgitation

- Based on the 2017 update to 2014 AHA/ACC valvular guidelines, decision regarding candidacy for intervention in chronic *primary* MR is dependent on disease severity, symptom status, LV size and function, rest or exercise pulmonary hypertension, new onset atrial fibrillation, likelihood for successful repair and patient preference

Secondary Mitral Regurgitation

- Optimal pharmacologic therapy (GDMT) is recommended in the management of HFrEF and severe MR
- Cardiac resynchronization therapy(CRT) among selected patients with LV dysfunction and dyssynchrony
- In general, neither MV replacement nor repair has been shown to improve survival in the treatment of severe *functional* MR, only symptoms

Mitra Clip- Percutaneous Mitral Valve Repair

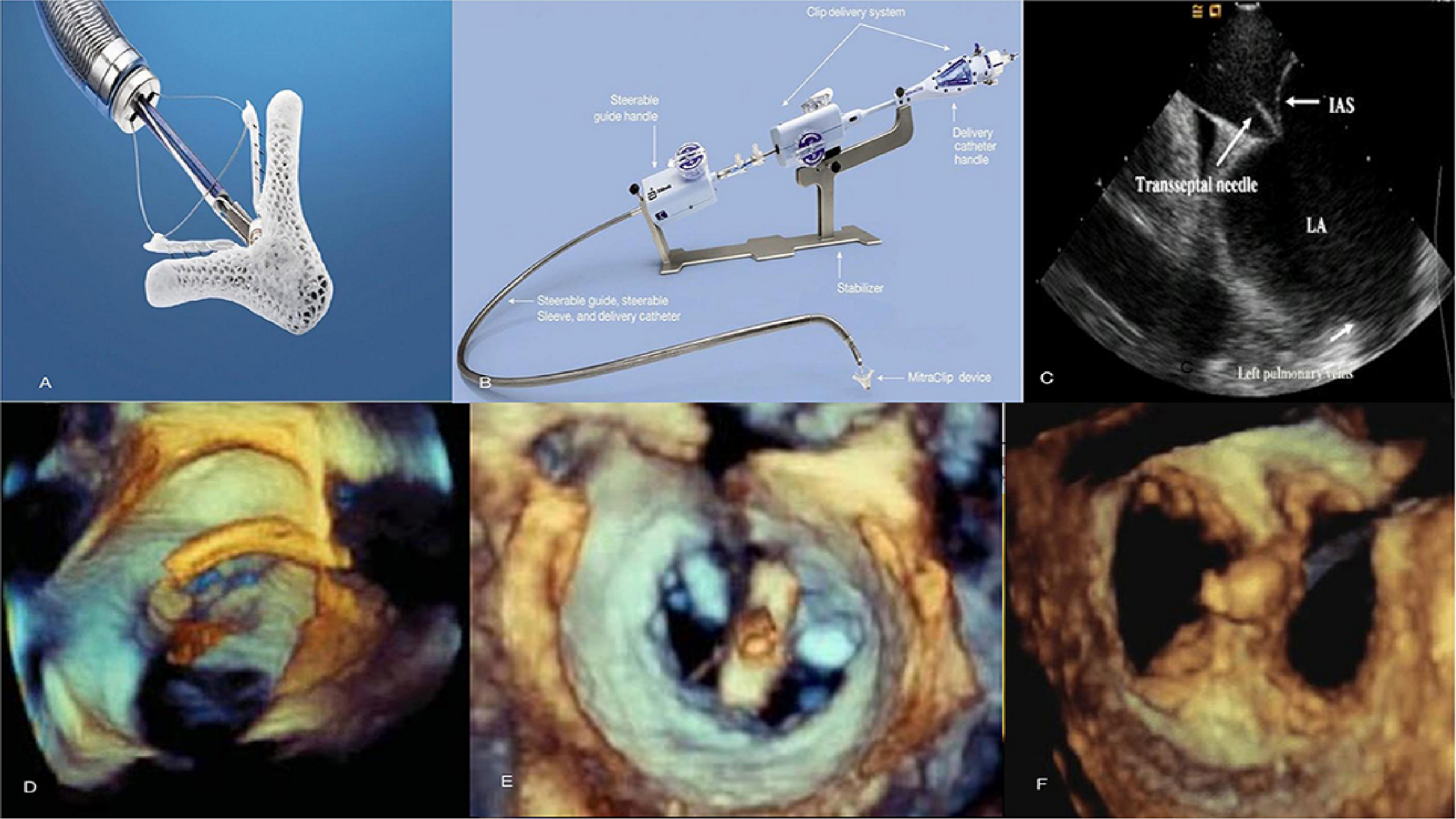
- MitraClip placement in a specific group of patients with disproportionately severe *functional* MR was shown to improve outcomes including survival

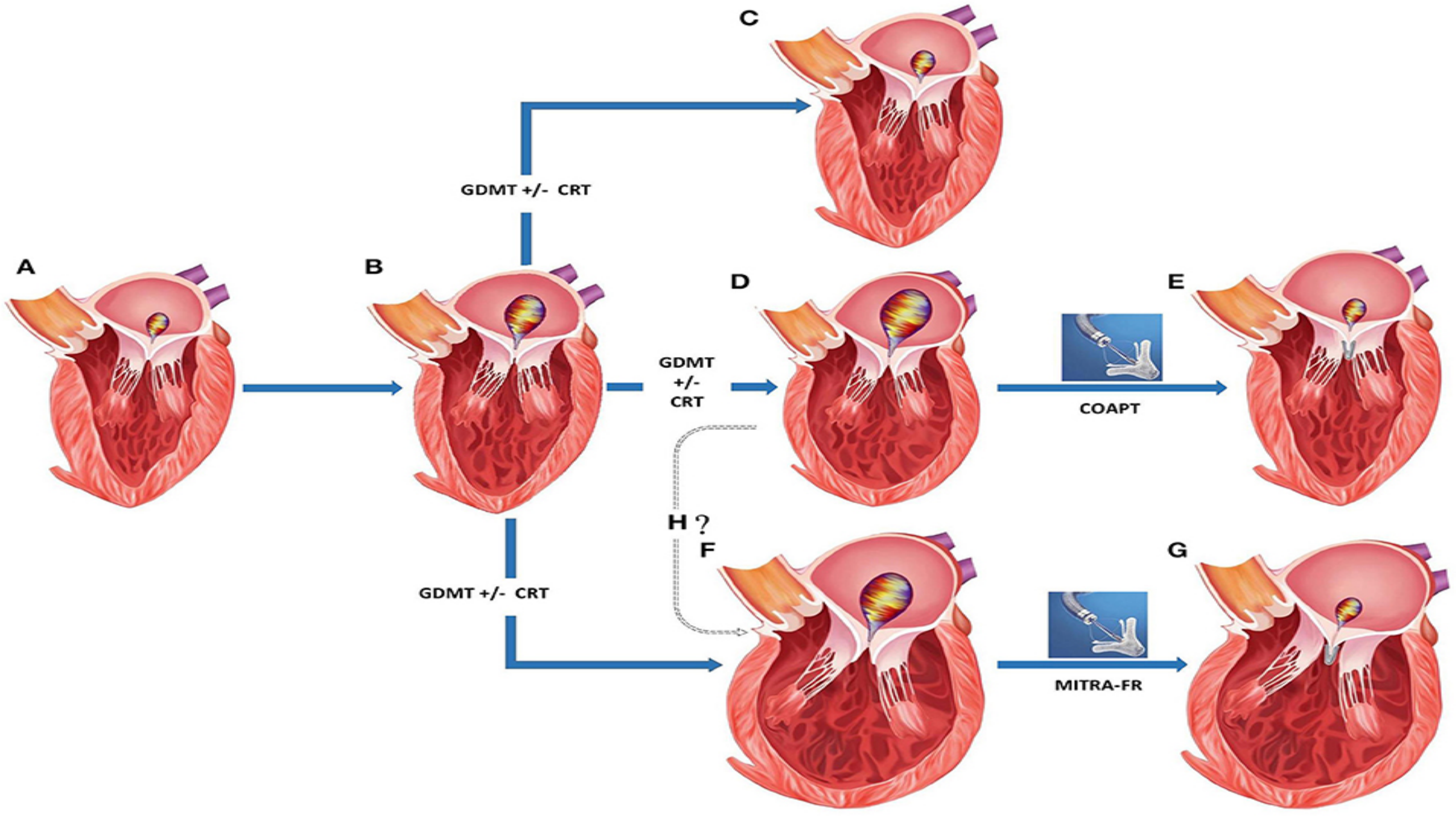
- Guidelines are yet to be updated to reflect recent data on use of percutaneous MV therapies such as the MitraClip in functional MR

Mitra Clip- Percutaneous Mitral Valve Repair

- MitraClip is a cobalt chromium clip with two arms and works by grasping and approximating edges of the anterior and posterior valvular leaflet segments in patients with severe MR.

- MitraClip received initial CE-Mark approval in Europe in 2008 and was approved by the FDA in 2013 for use in *primary* MR and 2019 for use in *functional* MR.


A
Clip delivery system
Steerable guide handle
Delivery catheter handle
Stabilizer
Steerable guide, steerable Sleeve, and delivery catheter
MitraClip device
B
IAS
Transseptal needle
LA
Left pulmonary veins
C
D
E
F


A
B
C
D
E
F
G
H ?
GDMT +/- CRT
GDMT +/- CRT
GDMT +/- CRT
COAPT
MITRA-FR

Original Article

Transcatheter Mitral-Valve Repair in Patients with Heart Failure

COAPT Trial

N Engl J Med
Volume 379(24):2307-2318
December 13, 2018

The NEW ENGLAND JOURNAL of MEDICINE

Conclusions

- Among patients with heart failure and moderate-to-severe or severe secondary mitral regurgitation who remained symptomatic despite the use of maximal doses of guideline-directed medical therapy, transcatheter mitral-valve repair resulted in a lower rate of hospitalization for heart failure and lower all-cause mortality within 24 months of follow-up than medical therapy alone.

- The rate of freedom from device-related complications exceeded a prespecified safety threshold.

The NEW ENGLAND JOURNAL of MEDICINE

Original Article

Percutaneous Repair or Medical Treatment for Secondary Mitral Regurgitation

MITRA FR trial

N Engl J Med
Volume 379(24):2297-2306
December 13, 2018

The NEW ENGLAND JOURNAL of MEDICINE

Conclusions

- Among patients with severe secondary mitral regurgitation, the rate of death or unplanned hospitalization for heart failure at 1 year did not differ significantly between patients who underwent percutaneous mitral-valve repair in addition to receiving medical therapy and those who received medical therapy alone.

The NEW ENGLAND JOURNAL of MEDICINE

FDA NEWS RELEASE

FDA approves new indication for valve repair device to treat certain heart failure patients with mitral regurgitation

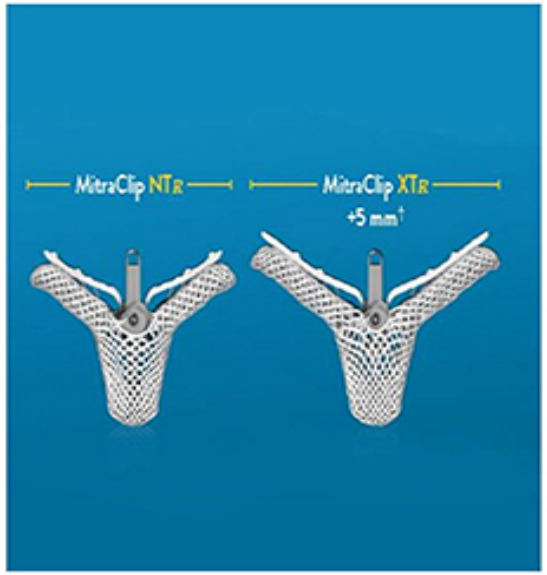
More Press Announcements

Press Announcements

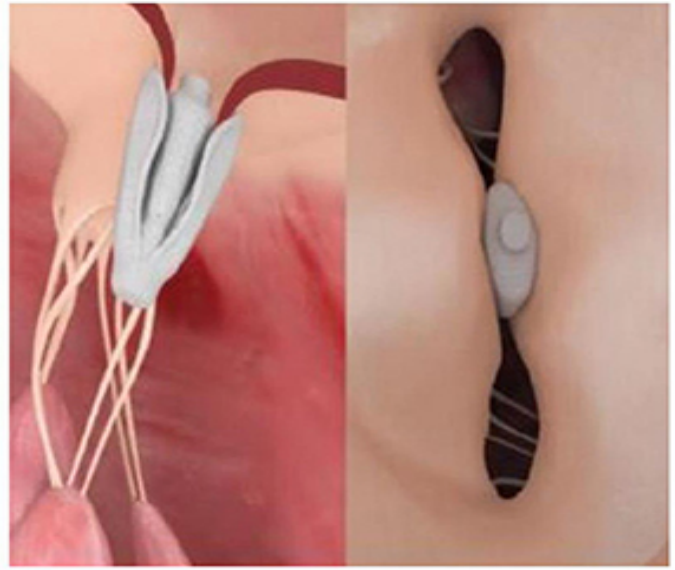
For Immediate Release: March 14, 2019

The U.S. Food and Drug Administration today approved a new indication for a heart valve repair device that is intended to reduce moderate-to-severe or severe mitral regurgitation, a leakage of blood backward through the mitral valve into the heart's left atrium that can cause heart failure symptoms such as shortness of breath, fatigue and swelling in the legs. When first approved in 2013, the MitraClip Clip Delivery System (MitraClip) was indicated

Edge-to-edge repair

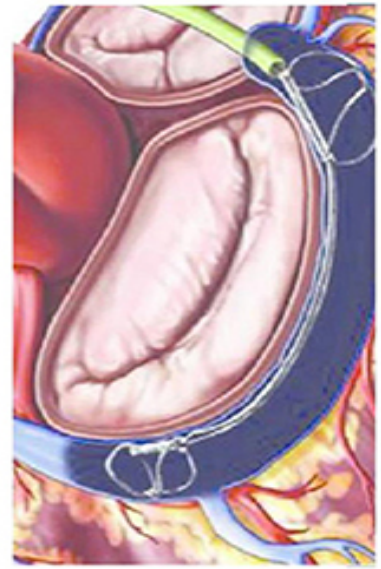


Newer generation MitraClip

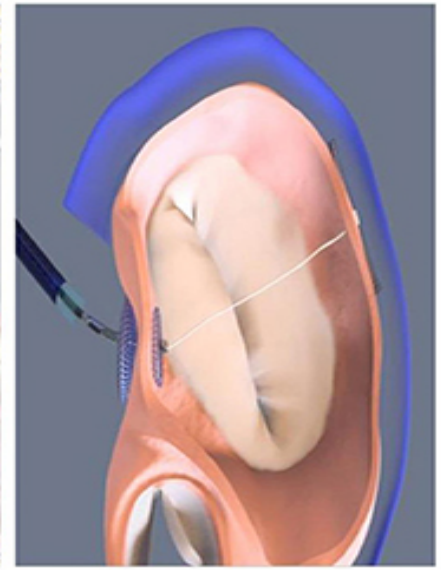


Pascal

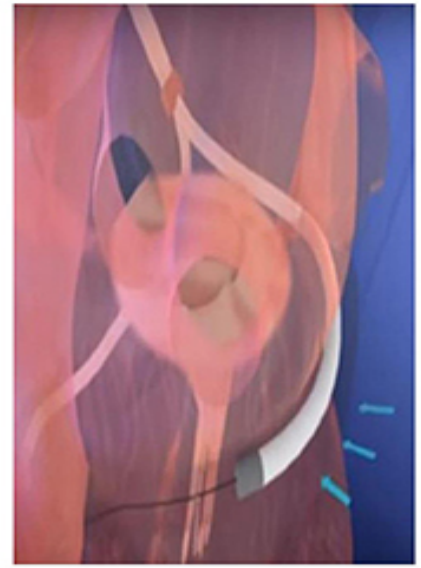
Indirect annuloplasty



Carillon

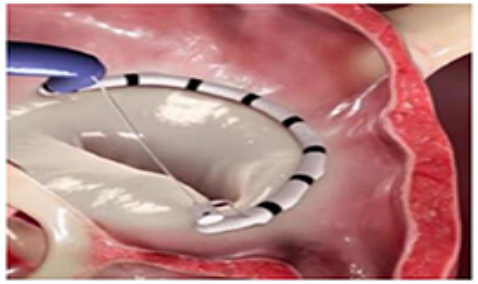


MVRx ARTO

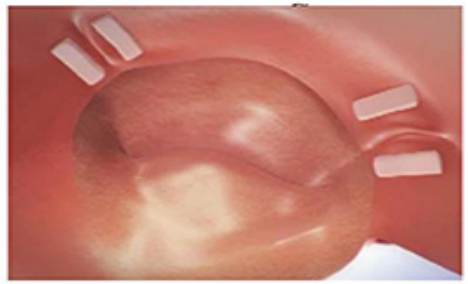


Mitral Loop Cerclage

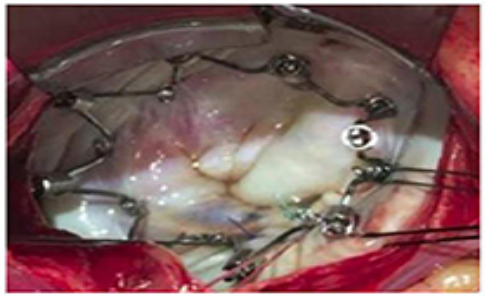
Direct annuloplasty



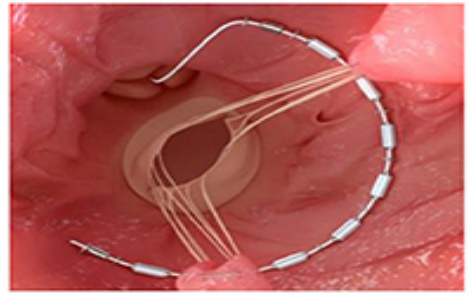
Cardioband



Mitralign

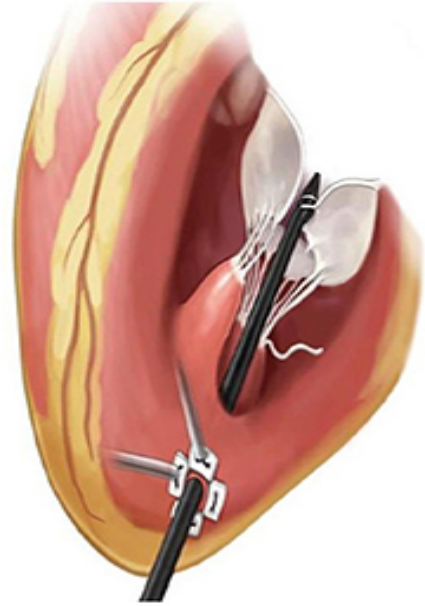


Millipede



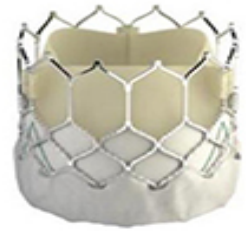
Accucinch

Chordal replacement



NeoChord

Transcatheter replacement



Sapien 3

Intrepid

CardiaQ

Tiara

Caisson

Summary: Mitral Regurgitation in 2019

- Primary MR : Surgery, repair when possible

- Secondary MR :

1. GDMT
2. CRT D (if indicated)
3. Revascularization (if needed)
4. Mitral Clip in selected patients

Thank you