NON SURGICAL TREATMENT OF CARDIAC DISEASE

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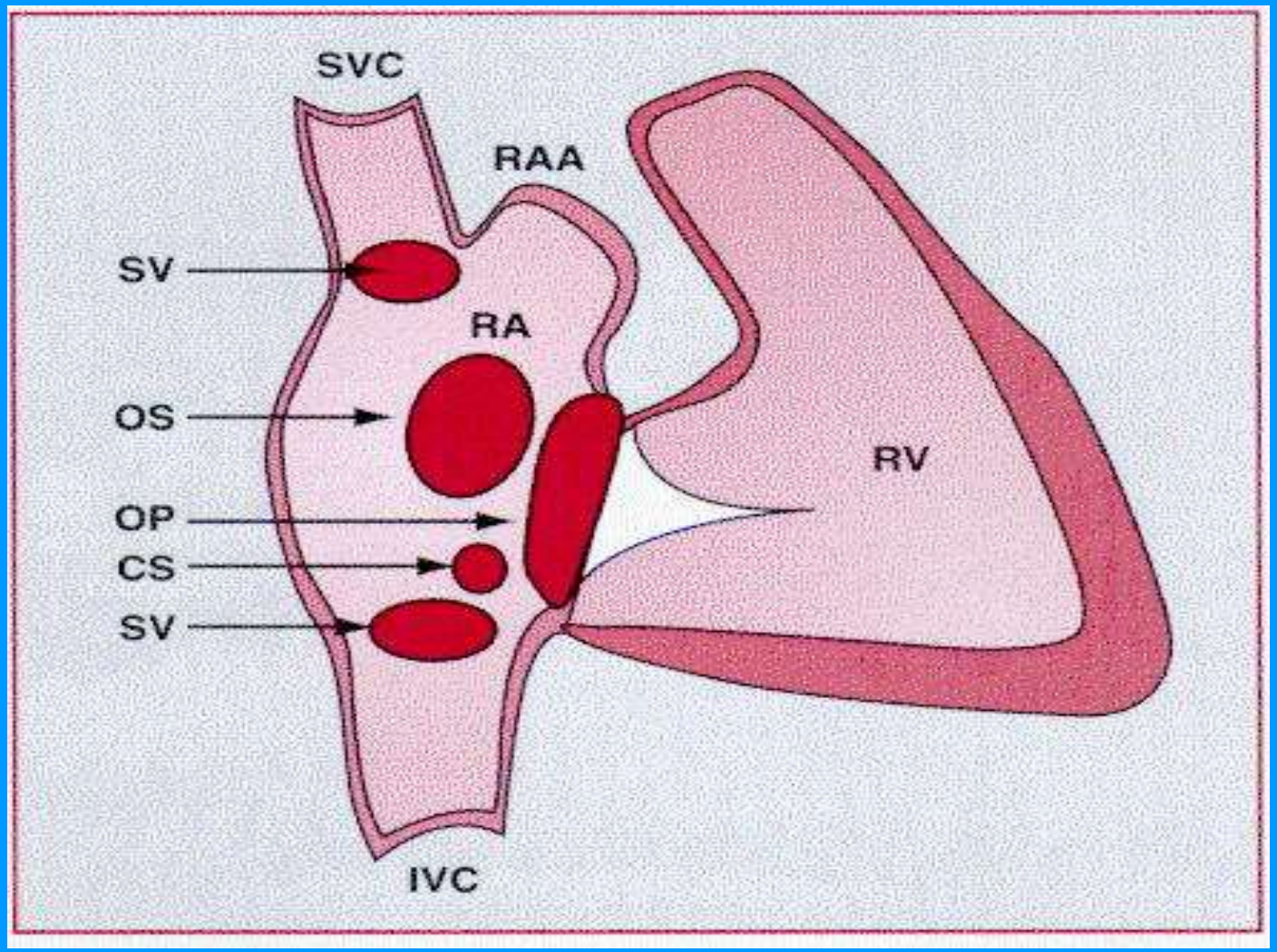
TOPICS

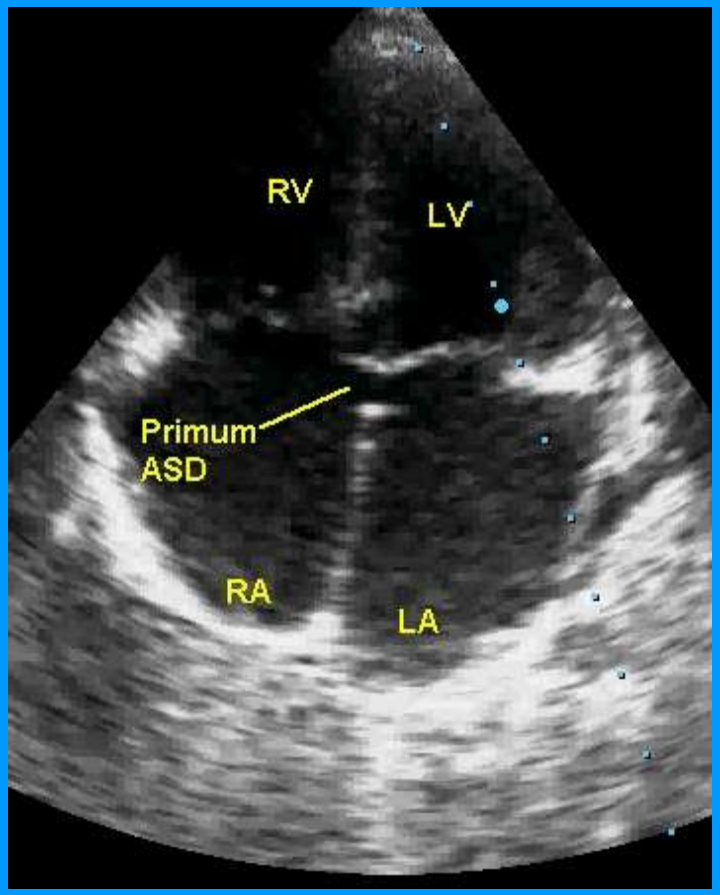
- ATRIAL SEPTAL DEFECT
- VSD
- IHSS
- PERCUTANEOUS AORTIC VALVE
- PERCUTANEOUS MITRAL VALVE
- LAA CLOSURE
- ABDOMINAL AORTIC ANEURYSM REPAIR

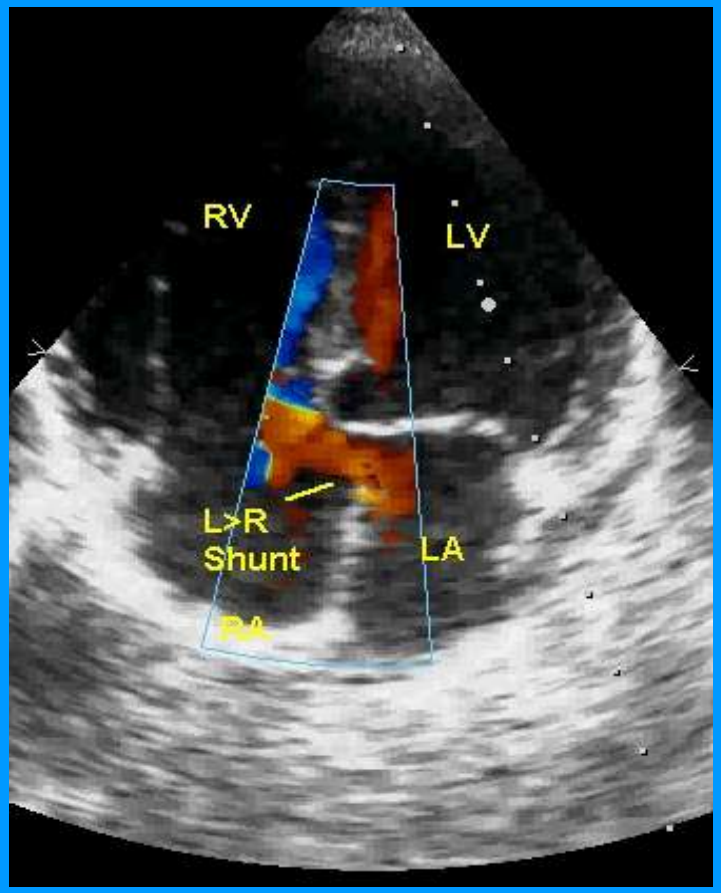
ATRIAL SEPTAL DEFECT

TYPES OF ASD

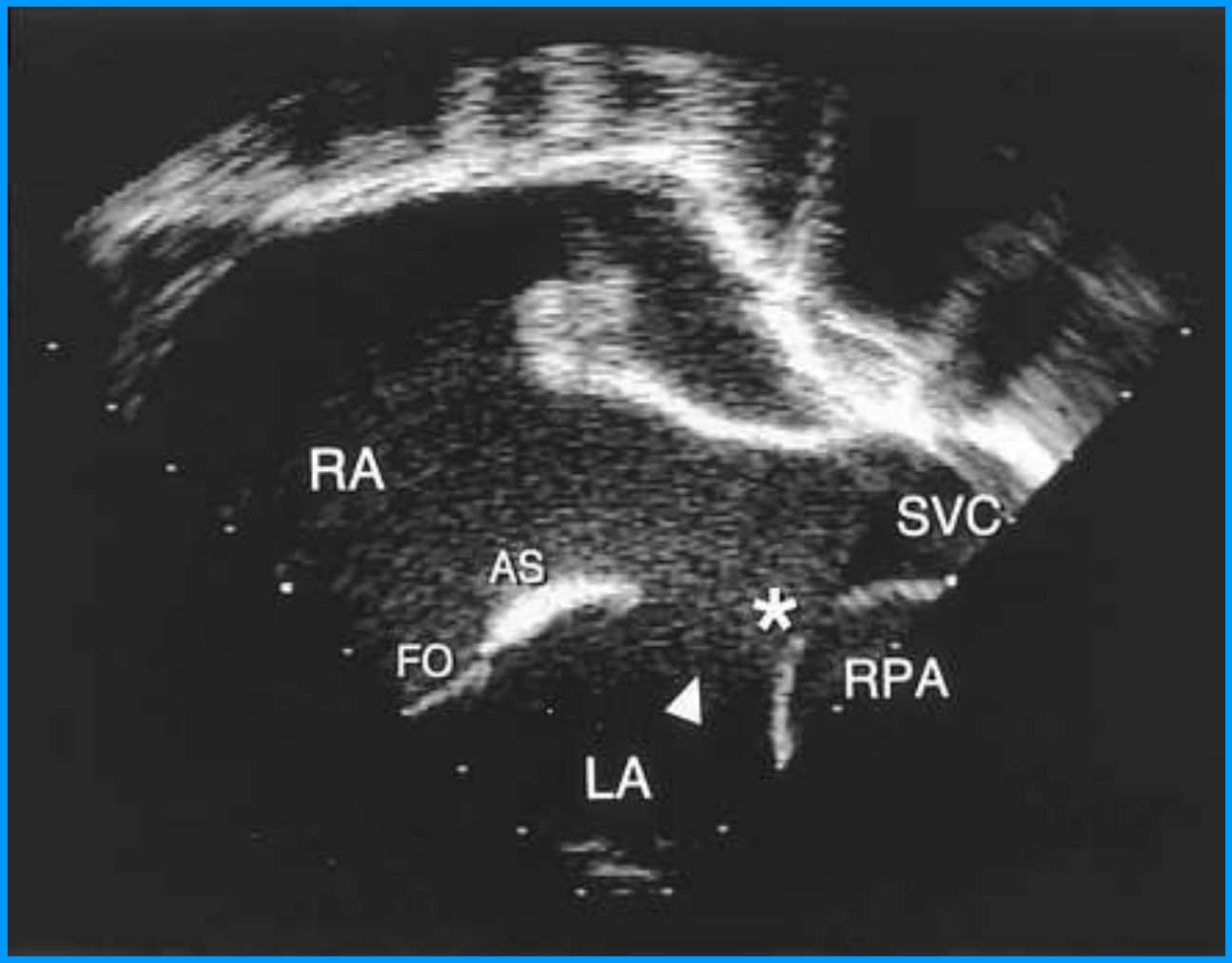


PRIMUM ATRIAL SEPTAL DEFECT

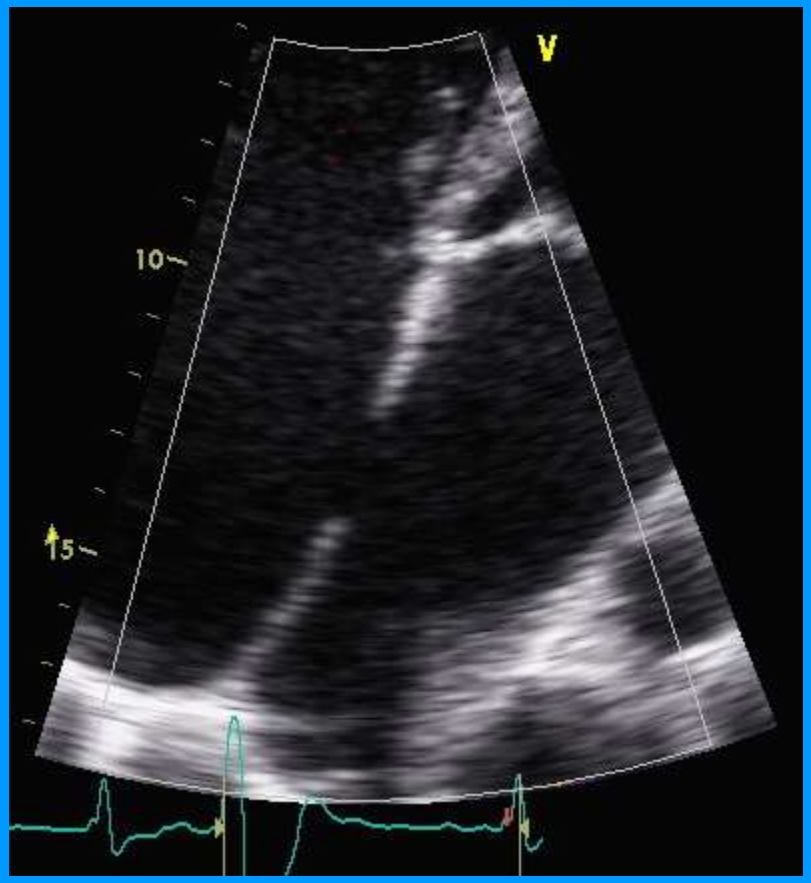


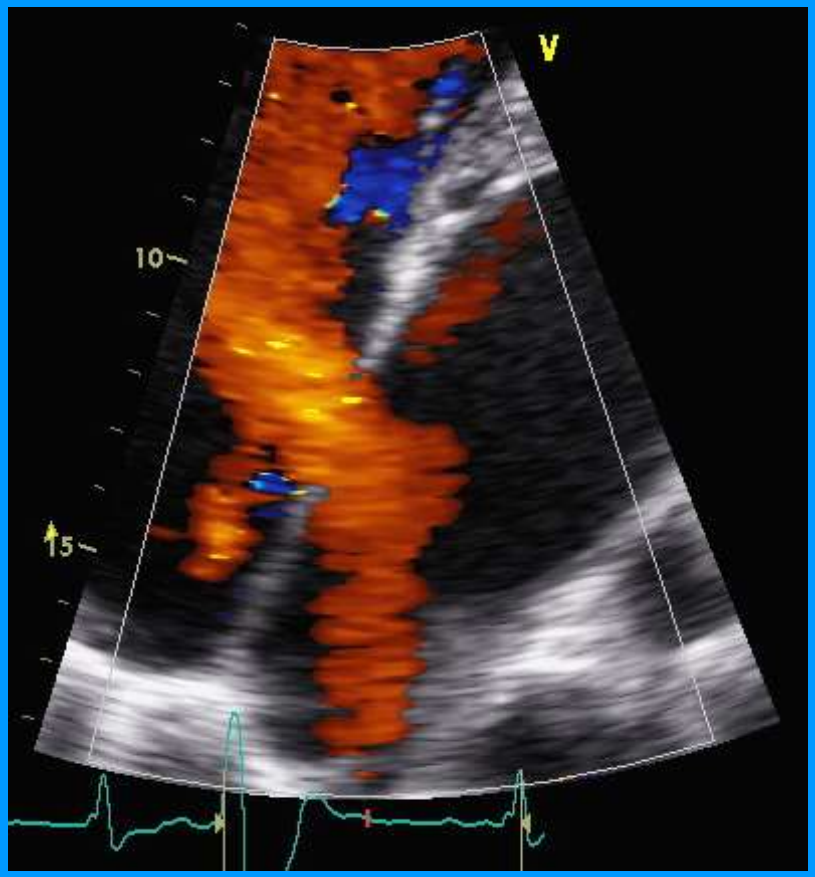


SINUS VENOSUS ASD

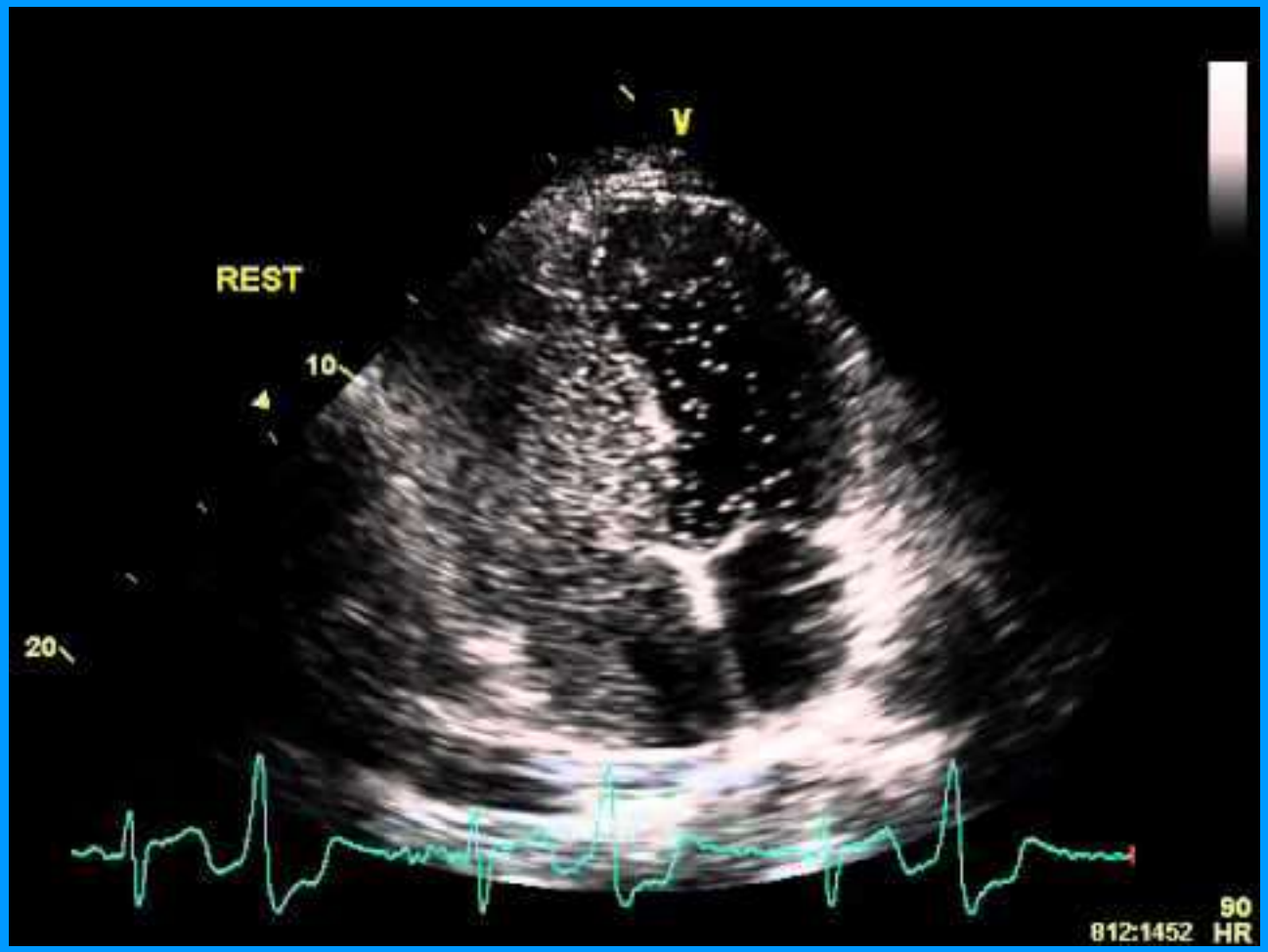


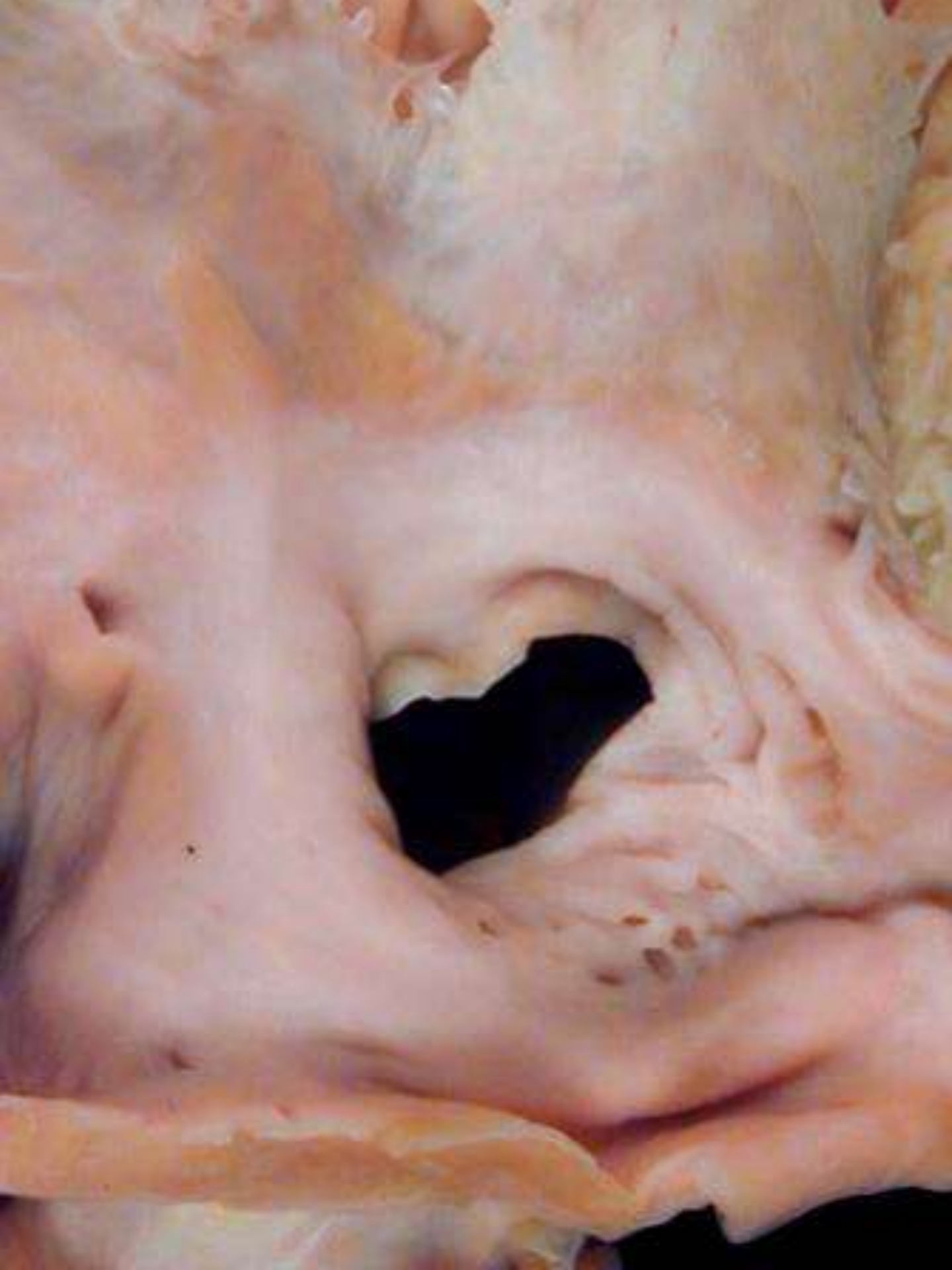
SECUNDUM ATRIAL SEPTAL DEFECT





ASD BUBBLE STUDY





INDICATIONS FOR CLOSURE

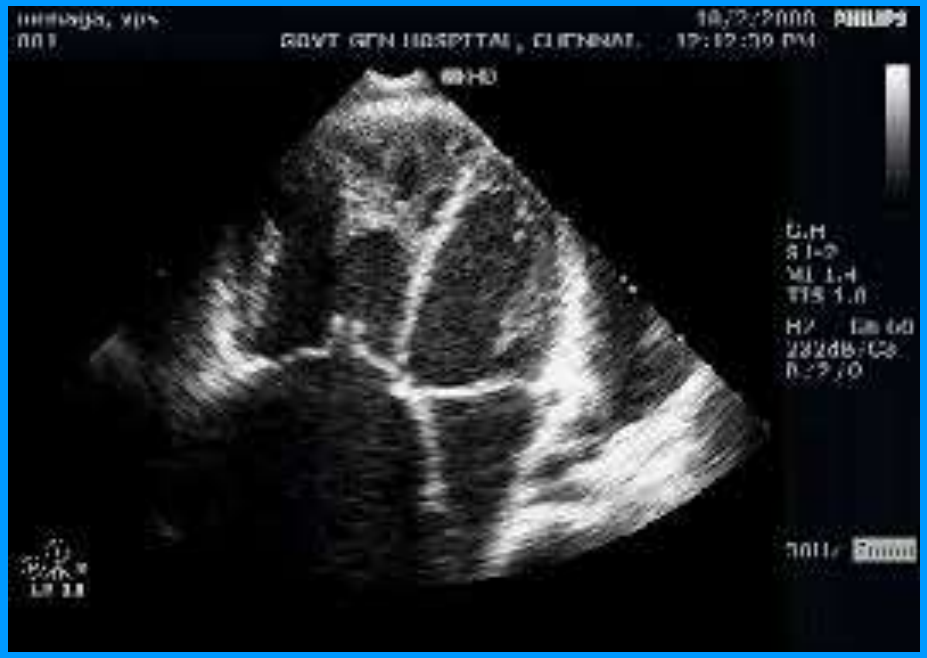
- **Class 1- Closure of an ASD either percutaneously or surgically is indicated for right atrial and RV enlargement with or without symptoms. (*LoE: B*)**

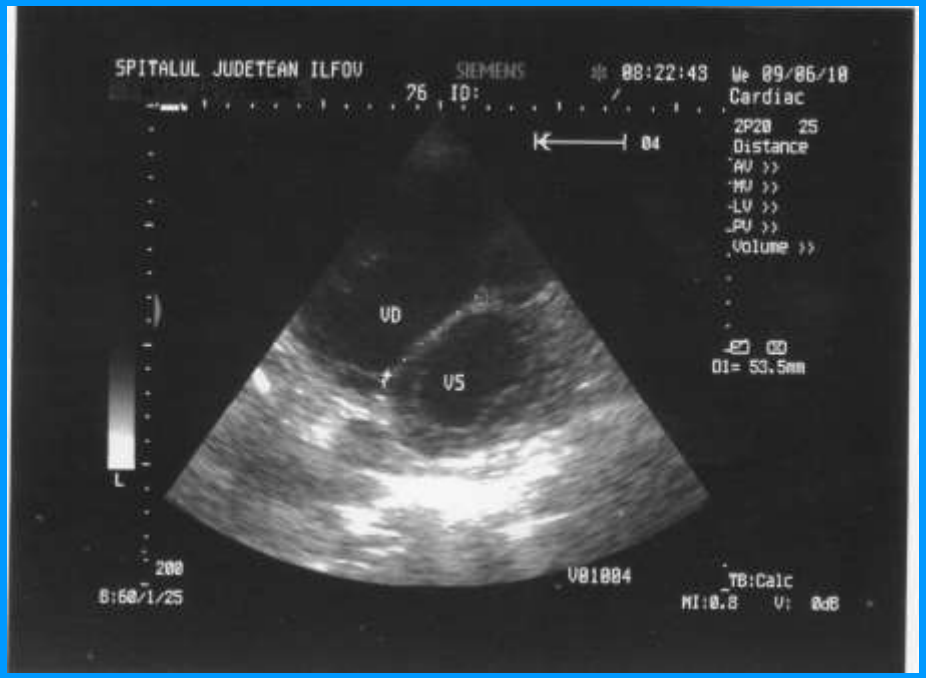
- **Class 2a-Closure of an ASD, either percutaneously or surgically, is reasonable in the presence of:**

  a. Paradoxical embolism. (*Level of Evidence: C*)
  b. Documented orthodeoxia-platypnea. (*LoE: B*)

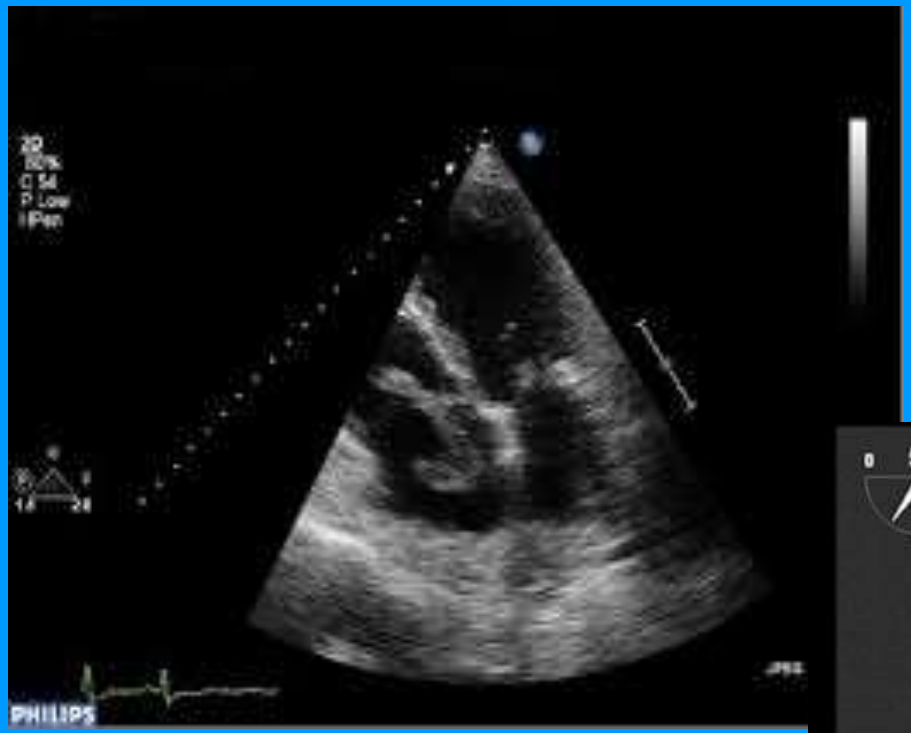
Class 3-Patients with severe irreversible PAH and no evidence of a left-to-right shunt should not undergo ASD closure.

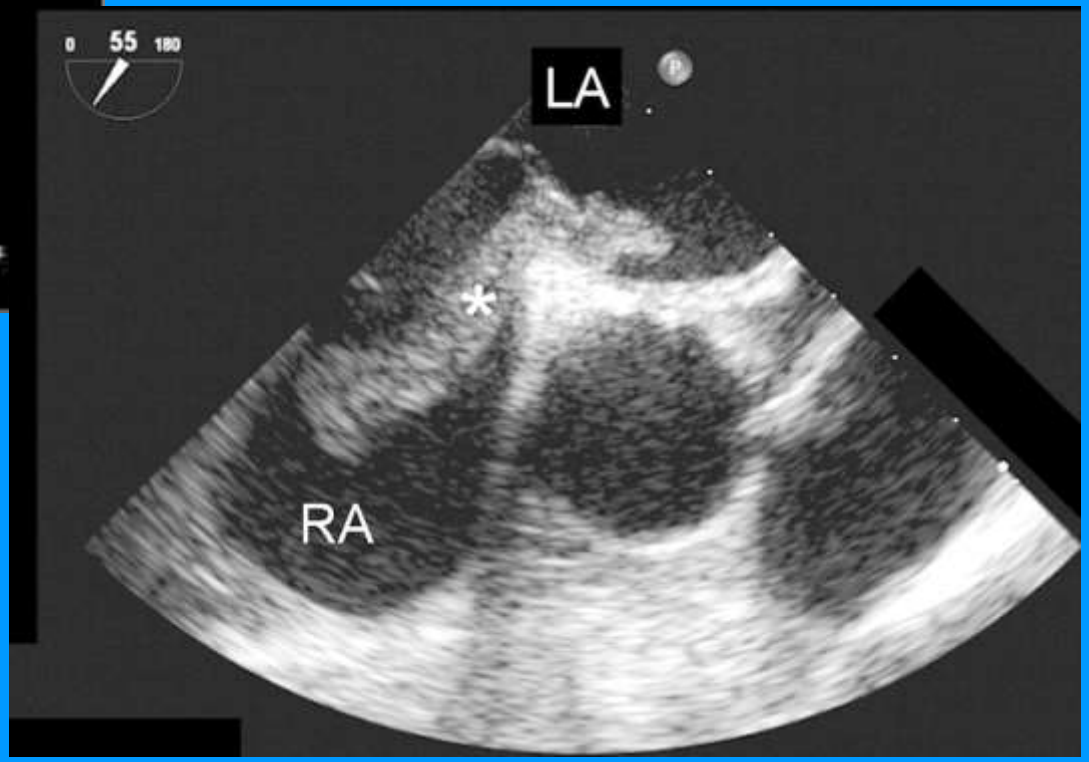
ASD with RVE and Flat IVS



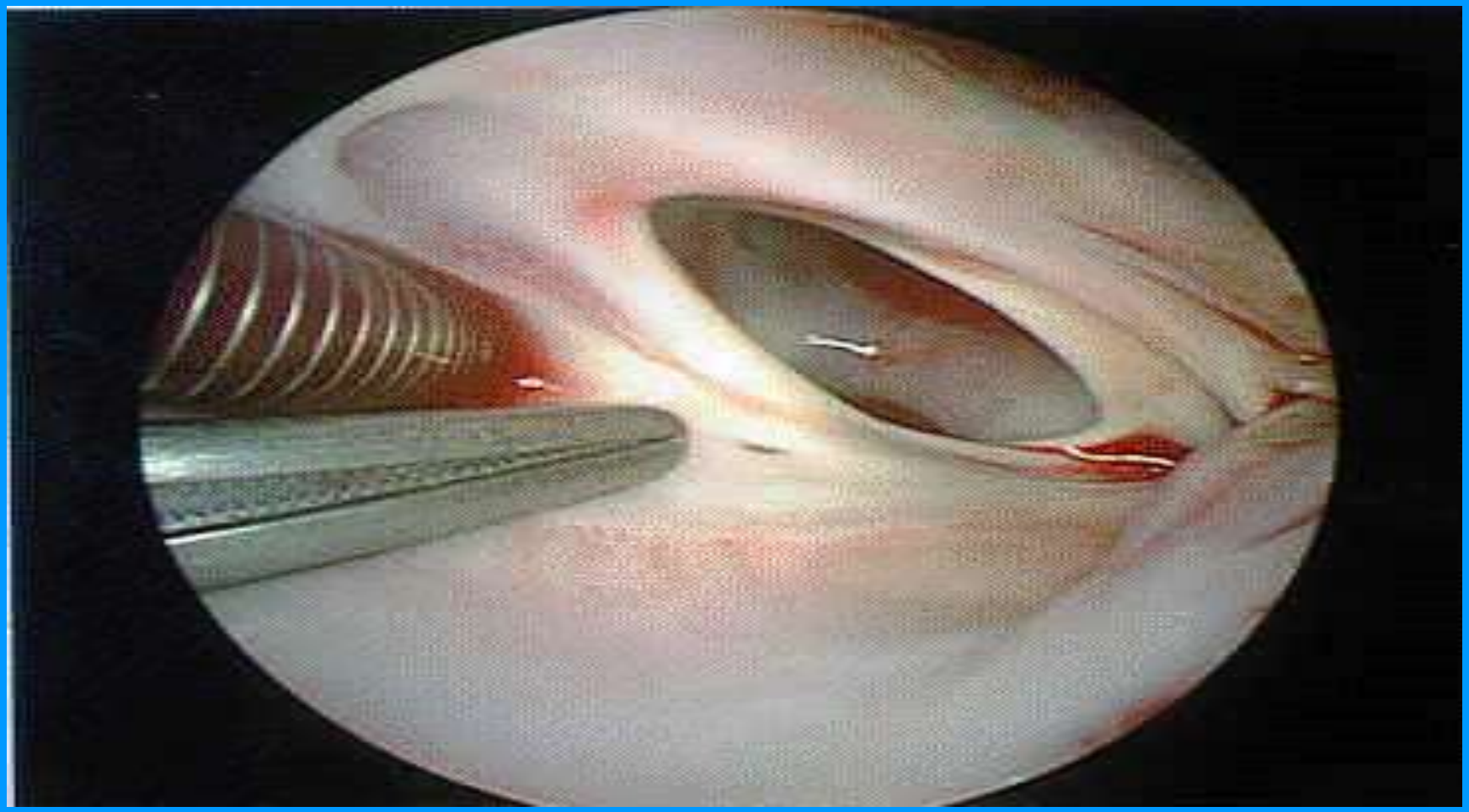


THROMBUS

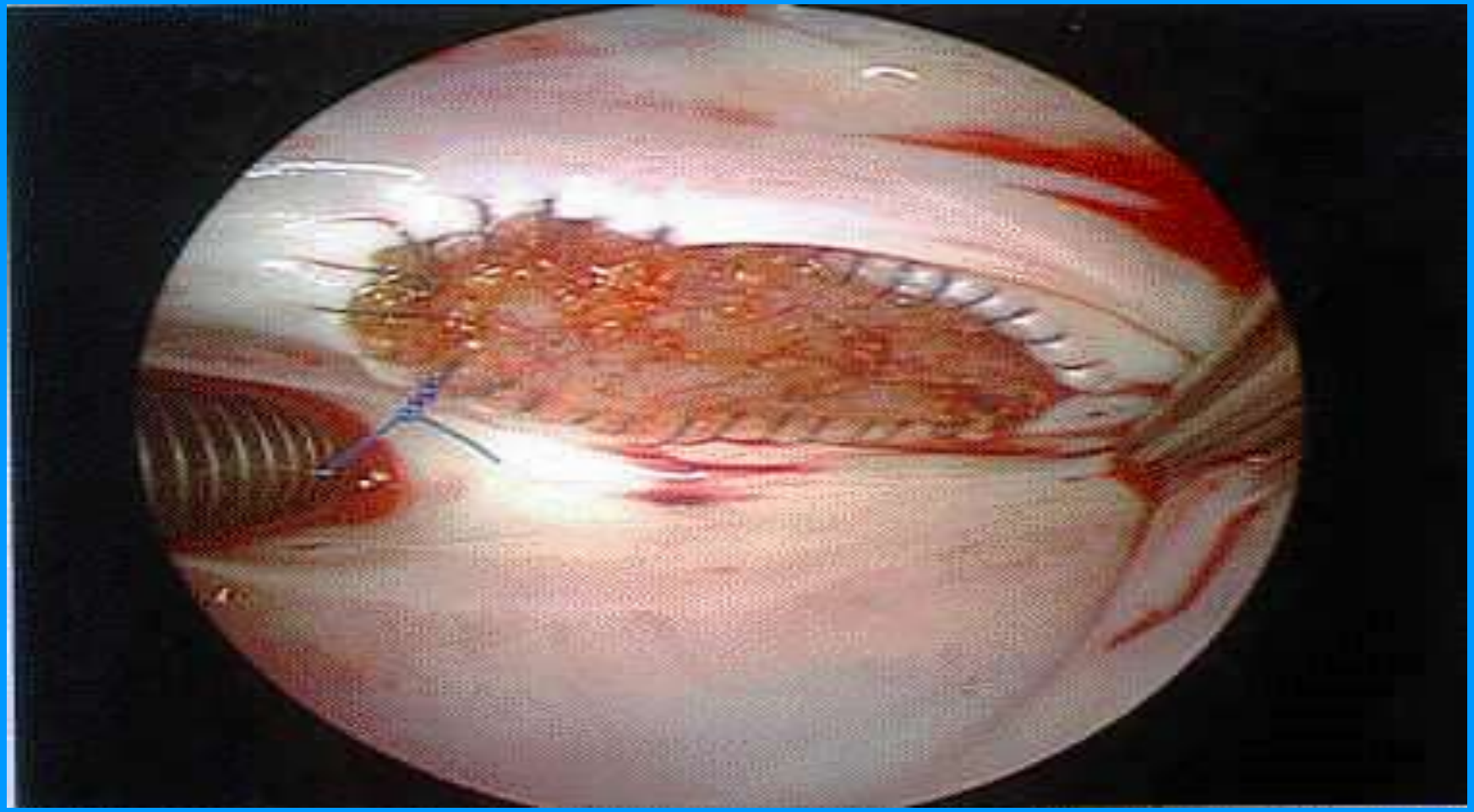




SURGICAL VIEW OF ASD

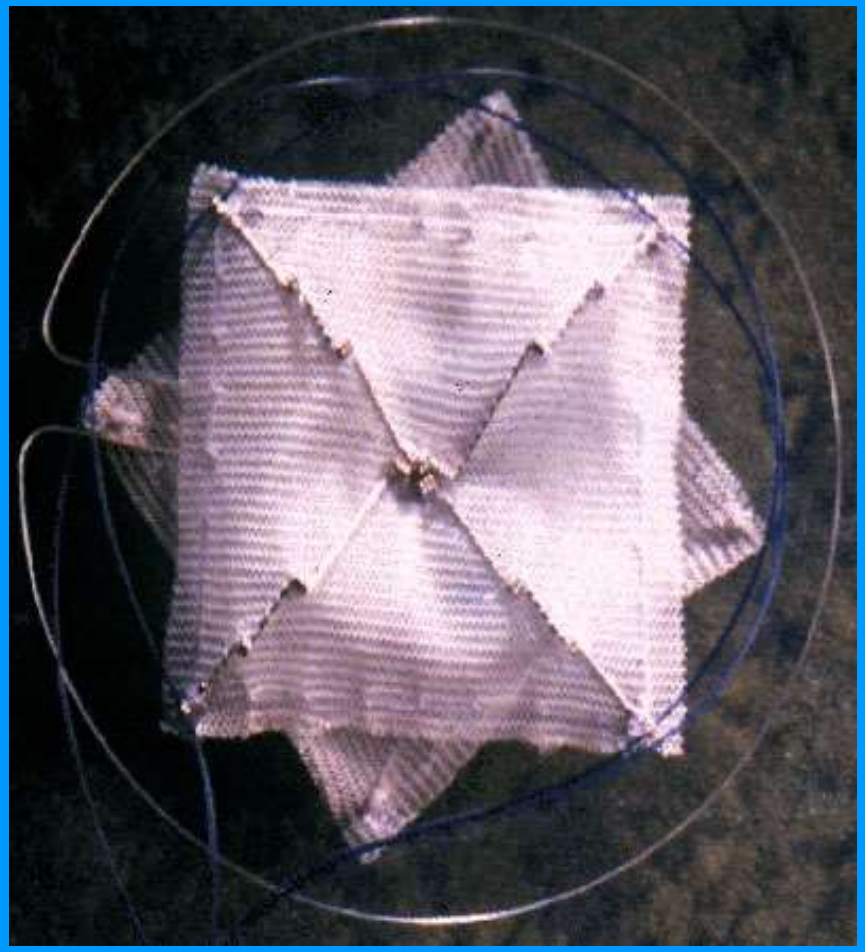


SURGICAL CLOSURE ASD



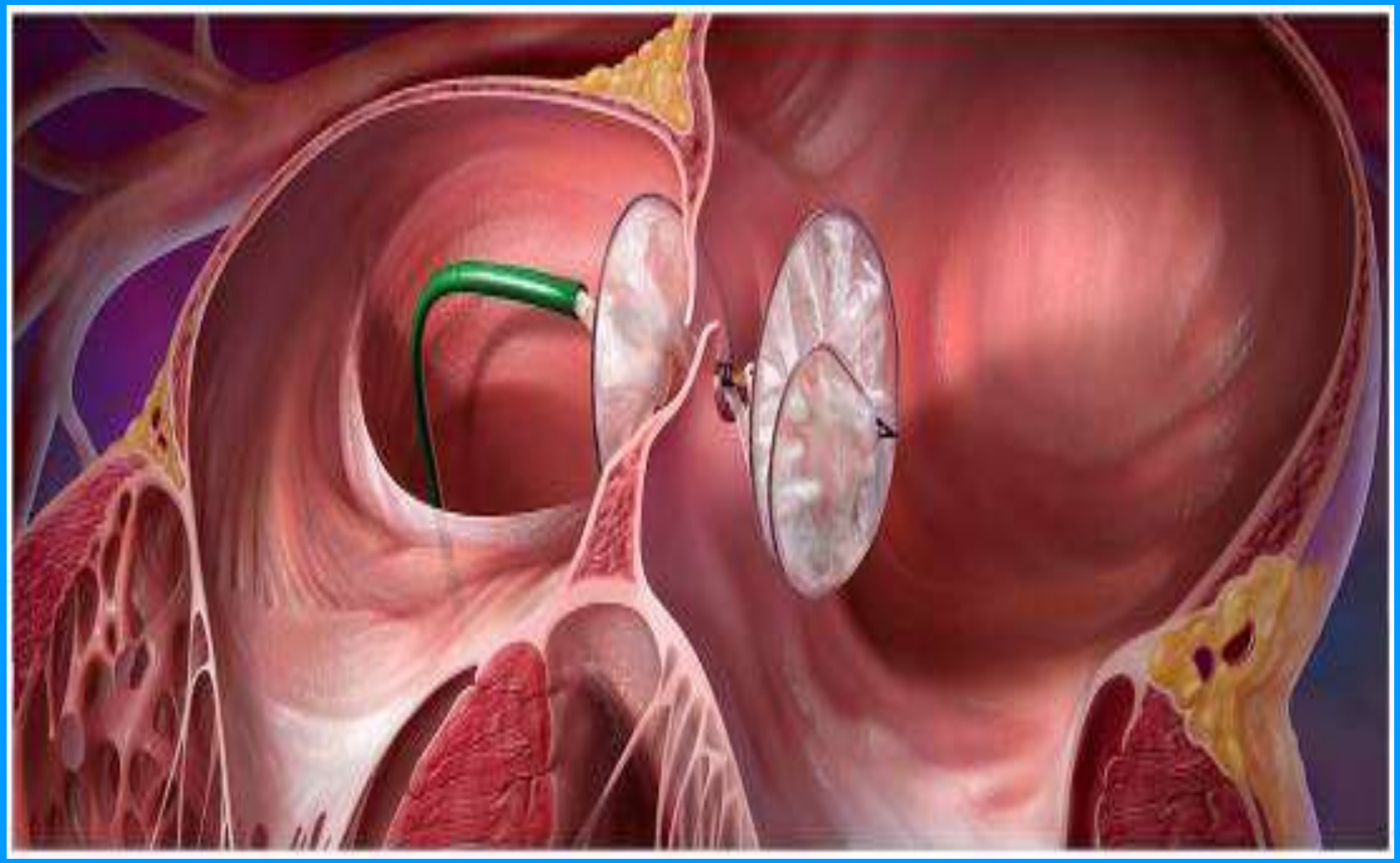
ASD DEVICES

Amplatzer® Septal Occluder
Licensed work is the sole property of AGA Medical

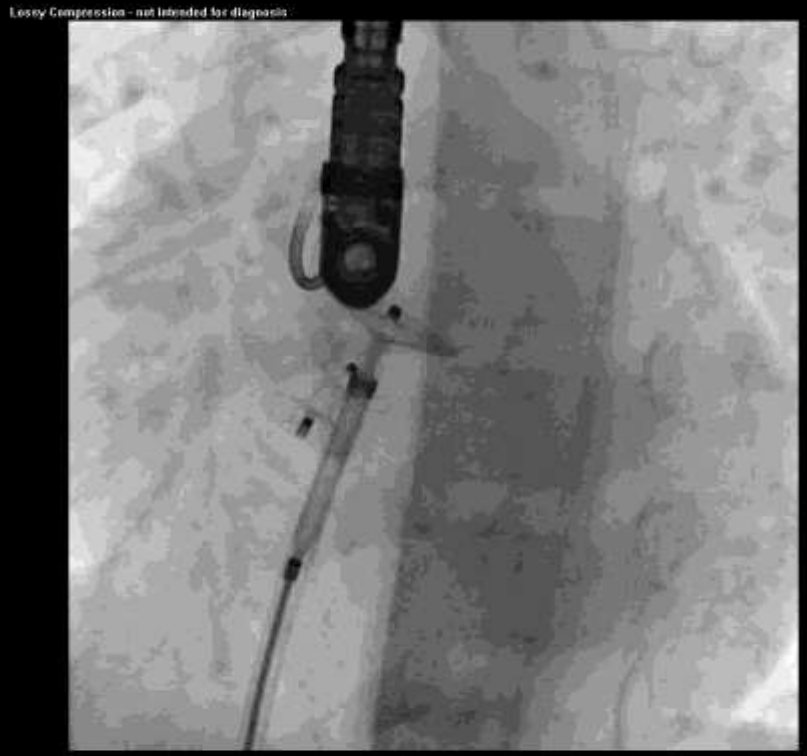


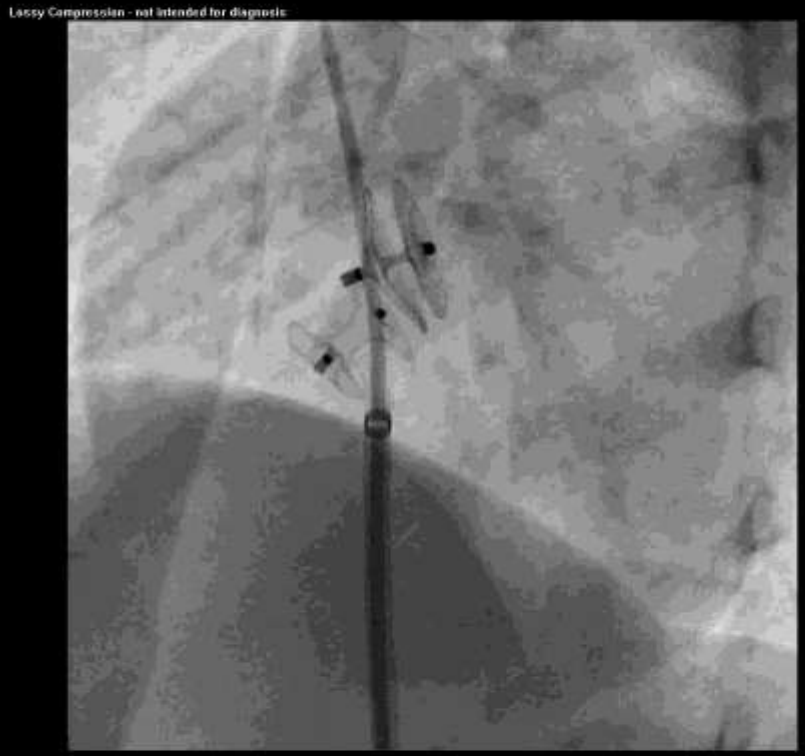
ASD CLOSURE DEVICES

ASD CLOSURE

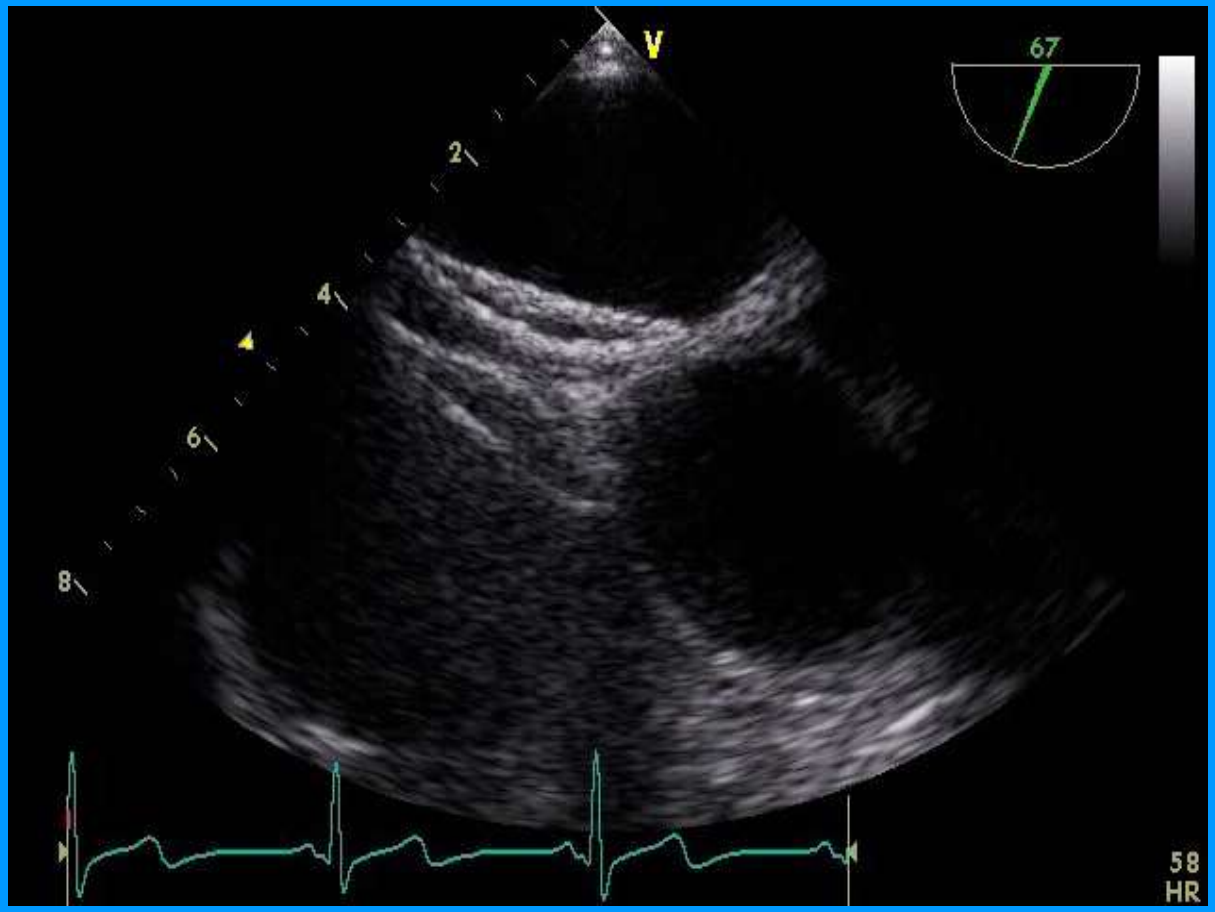


18mm Amplatzer Cribriform ASO

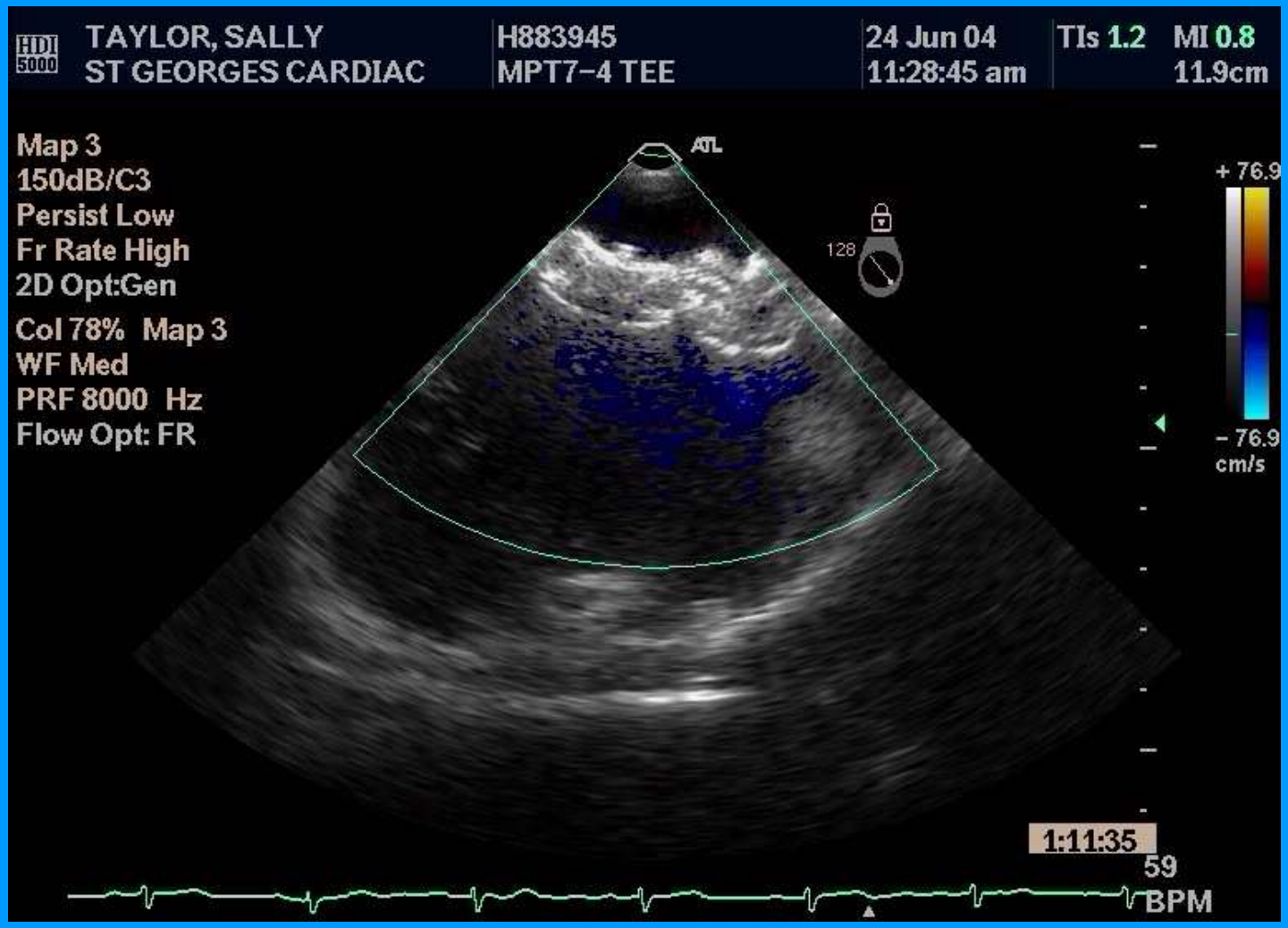




ECHO OF ASD CLOSURE



MULTIPLE ASD CLOSURE



ASD CLOSURE

- Preferential use for Ostium Secundum
- Out of 174 “intention to treat procedures”
  - 151 patients received a single device
  - 10 patients received > 1 device
  - 13 patients received no device (7.5%)
    - Defect > 40 mm : 5
    - Insufficient rim : 5
    - Three defects : 1
    - Multiple fenestrations : 1
    - Iliac vein access : 1

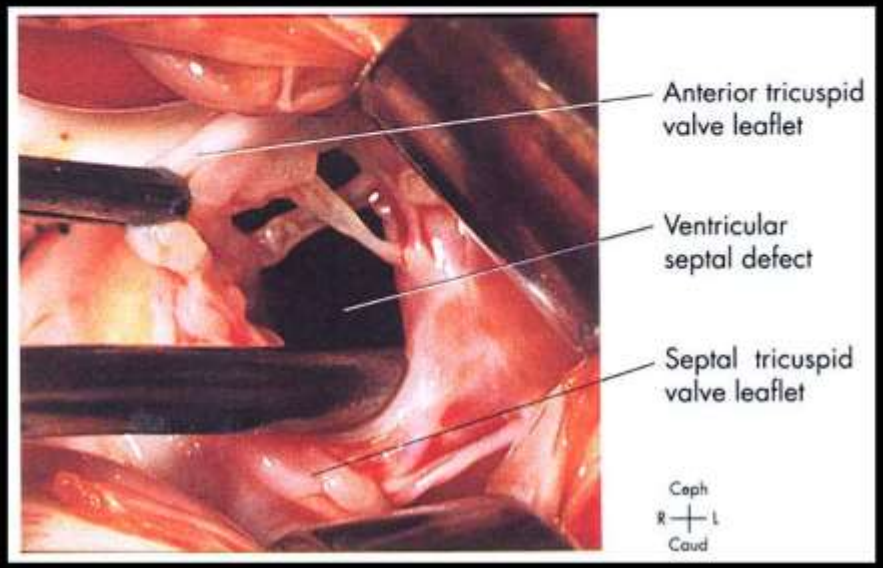
ASD ADVERSE EVENTS.

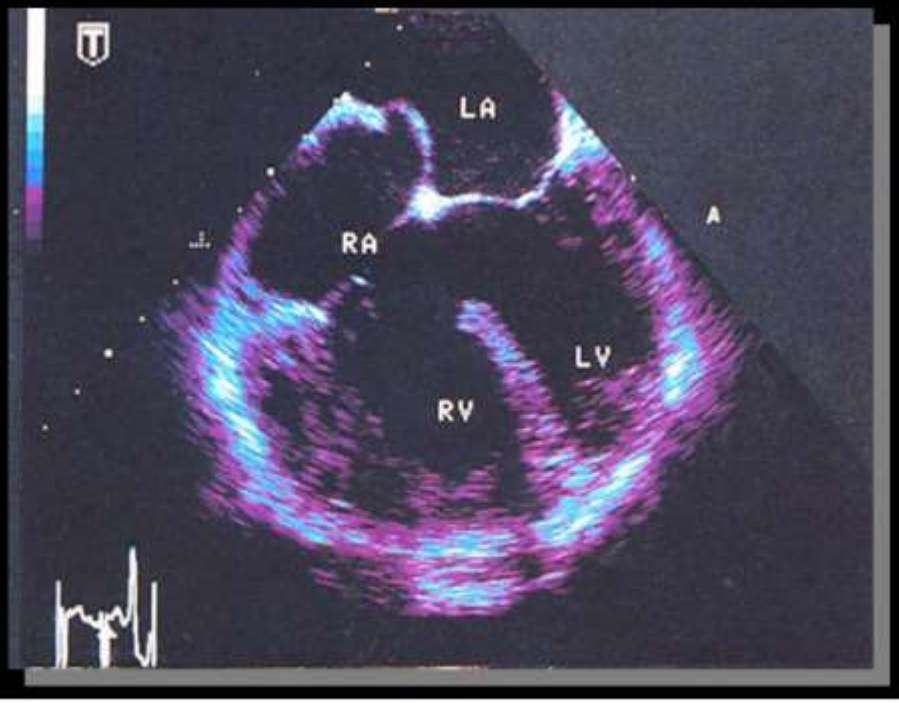
TABLE 1: ADVERSE EVENTS – PIVOTAL STUDY

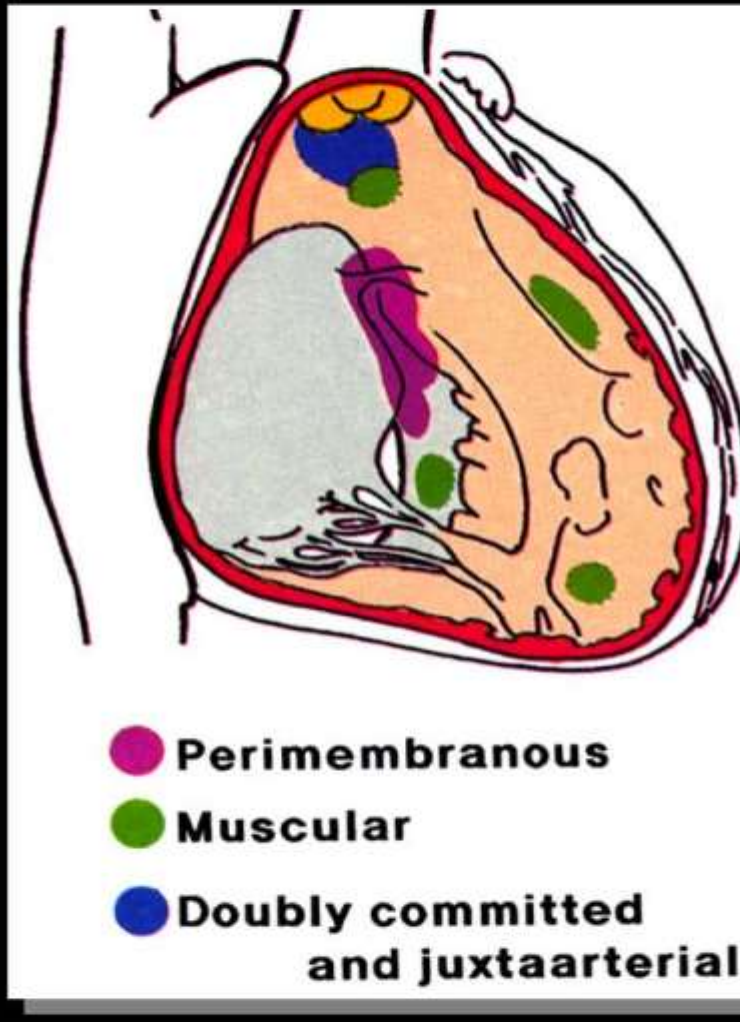
Major Adverse Events	AMPLATZER Patients	Surgical Control Patients	p-value
Cardiac Arrhythmia requiring major treatment	2/442 (0.5%)	0/154 (0.0%)	1.00
Device Embolization with surgical removal	3/442 (0.7%)	0/154 (0.0%)	0.57
Device Embolization with percutaneous removal	1/442 (0.2%)	0/154 (0.0%)	1.00
Delivery System Failure	1/442 (0.2%)	0/154 (0.0%)	1.00
Pericardial Effusion with tamponade	0/442 (0.0%)	3/154 (1.9%)	0.017
Pulmonary Edema	0/442 (0.0%)	1/154 (0.6%)	0.26
Repeat Surgery	0/442 (0.0%)	2/154 (1.3%)	0.066
Surgical Wound Adverse Events	0/442 (0.0%)	2/154 (1.3%)	0.066
Total Major Adverse Events Patients	**7/442 (1.6%)**	**8/154 (5.2%)**	**0.030**

VENTRICULAR SEPTAL DEFECT CLOSURE

Large perimembranous inlet VSD – no role for a device







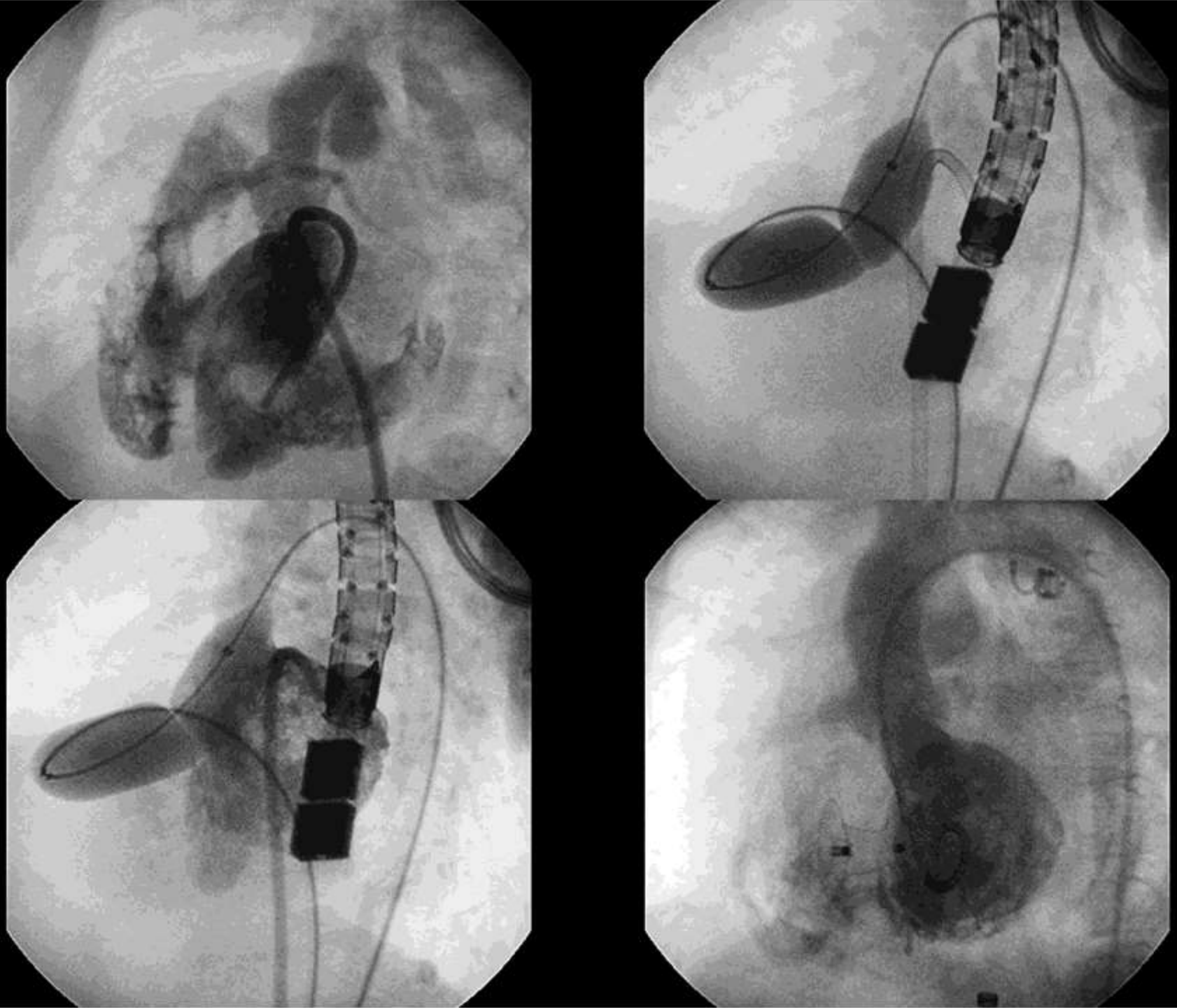
Patient Selection for Device Closure of VSD

- Hemodynamically significant
- Qp/Qs >1.5
- LA or LV enlargement
- Cardiomegaly on CXR
- Failure to thrive because of VSD
- Aortic valve rim 4 mm or more
- AV valve rim 4 mm or more

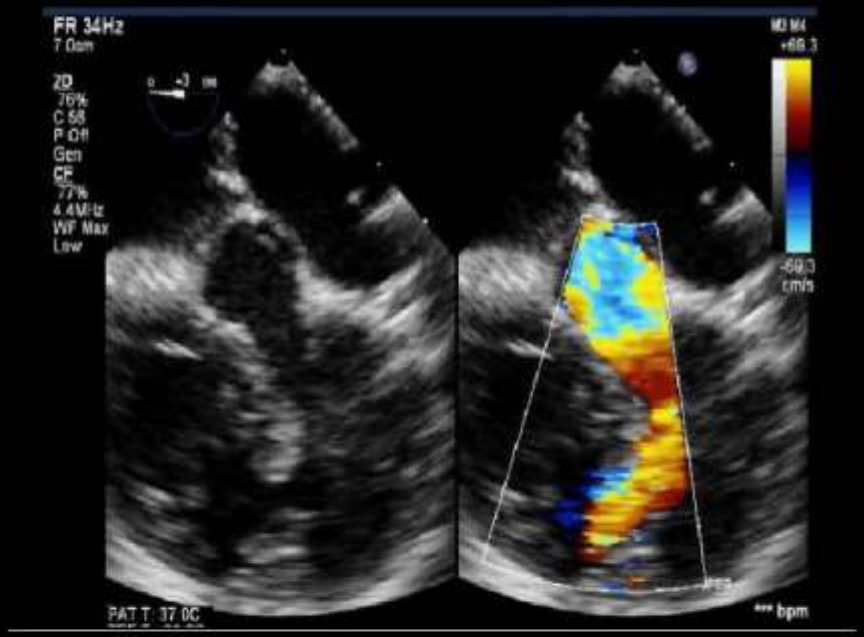
Different Amplatzer VSD Devices

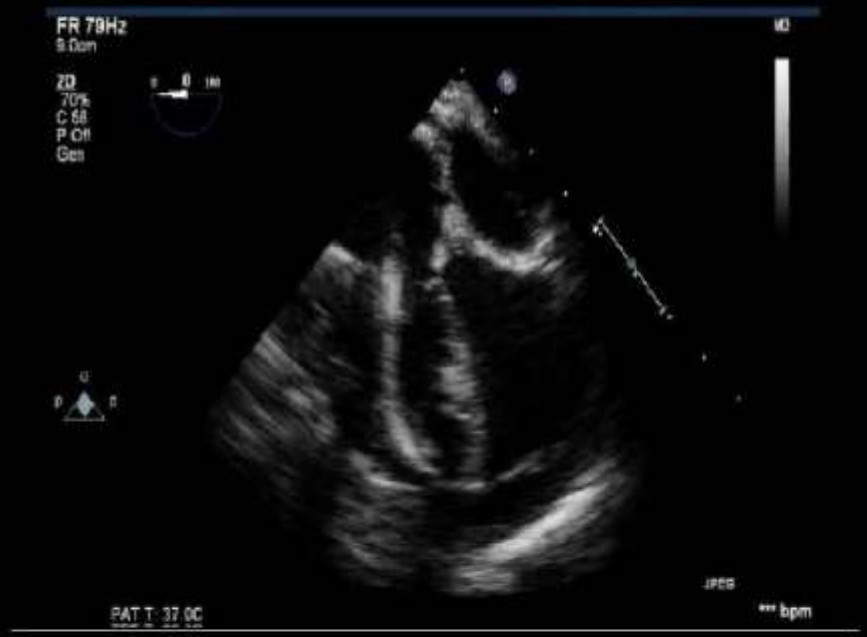
- **Muscular VSDs** being closed routinely by catheter techniques
- 4-18 mm sizes, waist 7 mm, discs = waist+8 mm
- Waist should be 1 – 3mm larger than VSD

Recent trend towards catheter closure of **Perimembranous VSDs**



TEE Guidance for Apical VSD





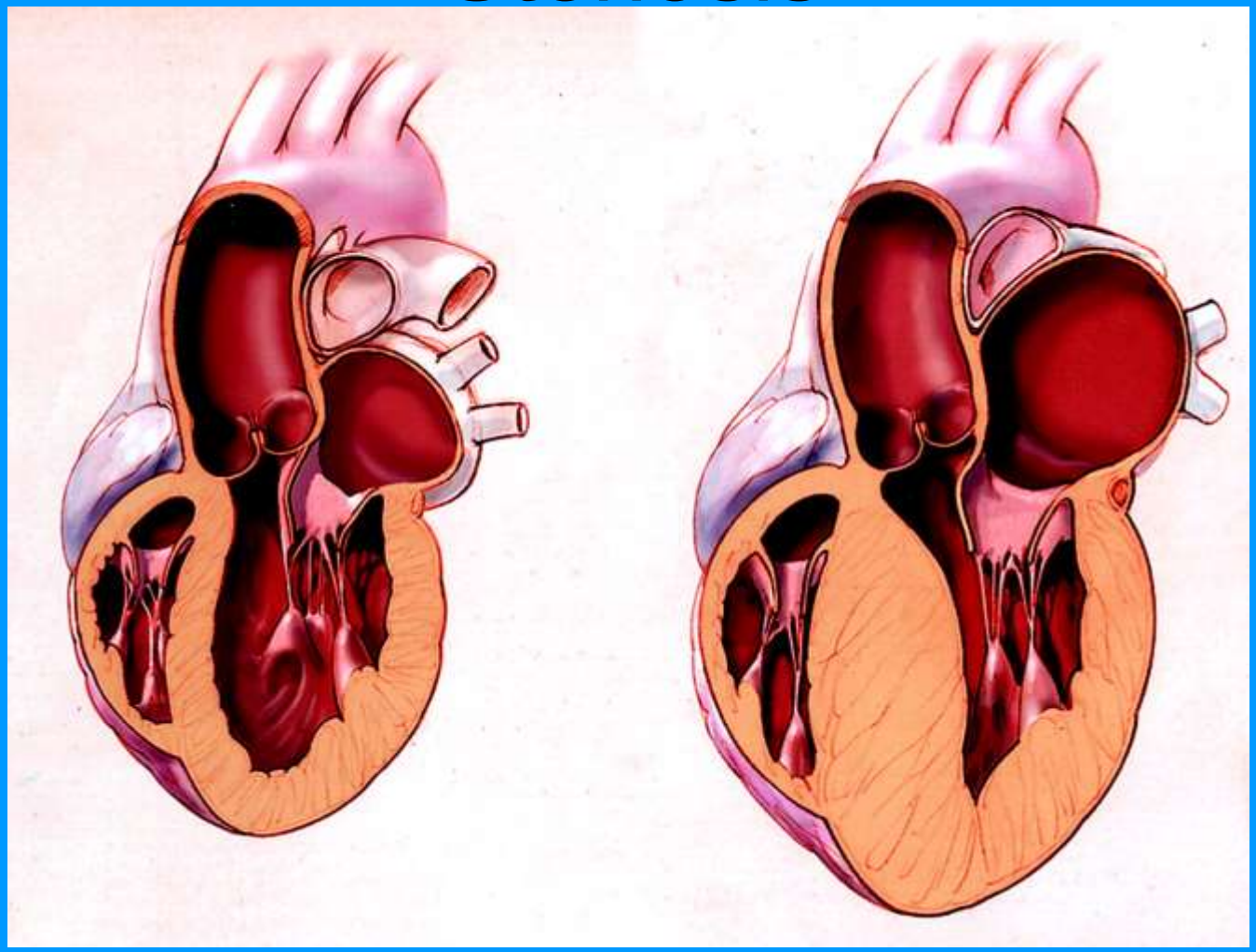
Muscular VSD
N=80

Technical Failure	
Unable to cross the defect	1
Defect too big	2
Patient developed hypotension & bradycardia	1
Device embolized to LV-surgical removal	1
Catheter dislodgment, blood loss, death	1
Cardiac perforation, death	1

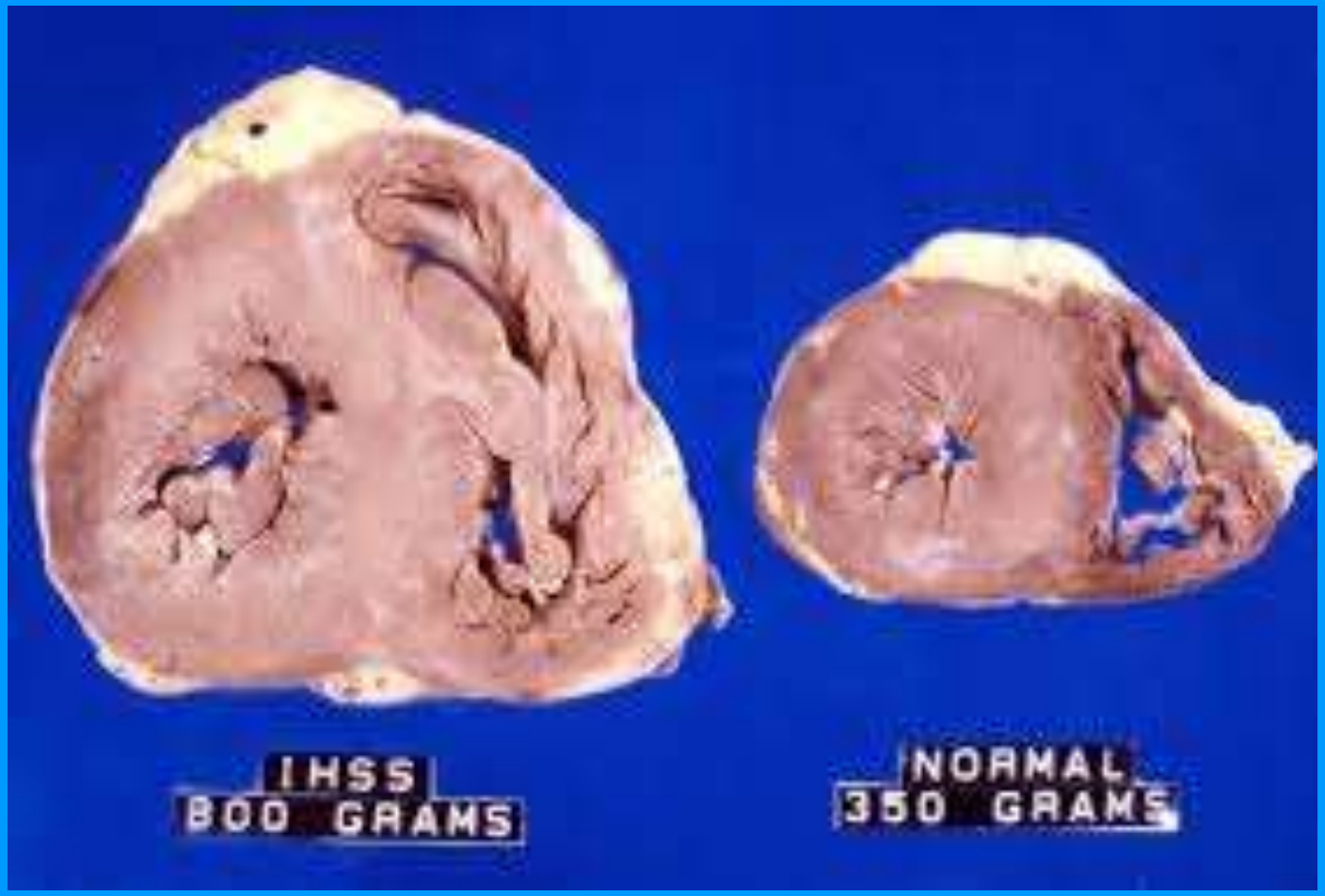
***Most SAE related to size of patient < 5.2Kg

IHSS

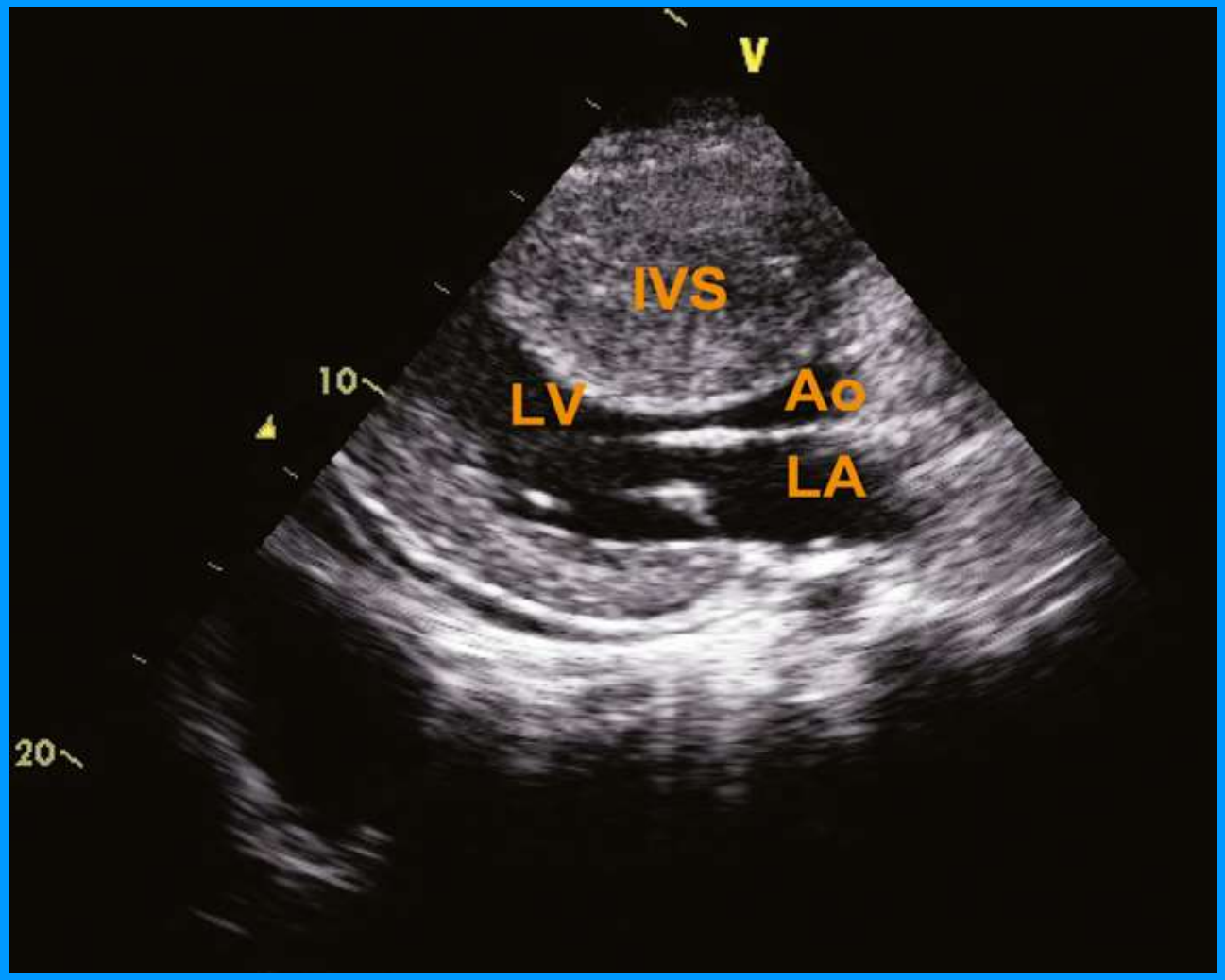
IHSS
Idiopathic Hypertrophic Subaortic Stenosis



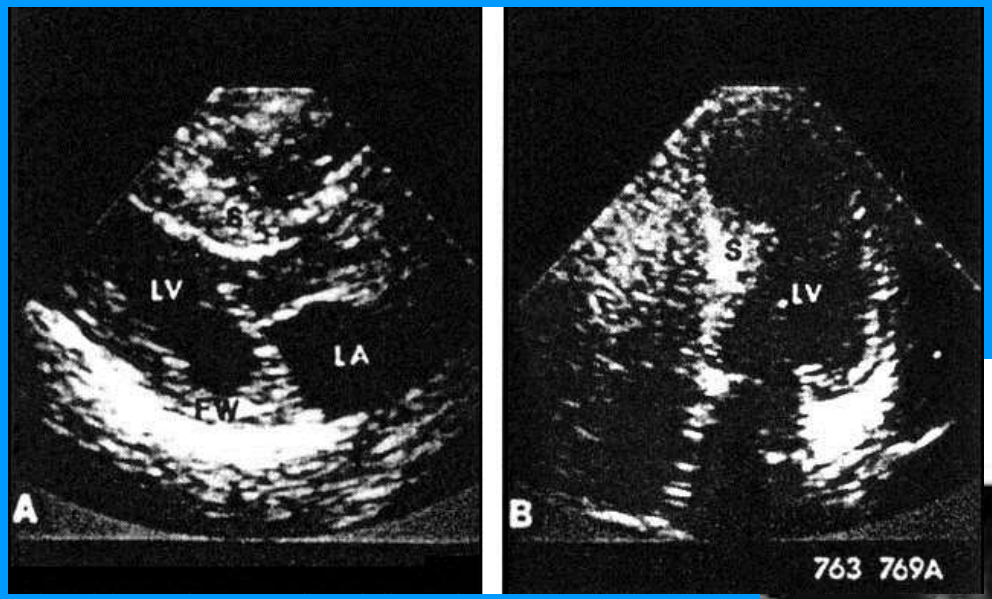
IHSS Pathology

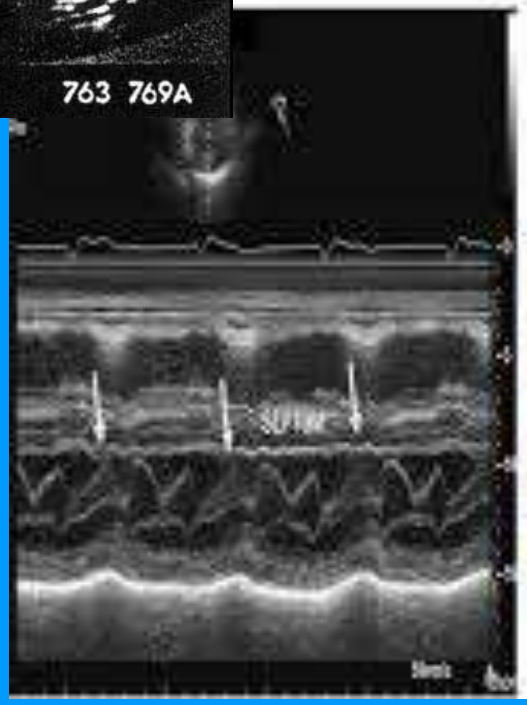


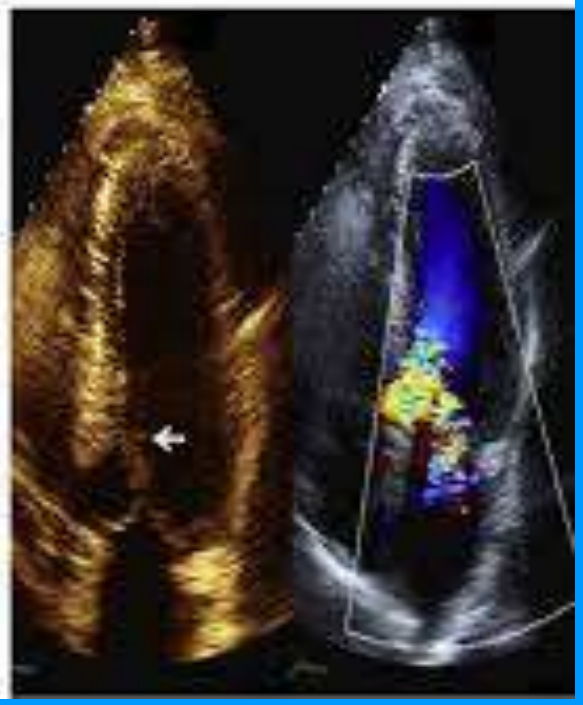
IHSS



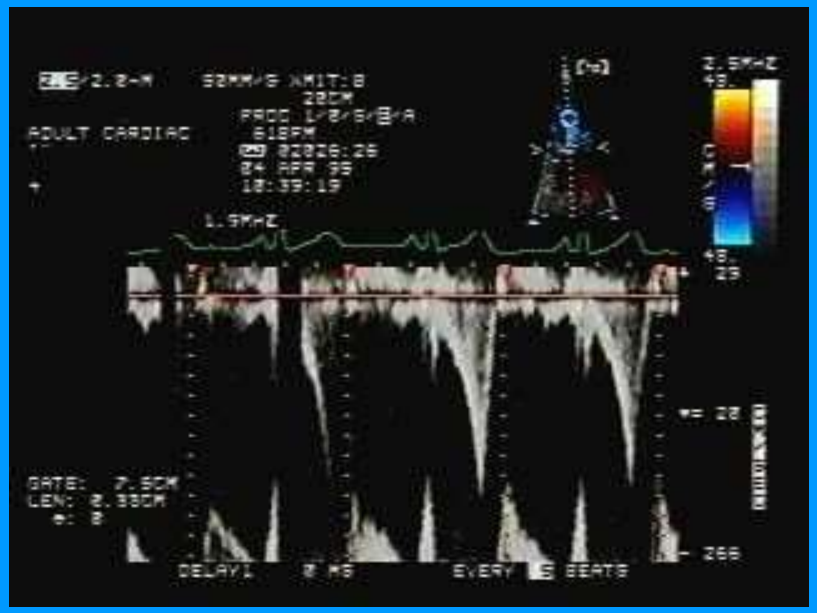
IHSS - SAM

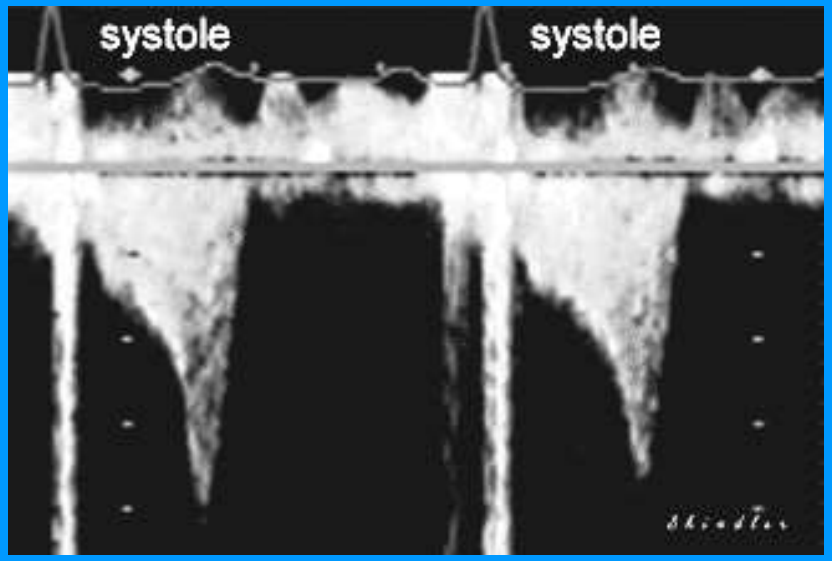


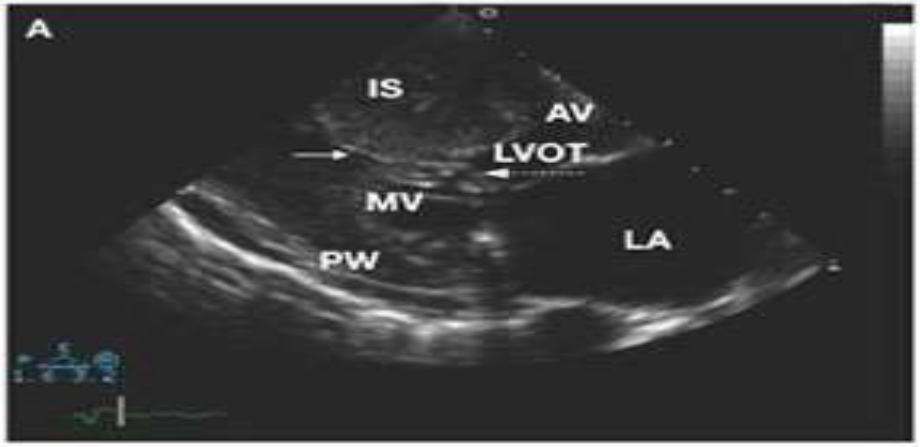


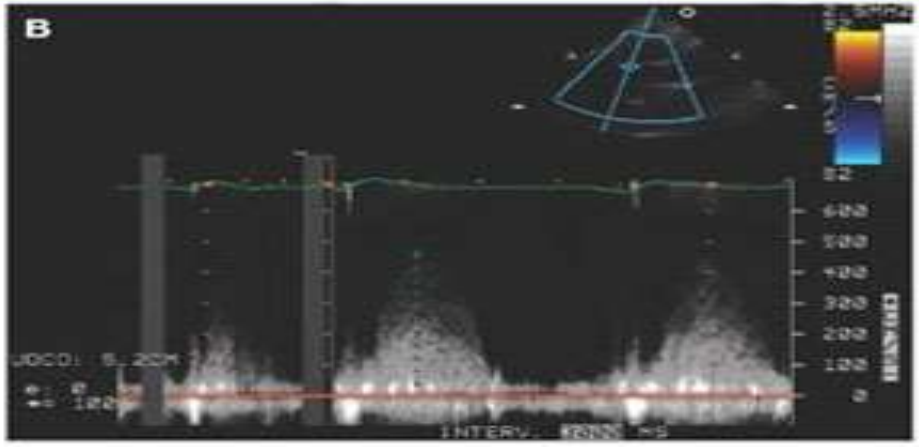


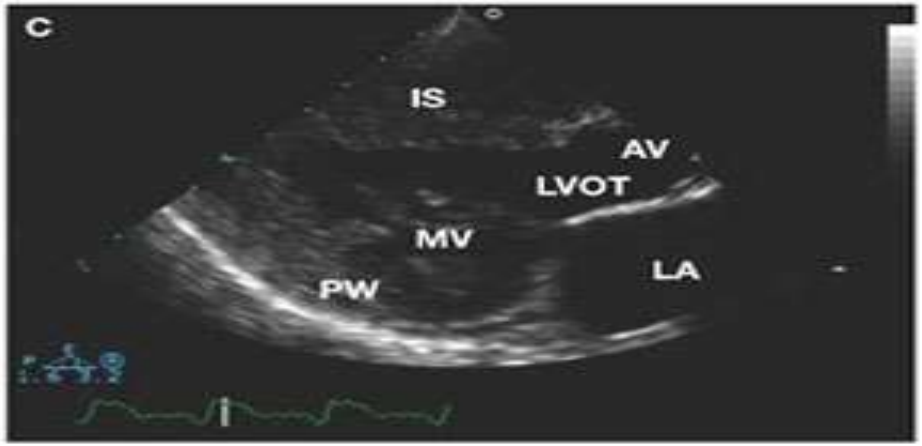
LVOT GRADIENT

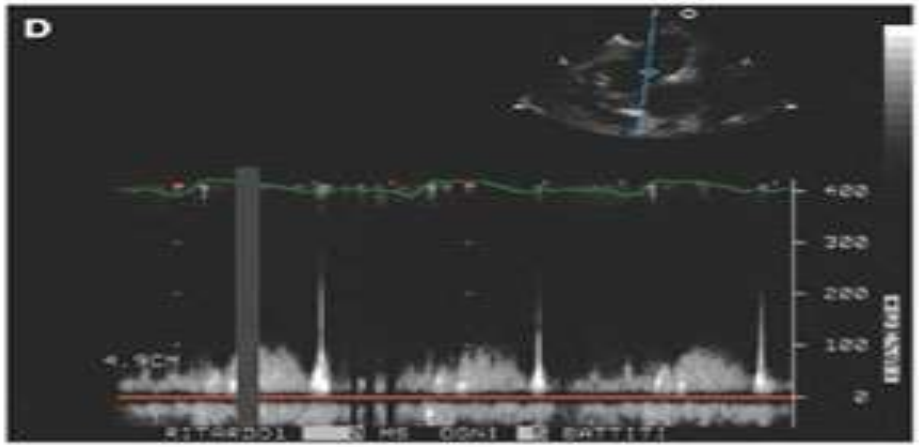


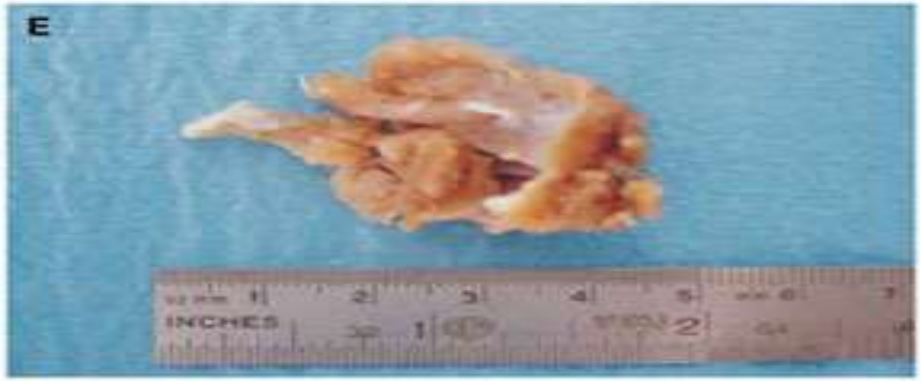






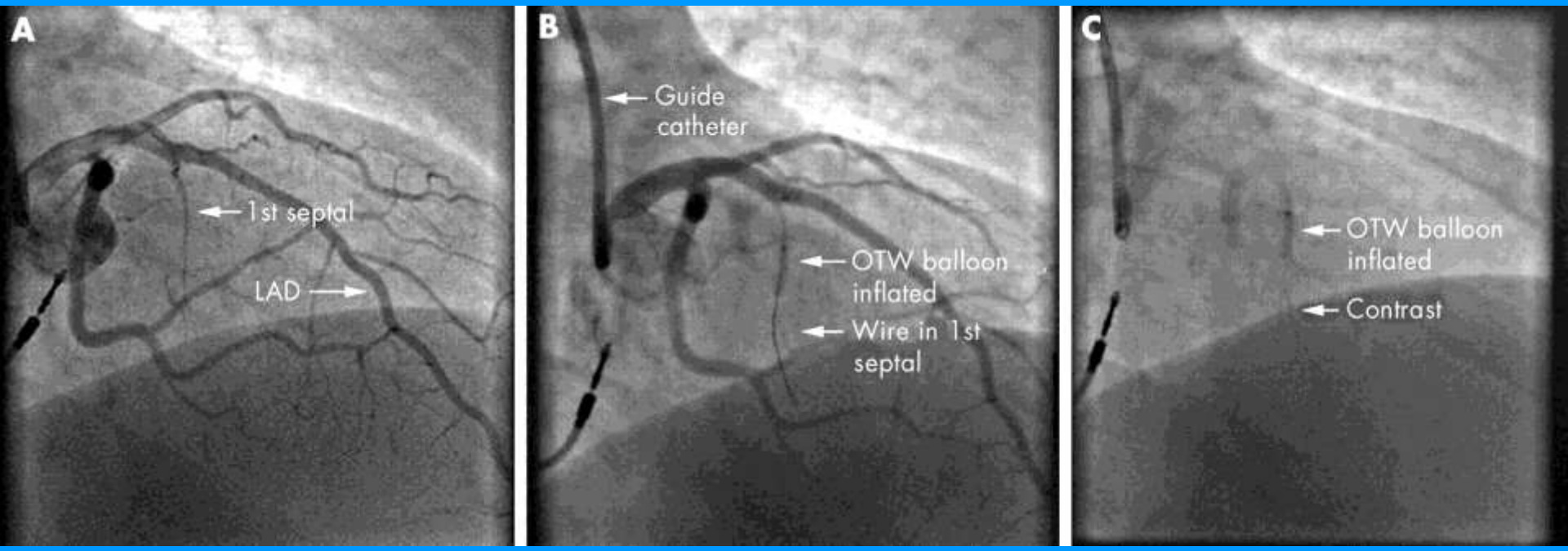






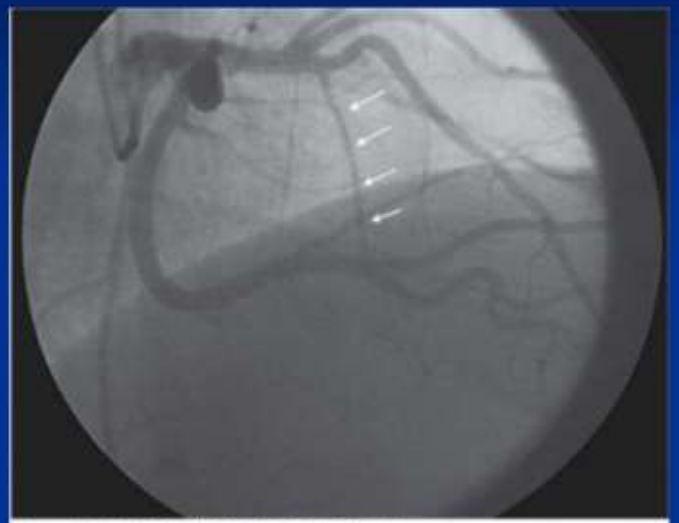

A
B
C
LV
LA
D
E
LV
LA

ALCOHOL SEPTAL ABLATION

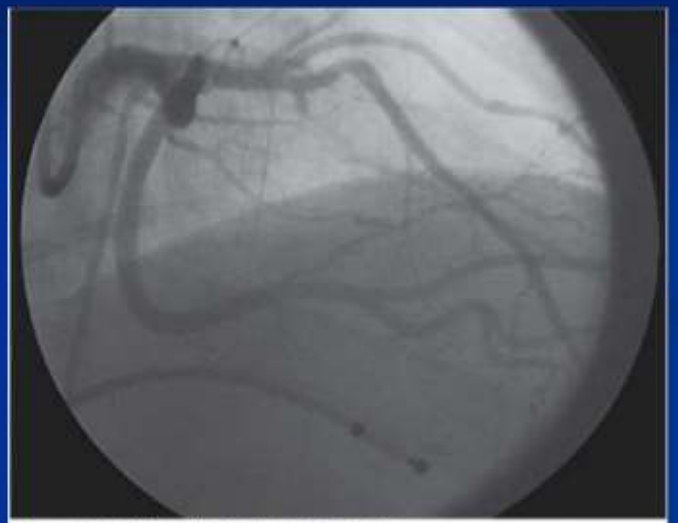


Septal Ablation

Alcohol Septal Ablation



Source: Fuster V, O'Rourke RA, Walsh RA, Poole-Wilson
P: *Hurst's The Heart*, 12th Edition: http://www.accessmedicine.com



Source: Fuster V, O'Rourke RA, Walsh RA, Poole-Wilson
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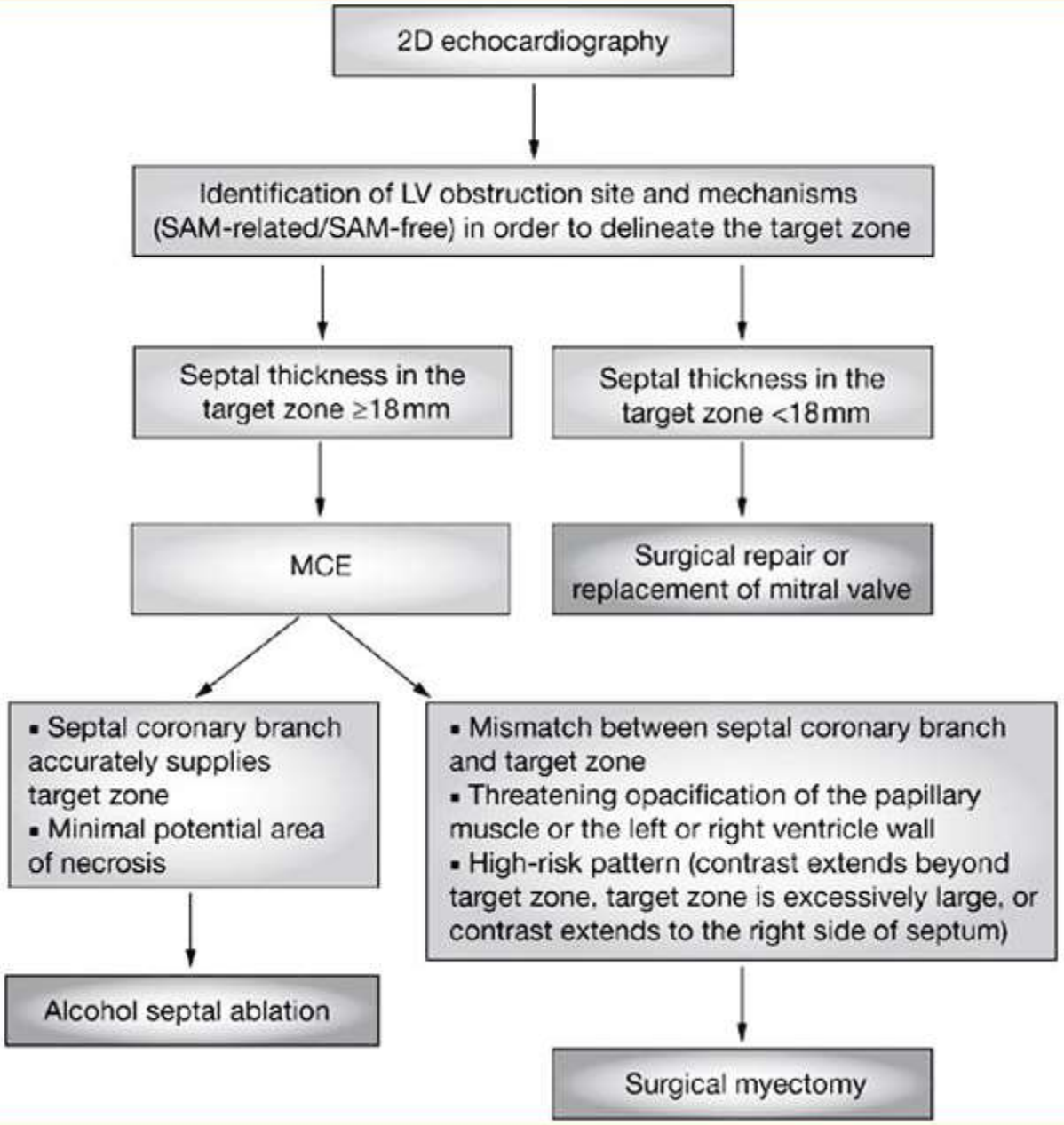
Before

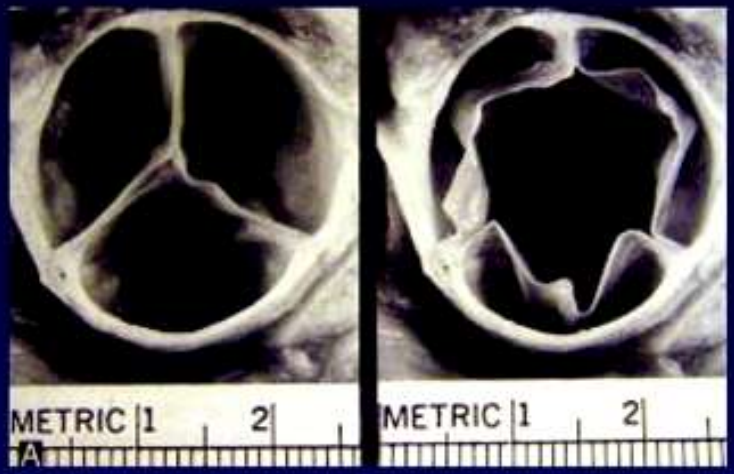
After



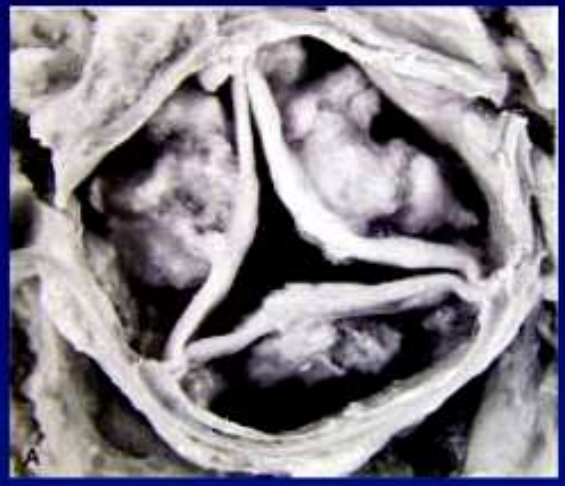
TAVI

TRANSVASCULAR AORTIC VALVE INTERVENTION.

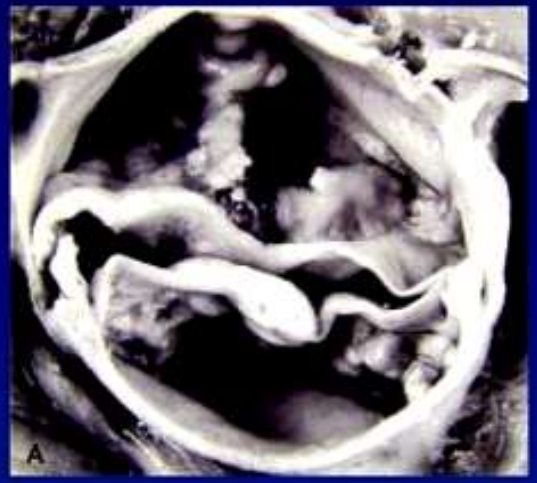
Aortic Stenosis



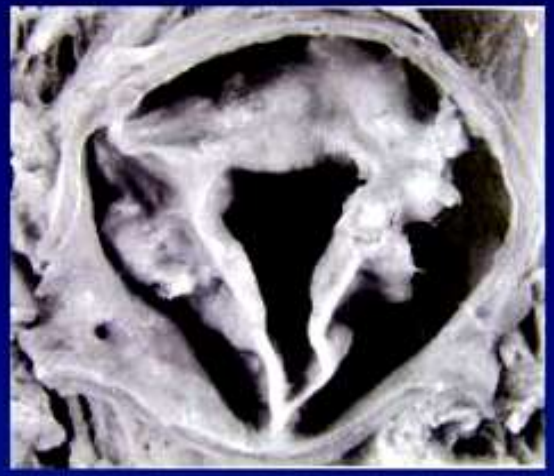
Normal



Degenerative calcific



Bicuspid



Rheumatic

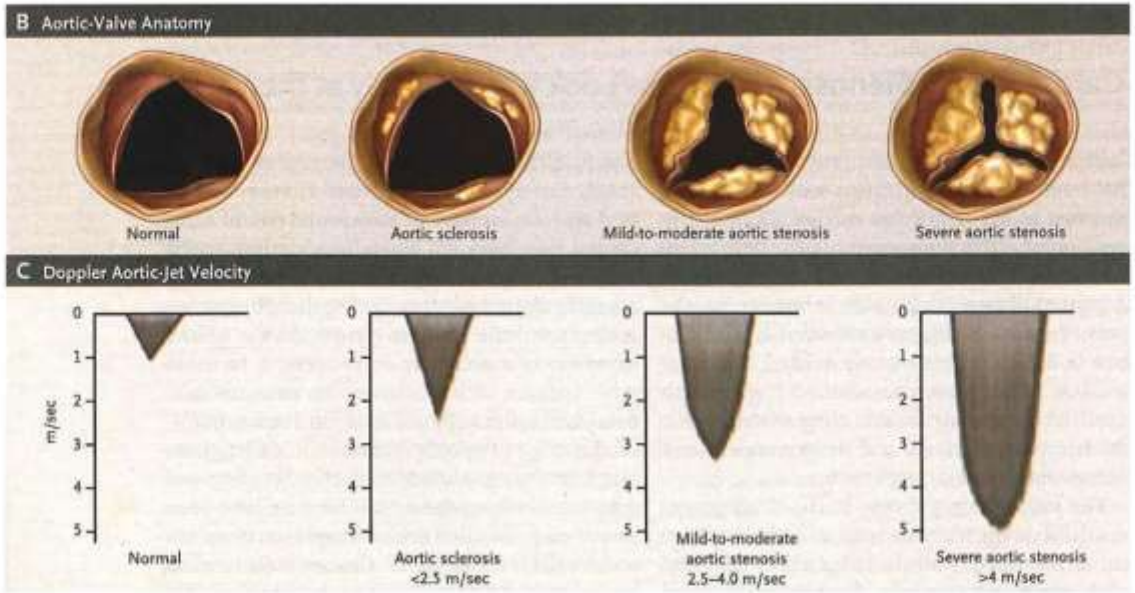


Figure 1. Disease Progression in Calcific Aortic Stenosis, Showing Changes in Aortic-Valve Histologic Features, Leaflet Opening in Systole, and Doppler Velocities.

In Panel A, the histology of the early lesion is characterized by a subendothelial accumulation of oxidized low-density lipoprotein (LDL), production of angiotensin (Ang) II, and inflammation with T lymphocytes and macrophages. Disease progression occurs by several mechanisms, including local production of proteins, such as osteopontin, osteocalcin, and bone morphogenic protein 2 (BMP-2), which mediate tissue calcification; activation of inflammatory signaling pathways, including tumor necrosis factor α (TNF-α), tumor growth factor β (TGF-β), the complement system, C-reactive protein, and interleukin-1β; and changes in tissue matrix, including the accumulation of tenascin C, and up-regulation of matrix metalloproteinase 2 and alkaline phosphatase activity. In addition, leaflet fibroblasts undergo phenotypic transformation into osteoblasts, regulated by the Wnt3–Lrp5–β catenin signaling pathway. Microscopic accumulations of extracellular calcification (Ca^{2+}) are present early in the disease process, with progressive calcification as the disease progresses and areas of frank bone formation in end-stage disease. The corresponding changes in aortic-valve anatomy are viewed from the aortic side with the valve open in systole (Panel B) and in Doppler aortic-jet velocity (Panel C).

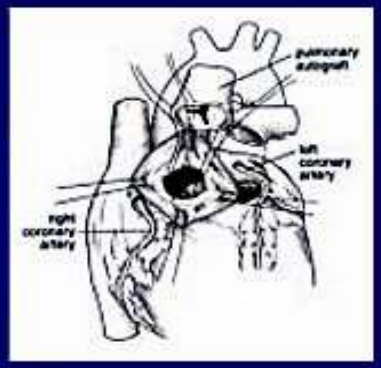
The standard for critical AS RX is Surgical AVR

Mechanical

Tissue

Stentless

Homograft



Ross

Lenox Hill Heart and Vascular Institute Of New York

CE Mark

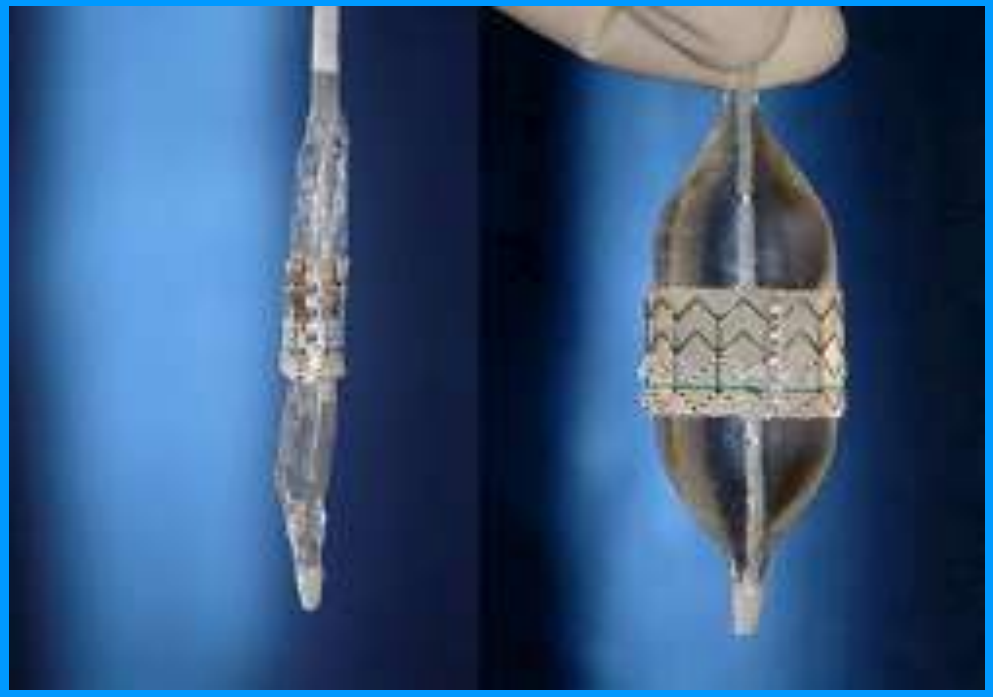
Edwards-Sapien

- **Bovine pericardium Tri-leaflet configuration**
- **Mounted on a 14 mm long x 23 mm or 26 mm highly resistant stainless steel balloon expandable stent**
- **Delivery system 24F - 26F (ID)**

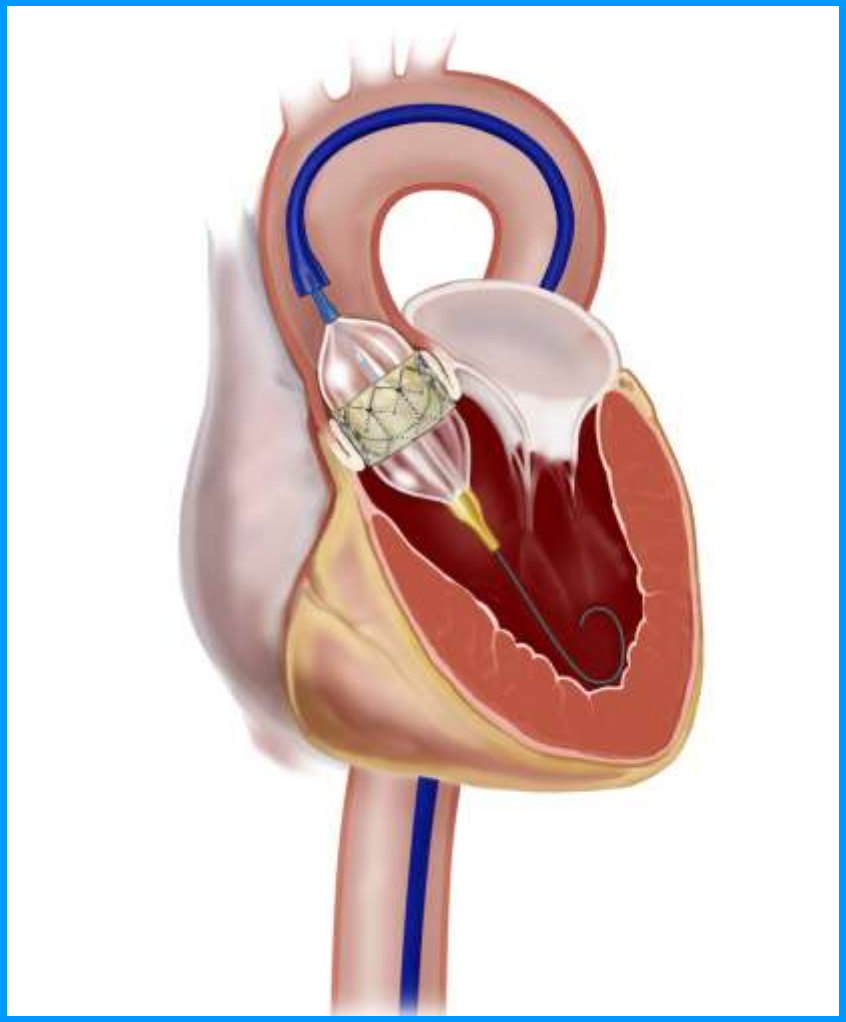
ReValving® System CoreValve

- Single layer porcine pericardium
- Tri-leaflet configuration
- Nitinol frame self-expandable - Inflow: 26 and 29 mm – 20 to 27 mm annulus
- Delivery system 18F / 12F (OD)

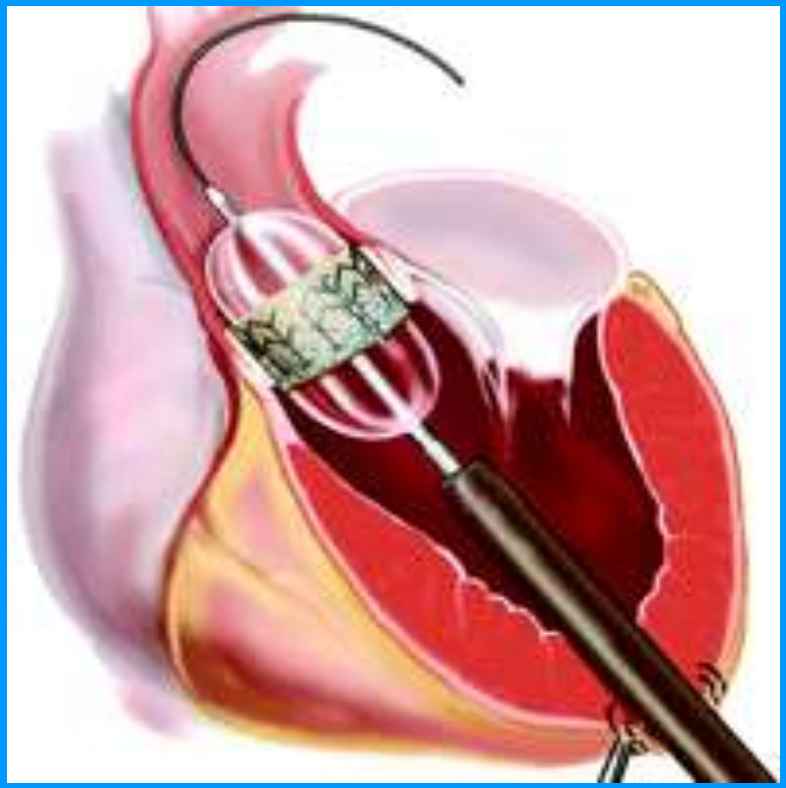
TAVI



TAVI



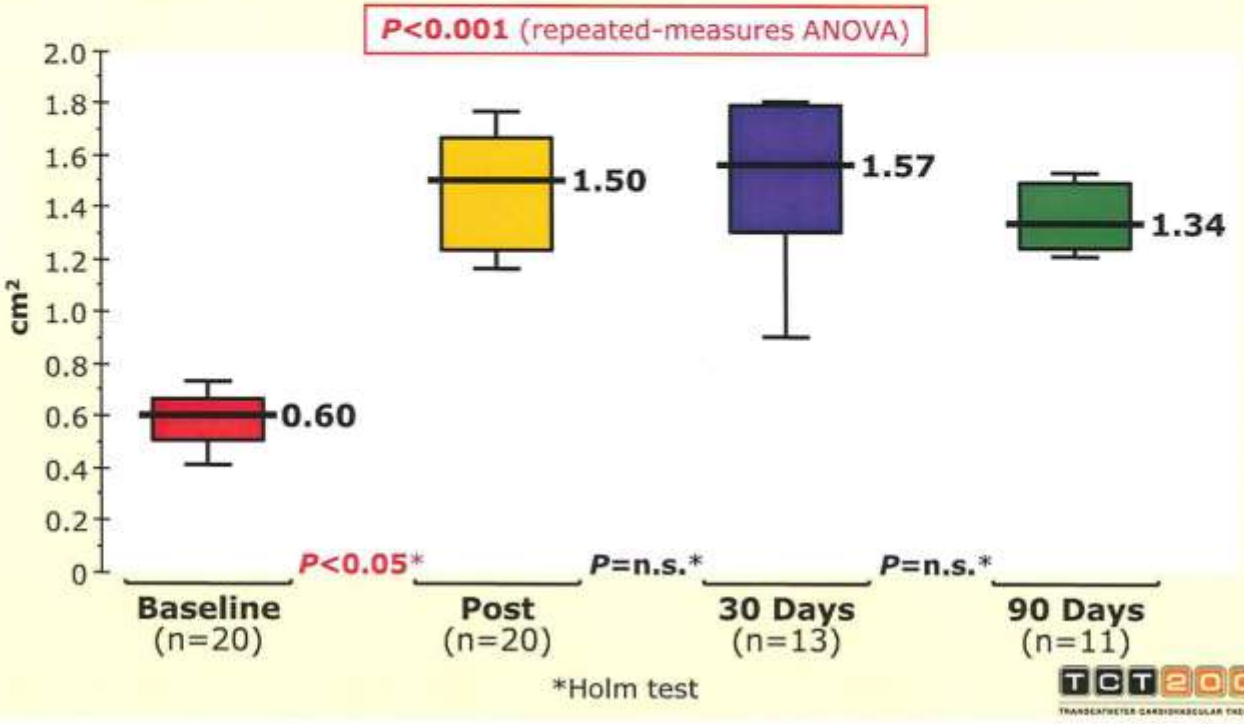
SAVI



CORE VALVE

The DFM AV Prosthesis
European Clinical Trial

- **Aortic orifice area** in patients with a permanent implant

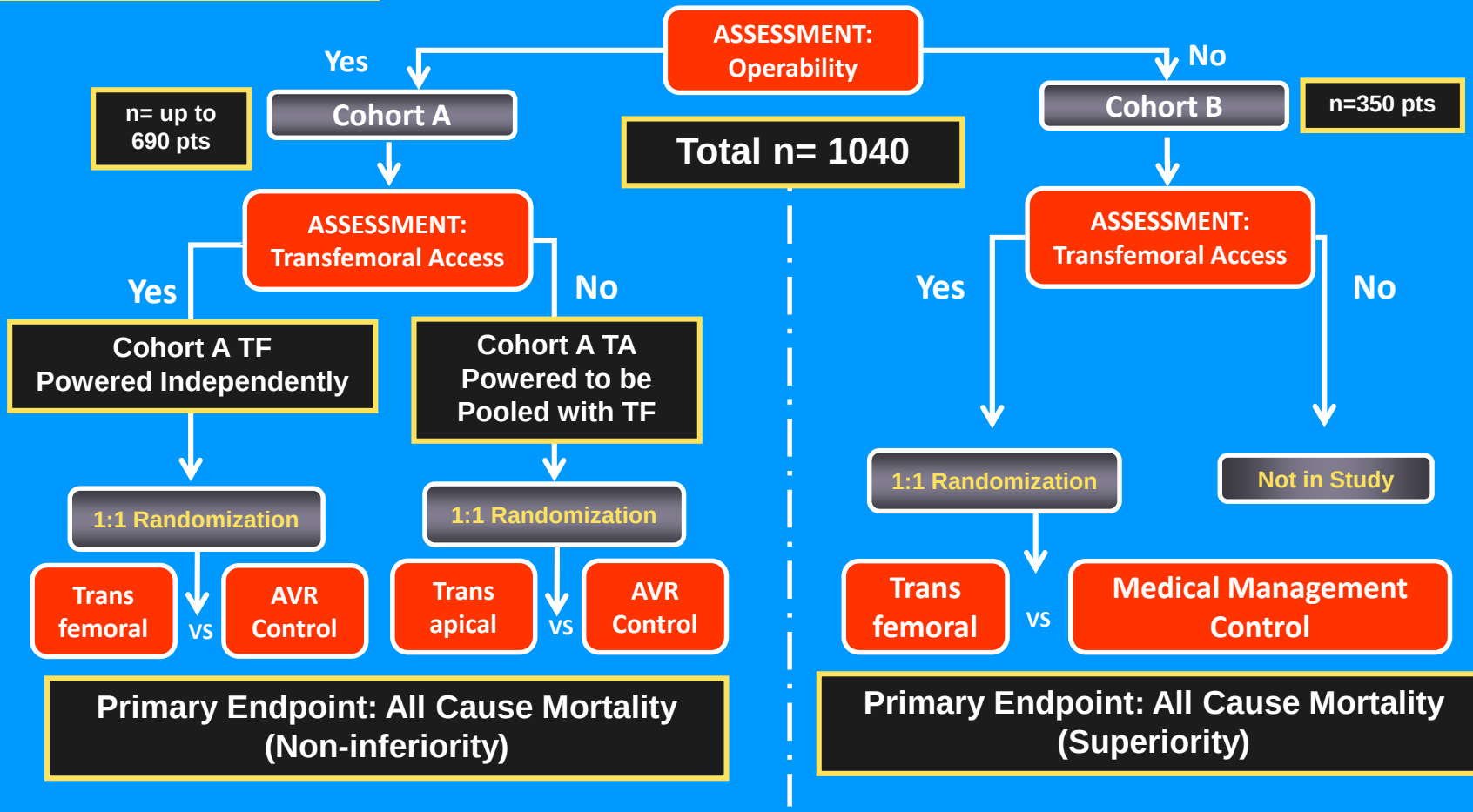


The PARTNER IDE Trial

Population: High Risk/Non-Operable Symptomatic, Critical Calcific Aortic Stenosis

Co-principal Investigators:
Martin B. Leon, MD Interventional Cardiology
Craig Smith, MD, Cardiac Surgeon
Columbia University

Two Trials: Individually Powered Cohorts (Cohorts A & B)

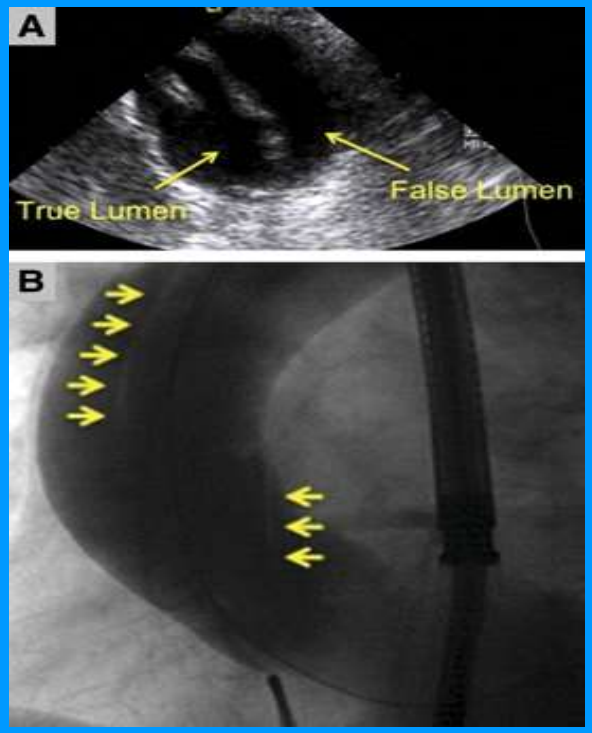


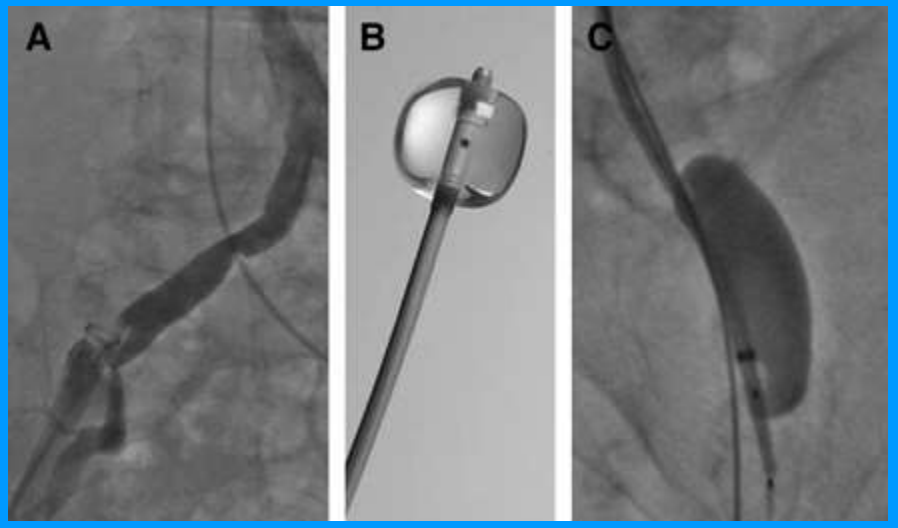
Update SEPT 2008

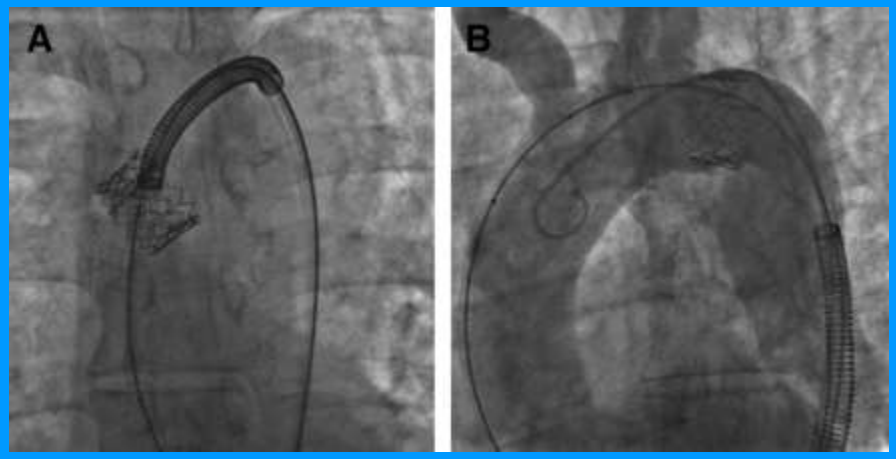
PARTNERS TAVI VS MED

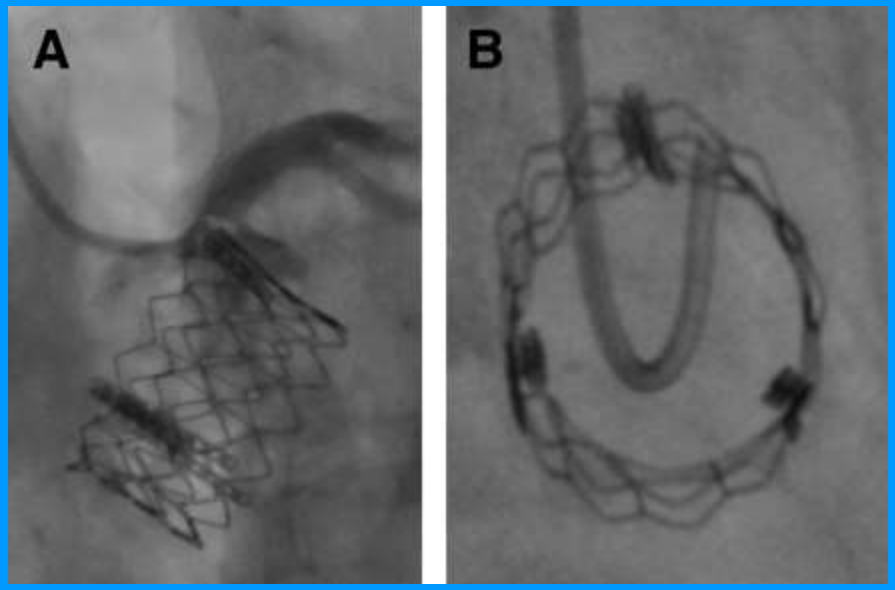
- **Primary End Points End point**
- **TAVI (%) Standard (%)**
- **1-y all-cause death** 30.7 50.7 <0.001
- **1-y all-cause death or repeat hospitalization** 42.5 71.6 <0.001
- **TAVI vs Standard Therapy Secondary End Points**
- **30-d major stroke** 5.0 1.1 0.06
- **30-d vascular comp** 16.2 1.1 <0.001
- **1-y cardiac death** 19.6 41.9 <0.001
- **1-y major bleeding** 22.3 11.2 0.007

COMPLICATIONS OF TAVI

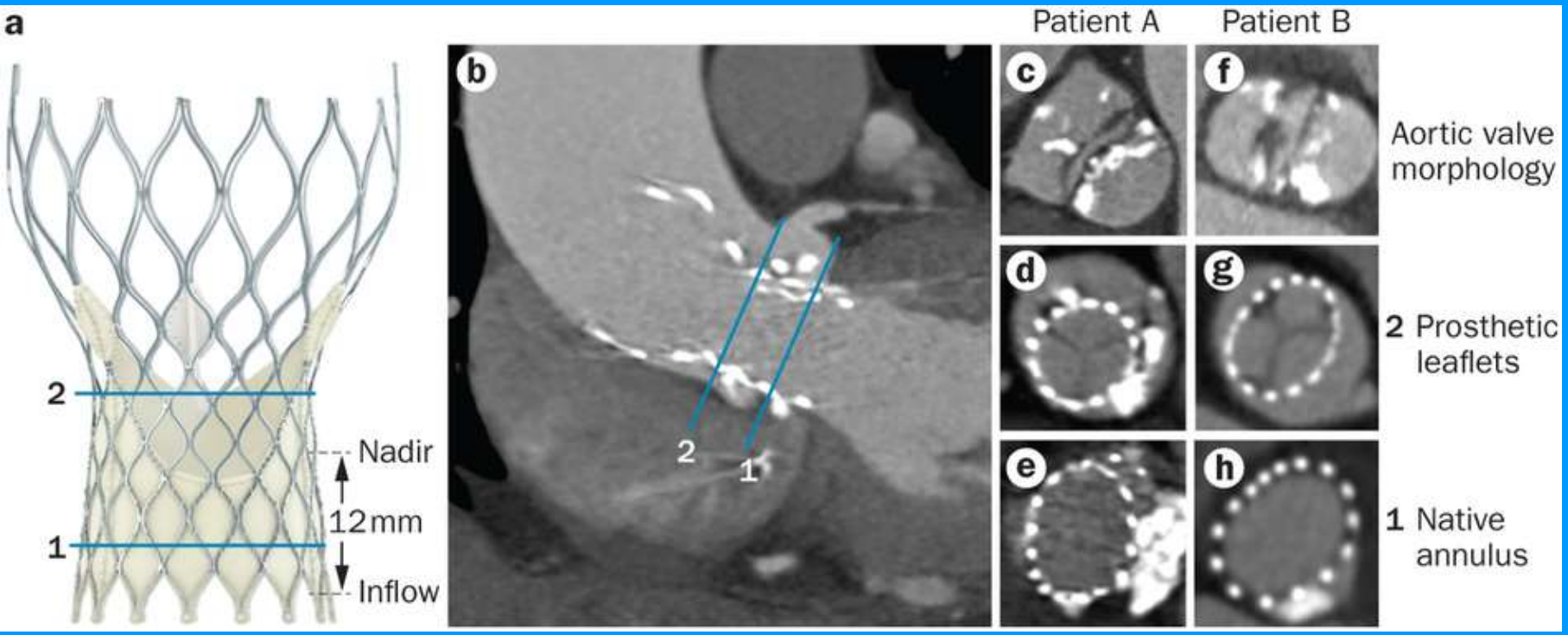




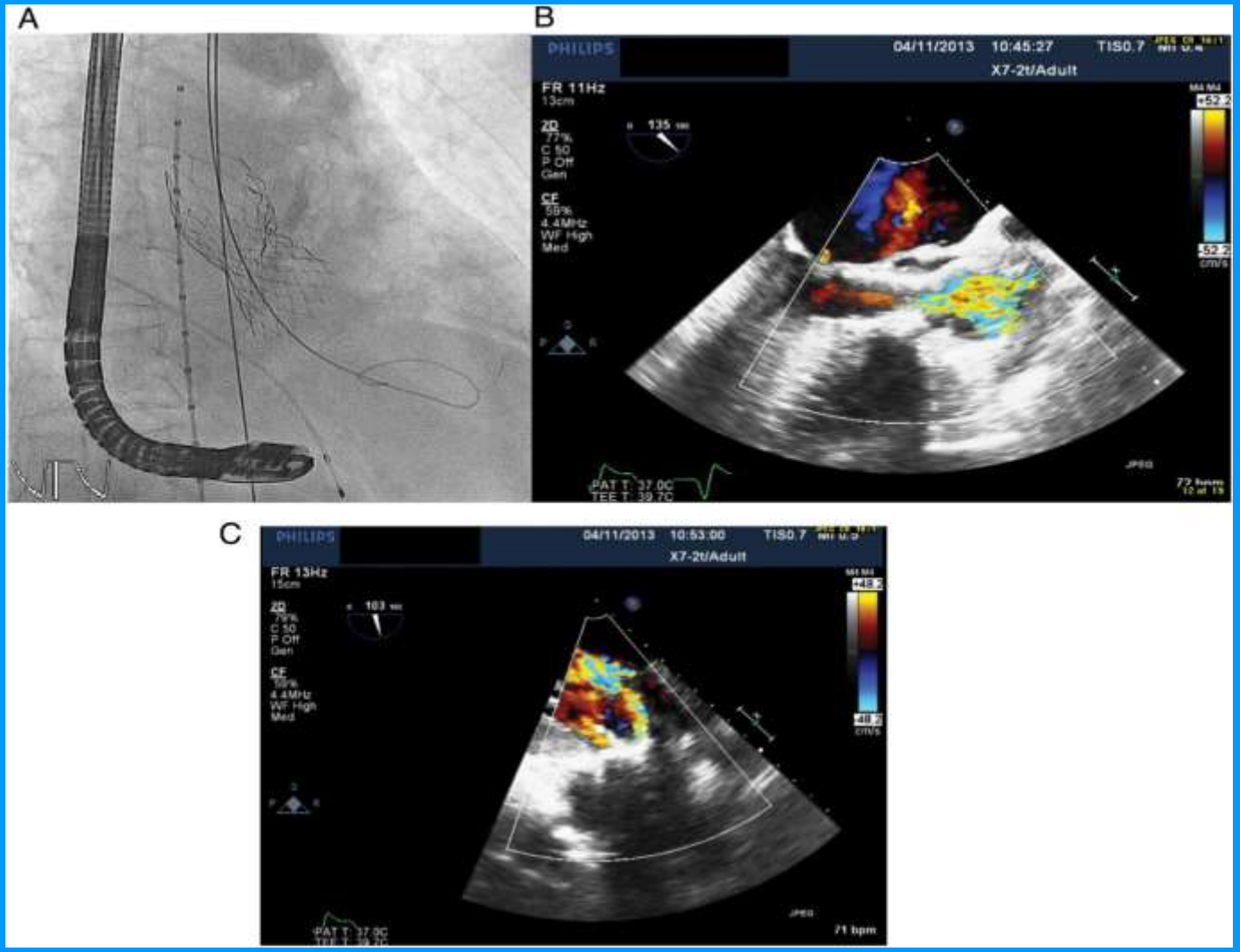




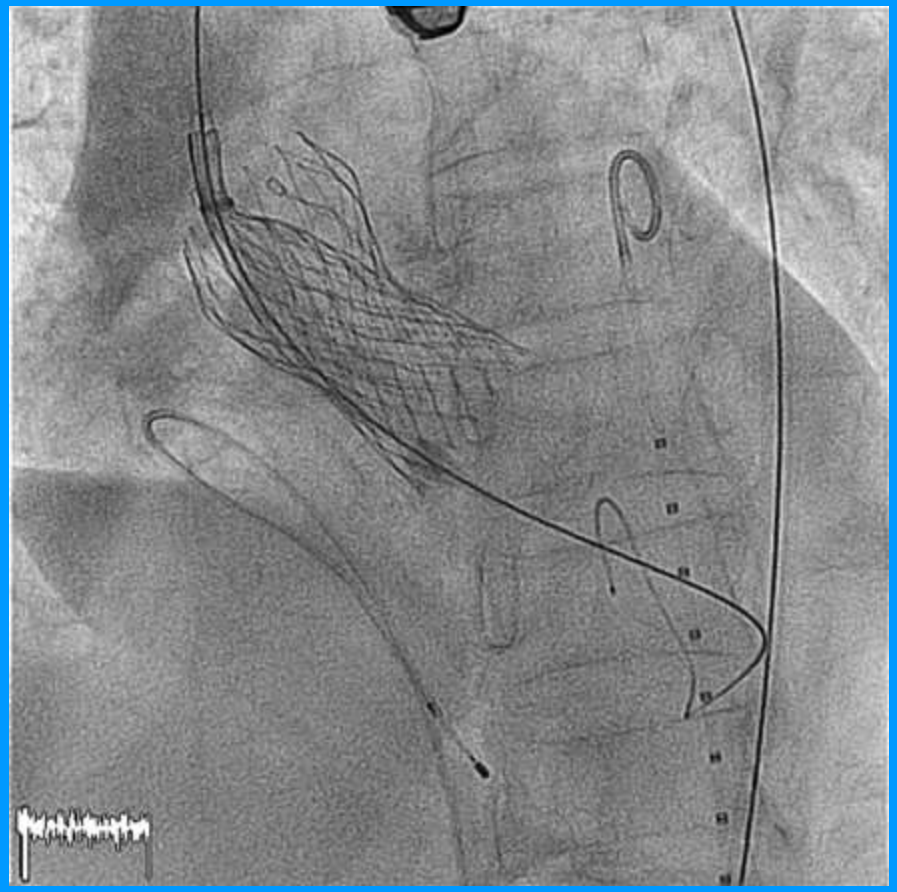
Core Valve in Bisucpid Valve



Incompletely Deployed Core Valve



Valve in Valve



Tavi Valve in Valve

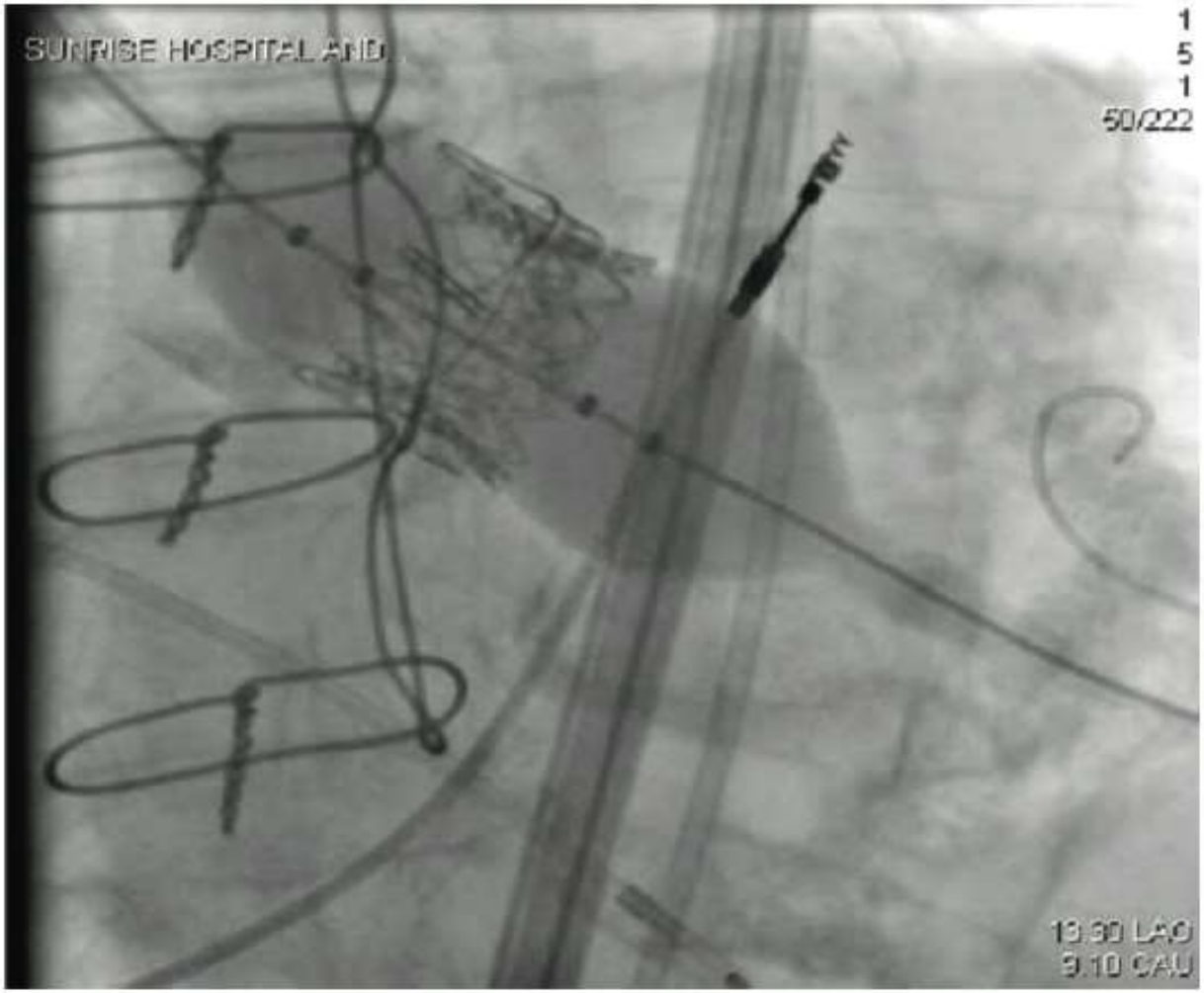
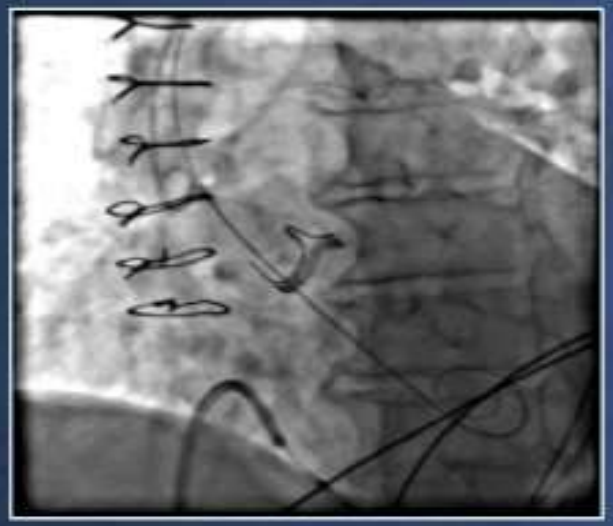
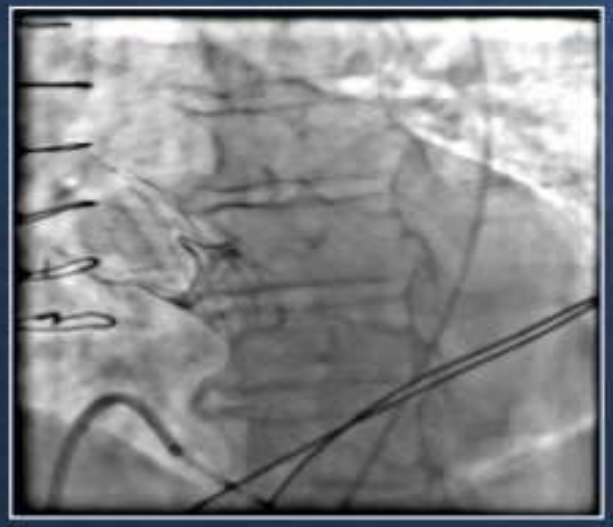
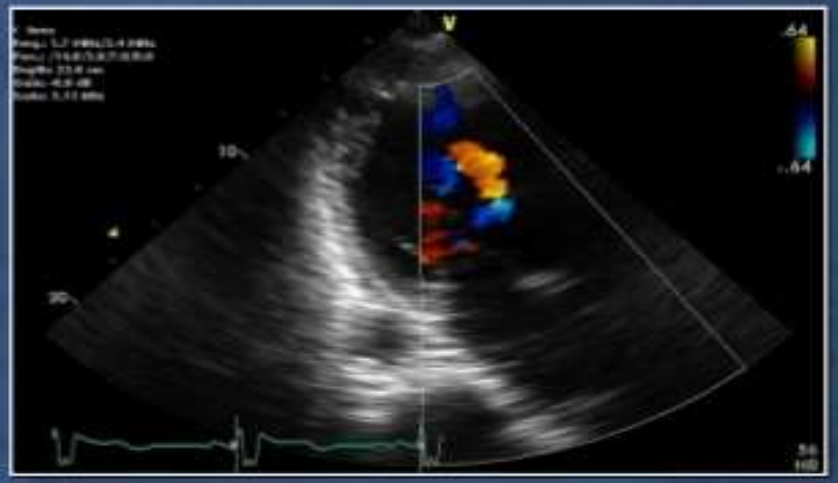


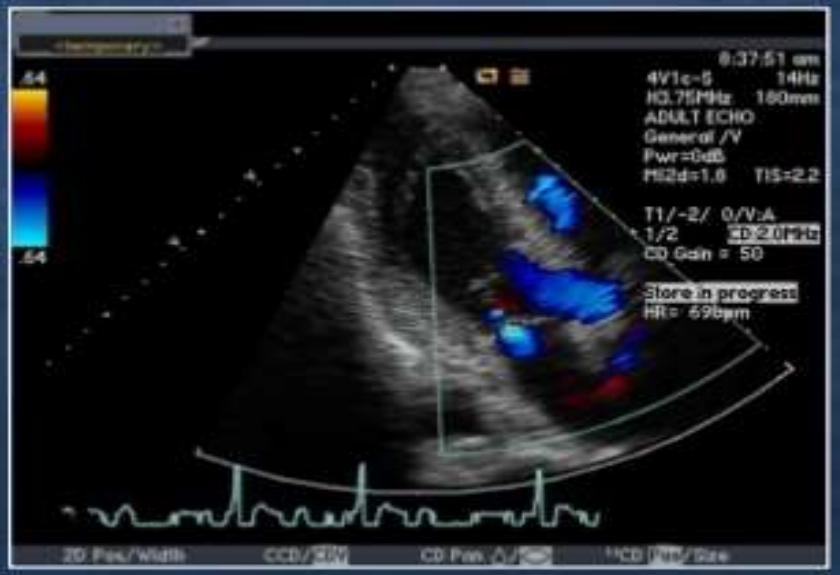
Figure 4. Deployment of 23 mm Sapien valve within pre-existing 21 mm Perimount valve. Delivery balloon has been prepped with 1 less milliliter of fluid.

TAVI Valve in Valve









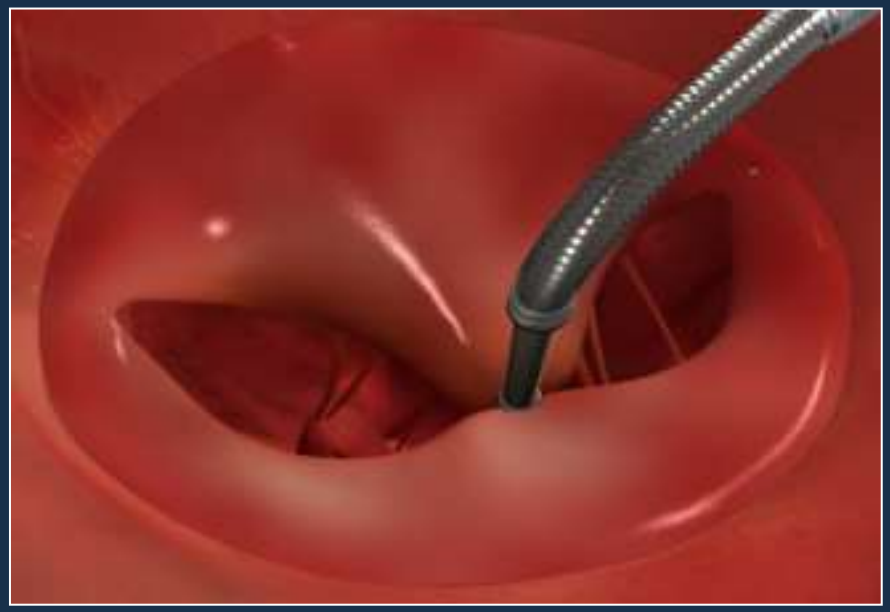
MITRAL REGURGITATION

Perspective

- >250,000 cases of significant Mitral Regurgitation diagnosed annually in the US
- Current therapeutic options:
  - Medical management
    - Effective in symptom management
    - Ineffective in treating underlying pathophysiology or disease progression
  - Surgical Repair or Replacement (Standard of Care)
    - Effective yet invasive with associated morbidity
    - Only ~20% of patients with significant MR undergo MV surgery
- Unmet need for an effective less invasive option

Catheter-Based Mitral Valve Repair

MitraClip® System



NorthShore University HealthSystem
Evanston Hospital

EVEREST II Randomized Clinical Trial

Study Design

279 Patients enrolled at 37 sites

Significant MR (3+-4+)
Specific Anatomical Criteria

↓

Randomized 2:1

Device Group	Control Group
MitraClip System	Surgical Repair or Replacement
N=184	N=95

↓

Echocardiography Core Lab and Clinical Follow-Up:
Baseline, 30 days, 6 months, 1 year, 18 months, and annually through 5 years

NorthShore University HealthSystem
Evanston Hospital

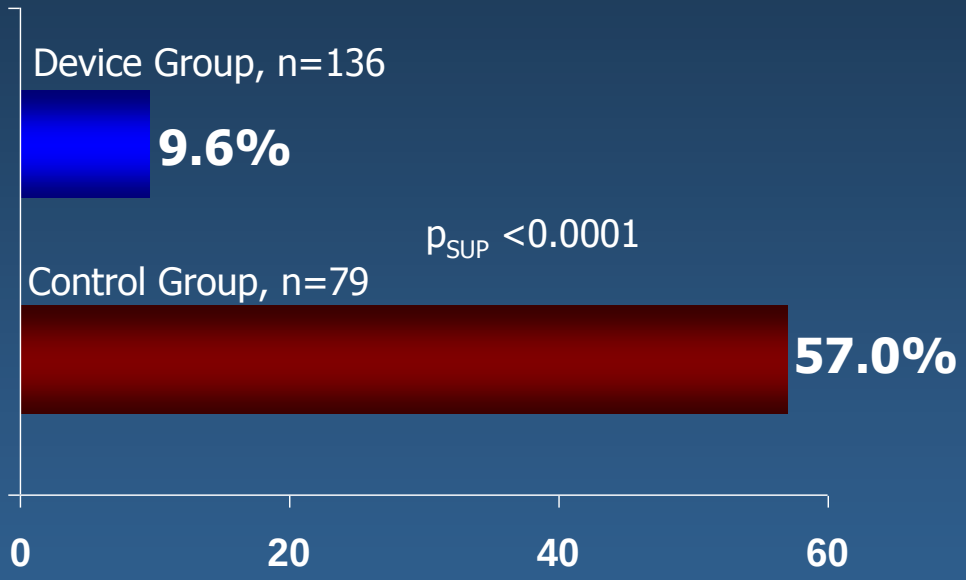
EVEREST II RCT: Primary Endpoints

Per Protocol Cohort

Safety

Major Adverse Events

30 days



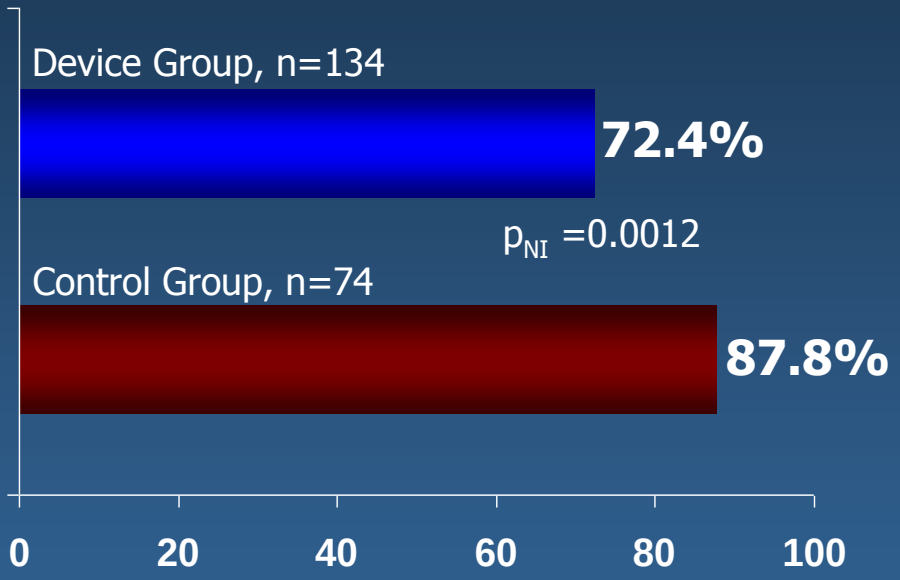
Met superiority hypothesis

- Pre-specified margin = 6%
- Observed difference = **47.4%**
- 97.5% LCB = 34.4%

Effectiveness

Clinical Success Rate*

12 months



Met non-inferiority hypothesis

- Pre-specified margin = 31%
- Observed difference = **15.4%**
- 95% UCB = 25.4%

LCB = lower confidence bound
UCB = upper confidence bound

* Freedom from the combined outcome of death, MV surgery or re-operation for MV dysfunction, MR >2+ at 12 months

NorthShore University HealthSystem
Evanston Hospital

EVEREST II RCT: Primary Safety Endpoint

Per Protocol Cohort

30 Day MAE, non-hierarchical	# Patients experiencing event Device Group (n=136)	Control Group (n=79)
Death	0	2 (2.5%)
Major Stroke	0	2 (2.5%)
Re-operation of Mitral Valve	0	1 (1.3%)
Urgent / Emergent CV Surgery	0	4 (5.1%)
Myocardial Infarction	0	0
Renal Failure	0	0
Deep Wound Infection	0	0
Ventilation >48 hrs	0	4 (5.1%)
New Onset Permanent Atrial Fib	0	0
Septicemia	0	0
GI Complication Requiring Surgery	1 (0.7%)	0
All Transfusions ≥2 units*	12 (8.8%)	42 (53.2%)
TOTAL % of Patients with MAE	**9.6%**	**57.0%**

p<0.0001*

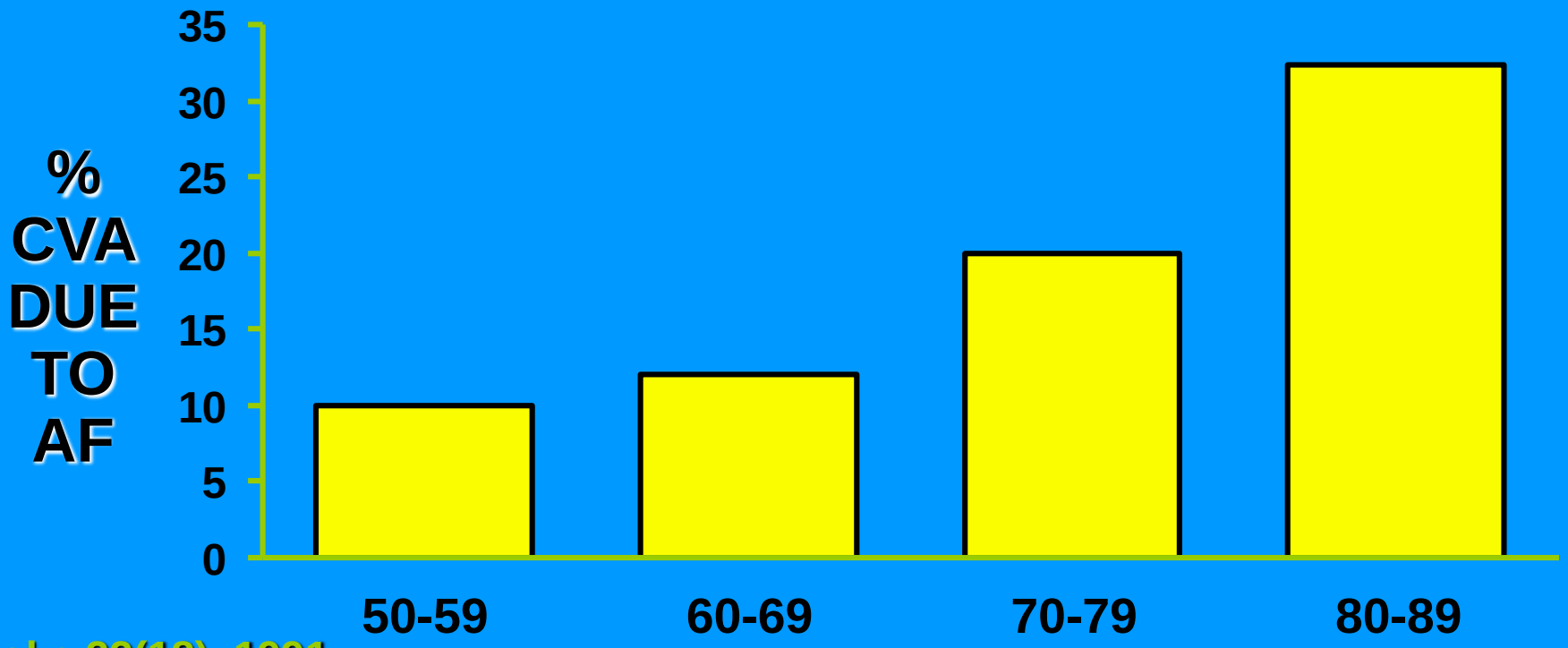
(95% CI 34.4%, 60.4%)

*p<0.0001 if include Major Bleeding only

LAA CLOSURE

Non-Valvular Atrial Fibrillation

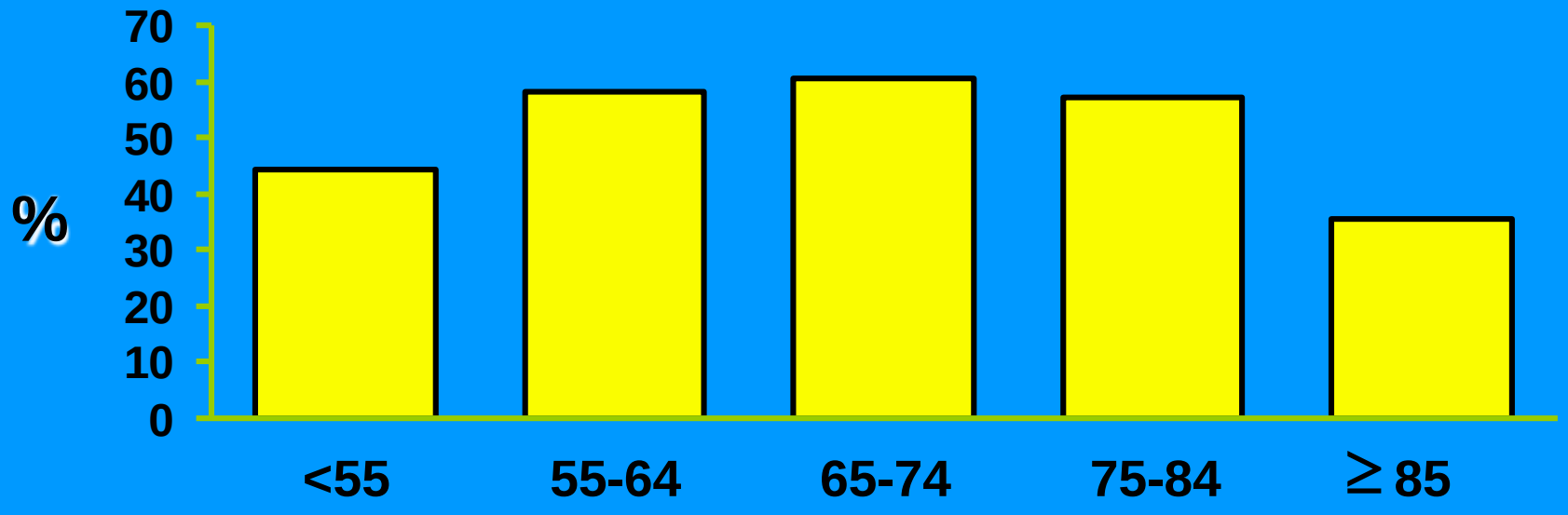
- 500,000 strokes/year in U.S.
- Up to 20% of ischemic strokes occur in patients with atrial fibrillation



Stroke 22(18), 1991

Non-Valvular Atrial Fibrillation Warfarin

Use in AF Patients by Age

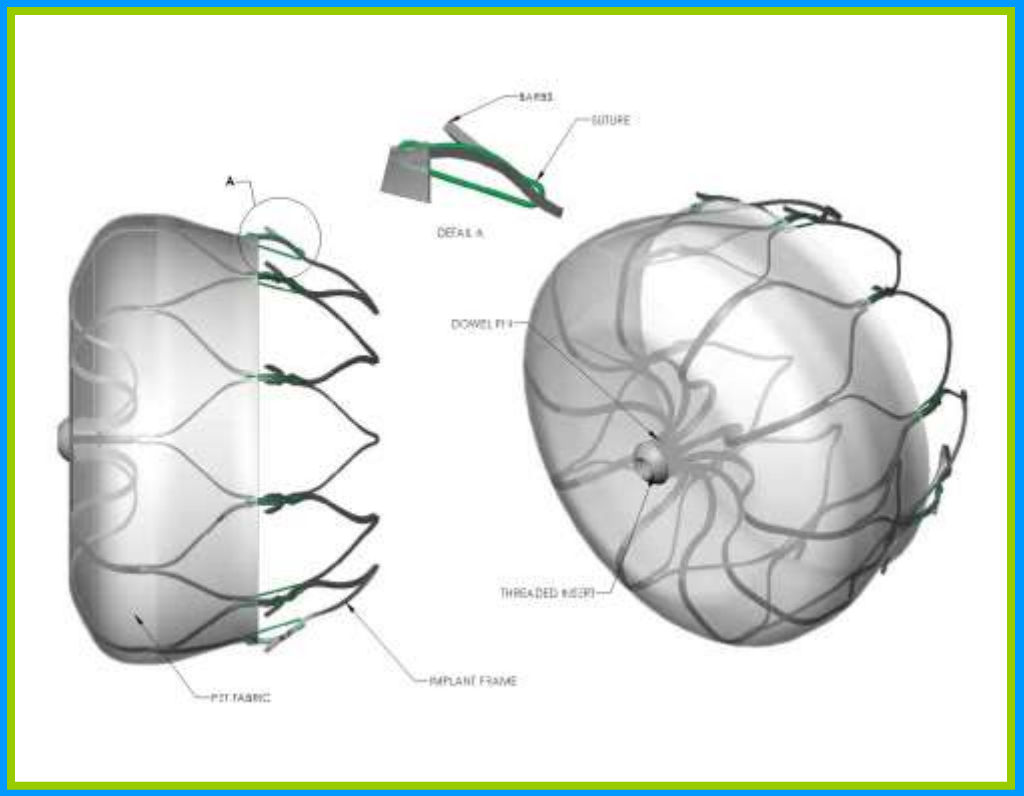


- Only 55% of AF patients with no contraindications have evidence of warfarin use in previous 3 months
- Other studies cite warfarin use 17-50%
- Elderly patients with increased absolute risk least likely to be taking warfarin; Contraindications 30-40%

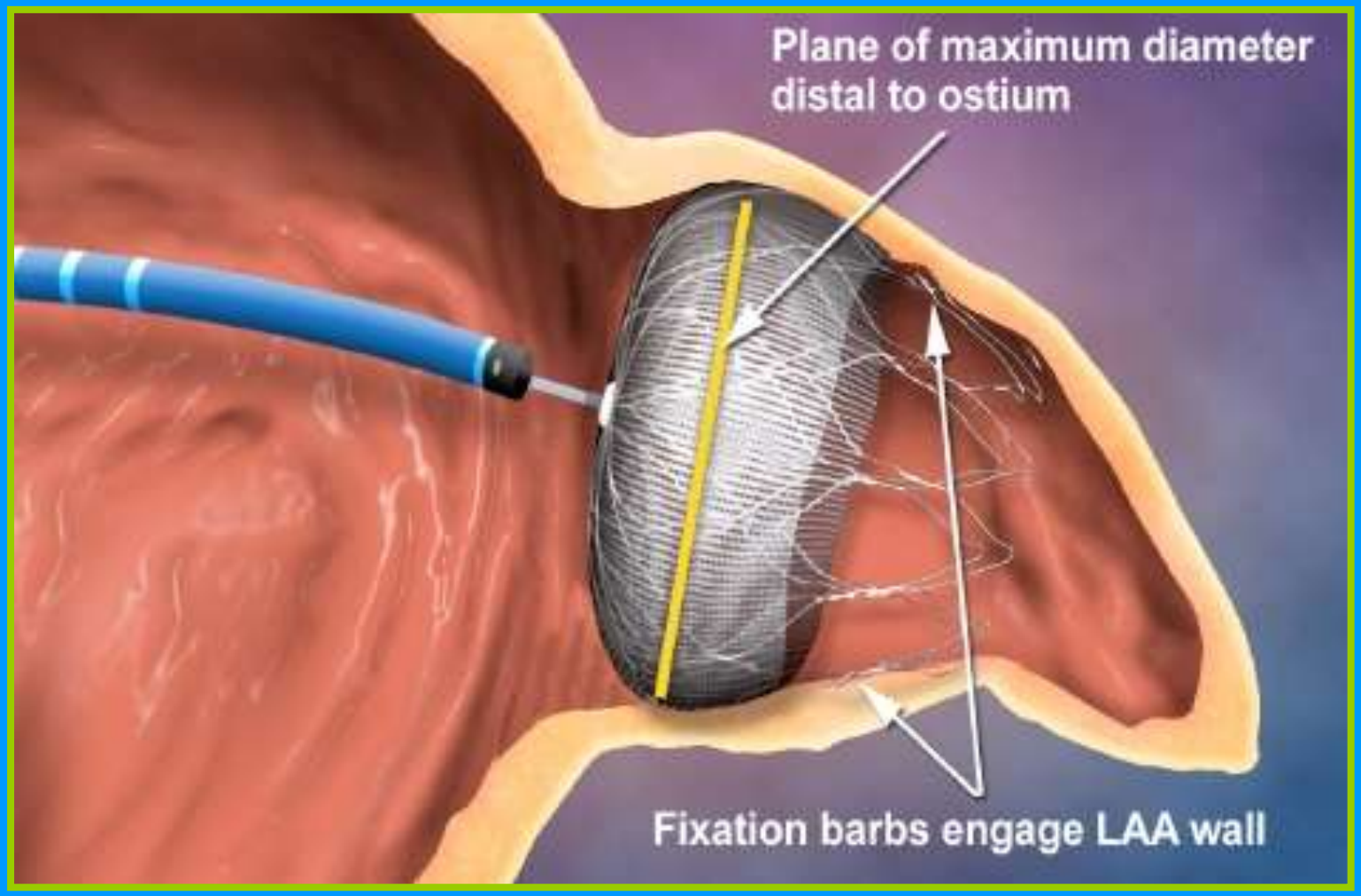
Ann Int Med 131(12), 1999

LAA Thrombus

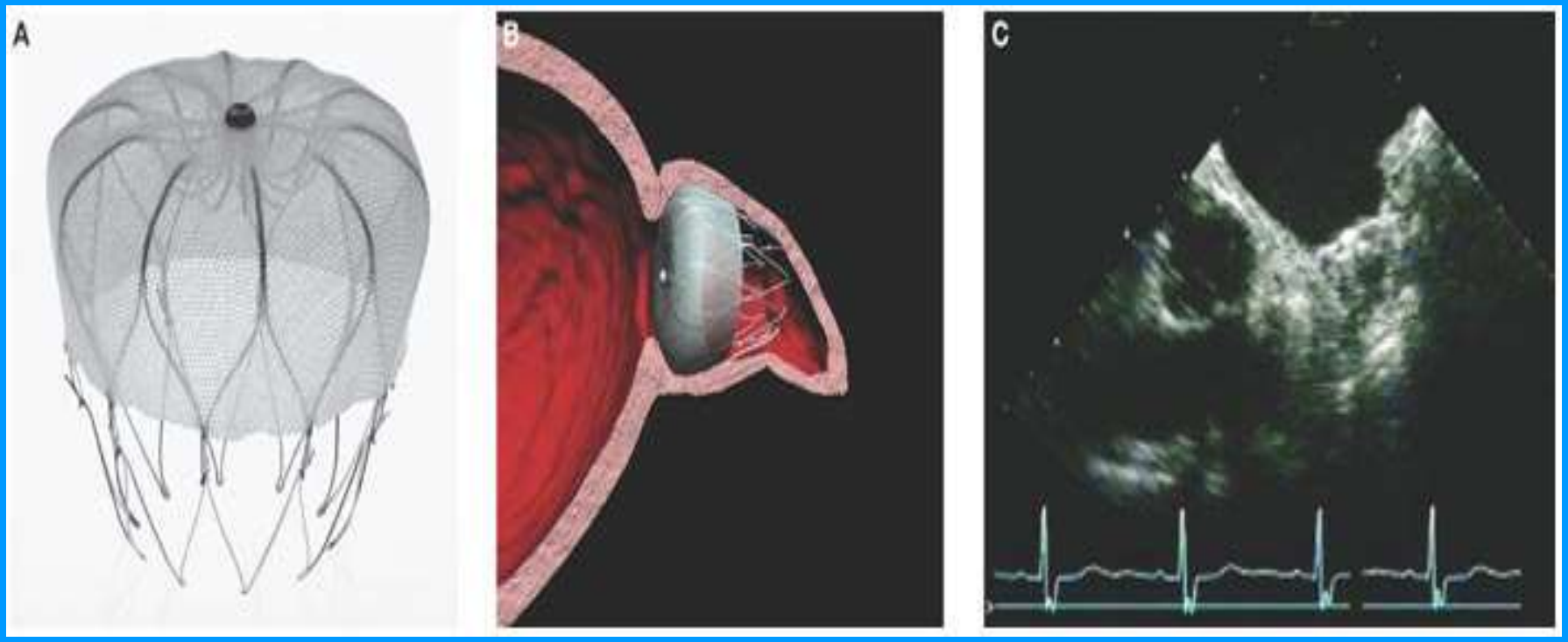
WATCHMAN® LAA Closure Technology



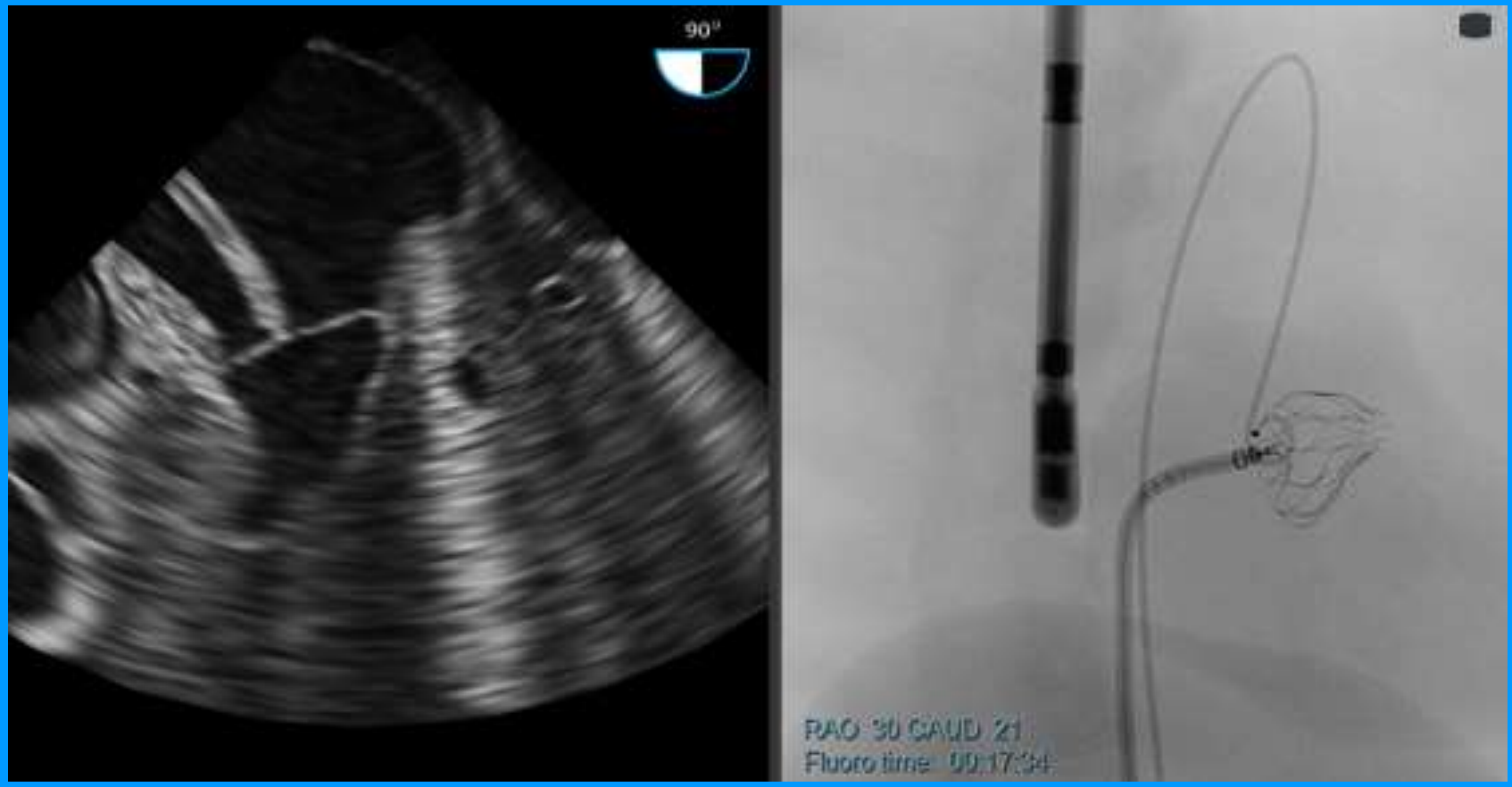
WATCHMAN LAA Closure Device in situ



LAA Closure



LAA Closure Device

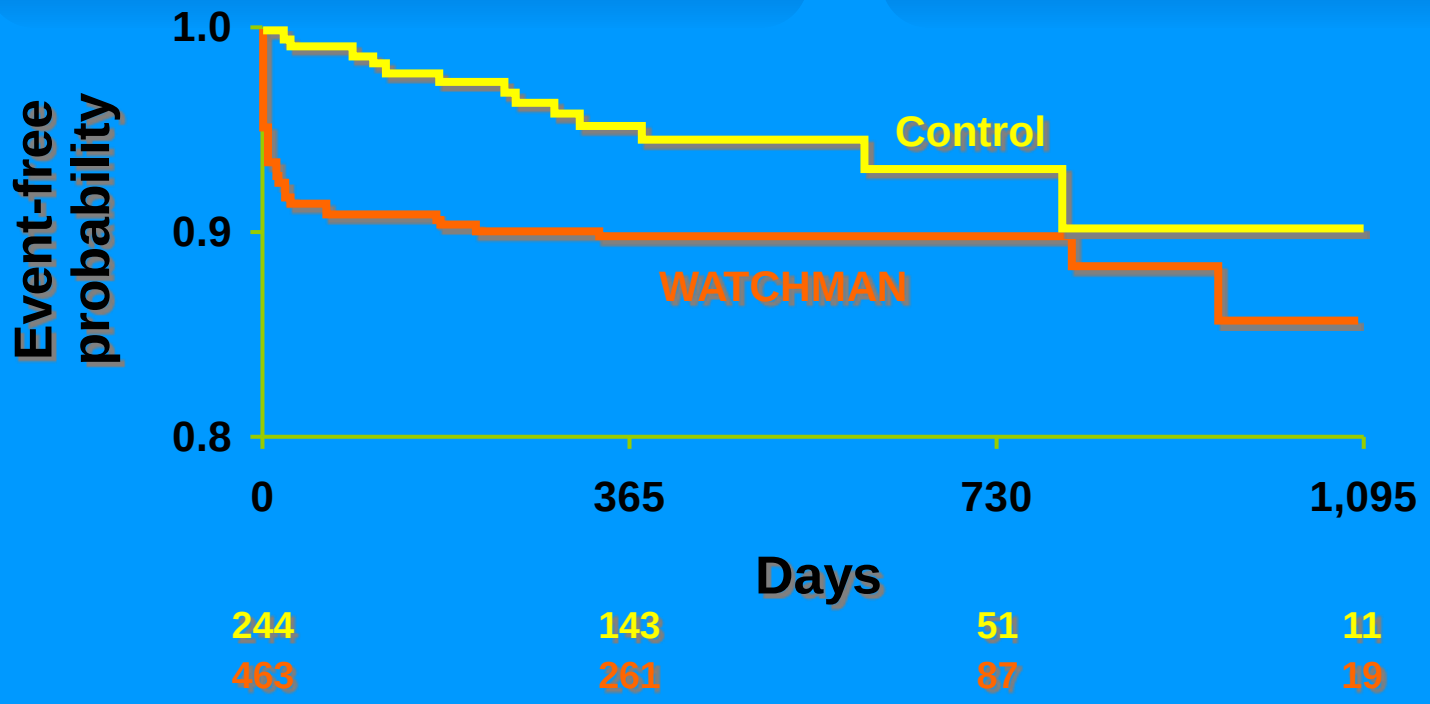


PROTECT AF Trial Endpoints

- **Primary Efficacy Endpoint**
  - **All stroke: ischemic or hemorrhagic**
    - **deficit with symptoms persisting more than 24 hours or**
    - **symptoms less than 24 hours confirmed by CT or MRI**
  - **Cardiovascular and unexplained death: includes sudden death, MI, CVA, cardiac arrhythmia and heart failure**
  - **Systemic embolization**
- **Primary Safety Endpoint**
  - **Device embolization requiring retrieval**
  - **Pericardial effusion requiring intervention**
  - **Cranial bleeds and gastrointestinal bleeds**
  - **Any bleed that requires ≥ 2uPRBC**
- **NB: Primary effectiveness endpoint contains safety events**

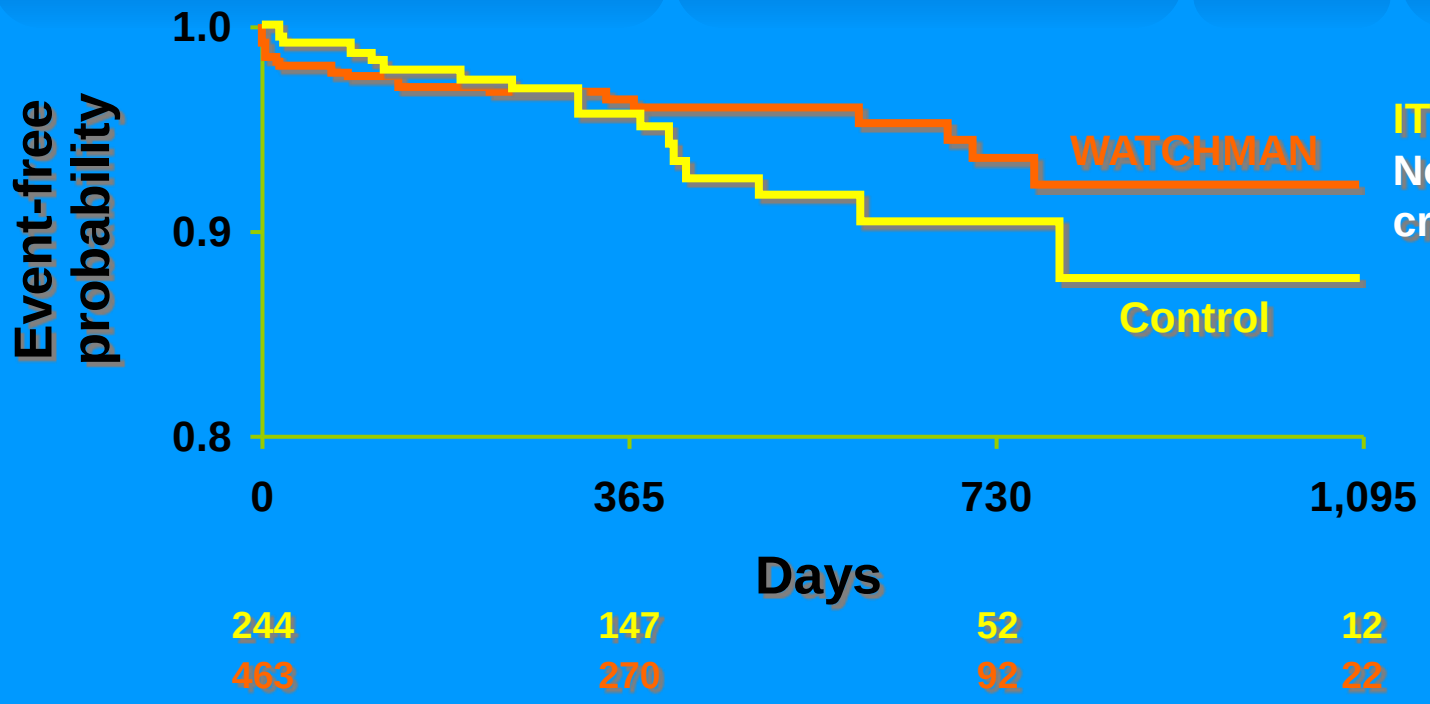
Intent-to-Treat
Primary Safety Results
Randomization allocation (2 device : 1 control)

Cohort	Device Events (no.)	Device Total pt-yr	Device Rate (95% CI)	Control Events (no.)	Control Total pt-yr	Control Rate (95% CI)	Rel. Risk (95% CI)
900 pt-yr	48	554.2	8.7 (6.4, 11.3)	13	312.0	4.2 (2.2, 6.7)	2.08 (1.18, 4.13)



Intent-to-Treat
Primary Efficacy Results
Randomization allocation (2 device : 1 control)

	Device			Control				Posterior Probabilities	
Cohort	Events (no.)	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	Rel. Risk (95% CI)	Non-inferiority	Superiority
900 pt-yr	20	582.3	3.4 (2.1, 5.2)	16	318.0	5.0 (2.8, 7.6)	0.68 (0.37, 1.41)	0.998	0.837

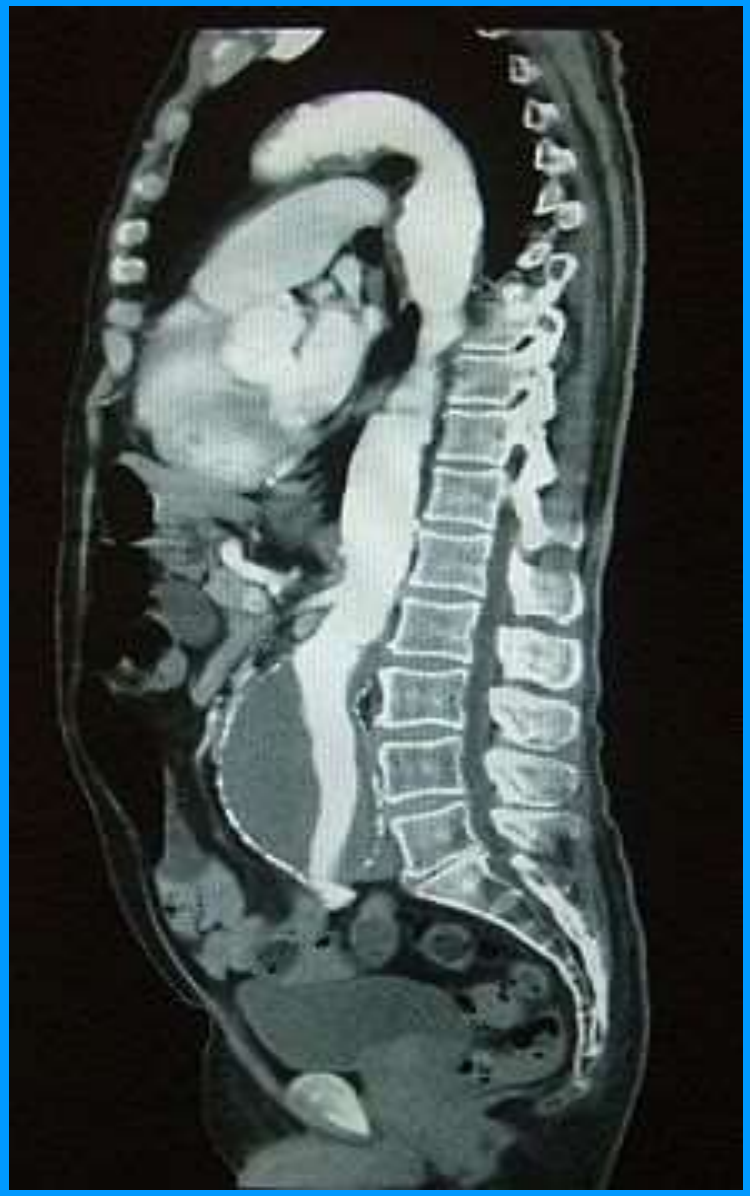


ITT Cohort:
Non-inferiority criteria met

EVAR

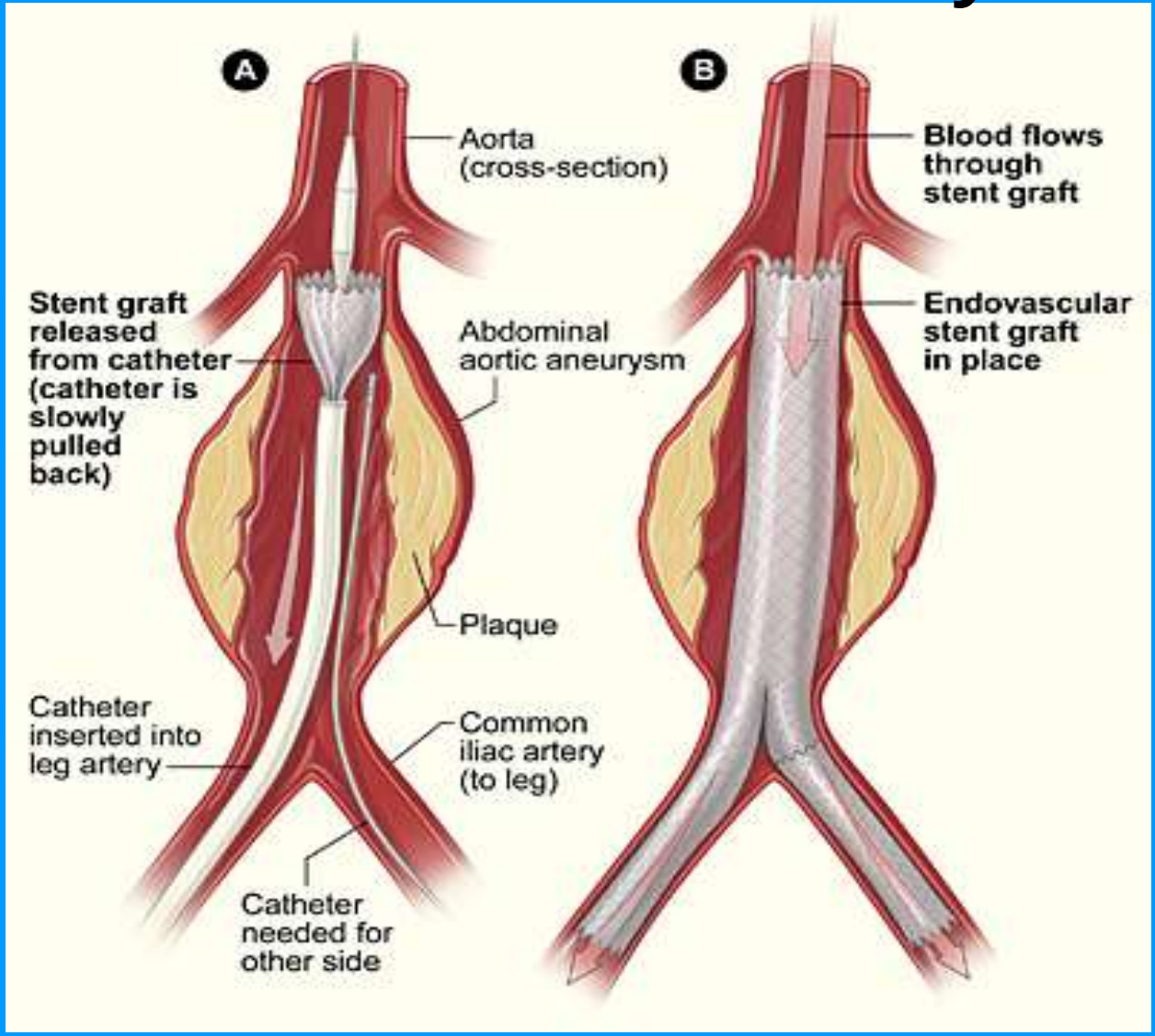
ENDOVASCULAR ANEURYSM REPAIR

ABDOMINAL AORTIC ANEURYSM

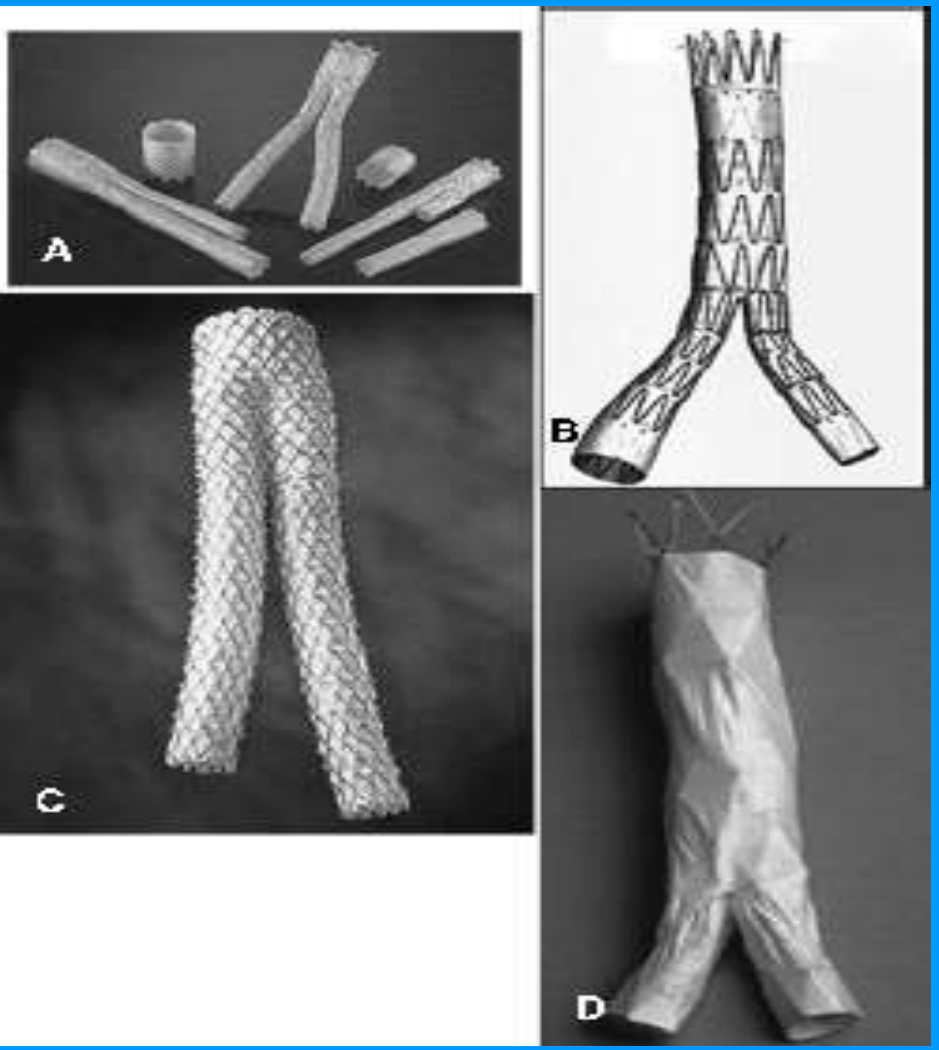


SURGICAL REPAIR

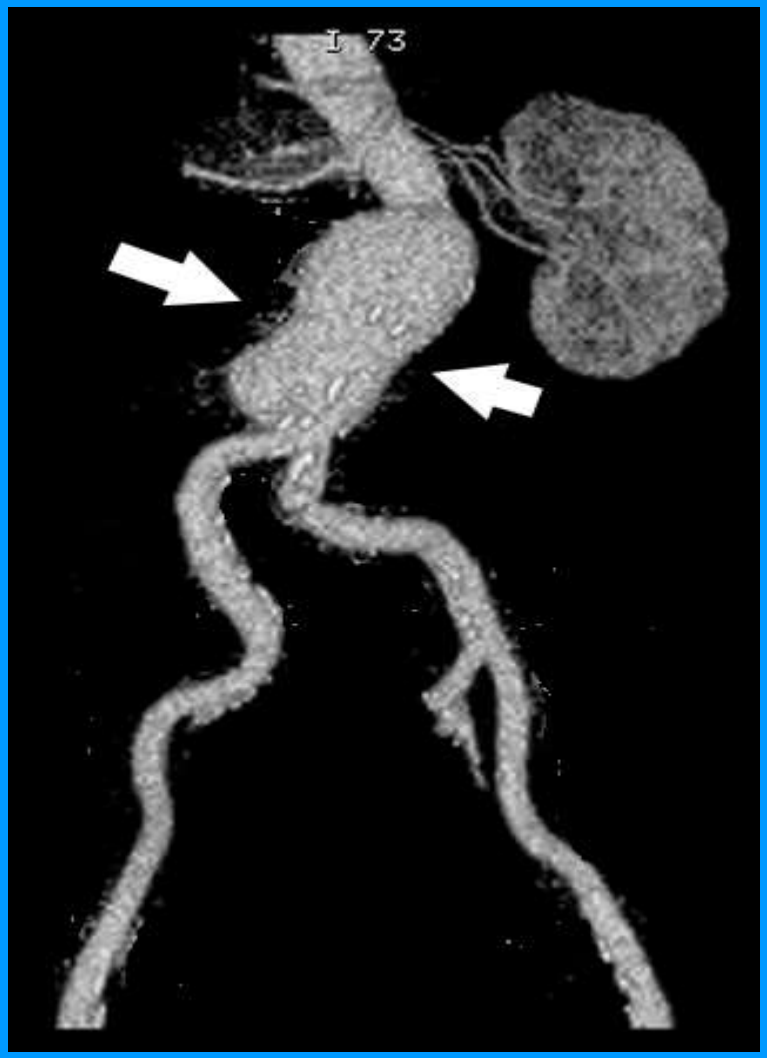
How to Fix an Aneurysm

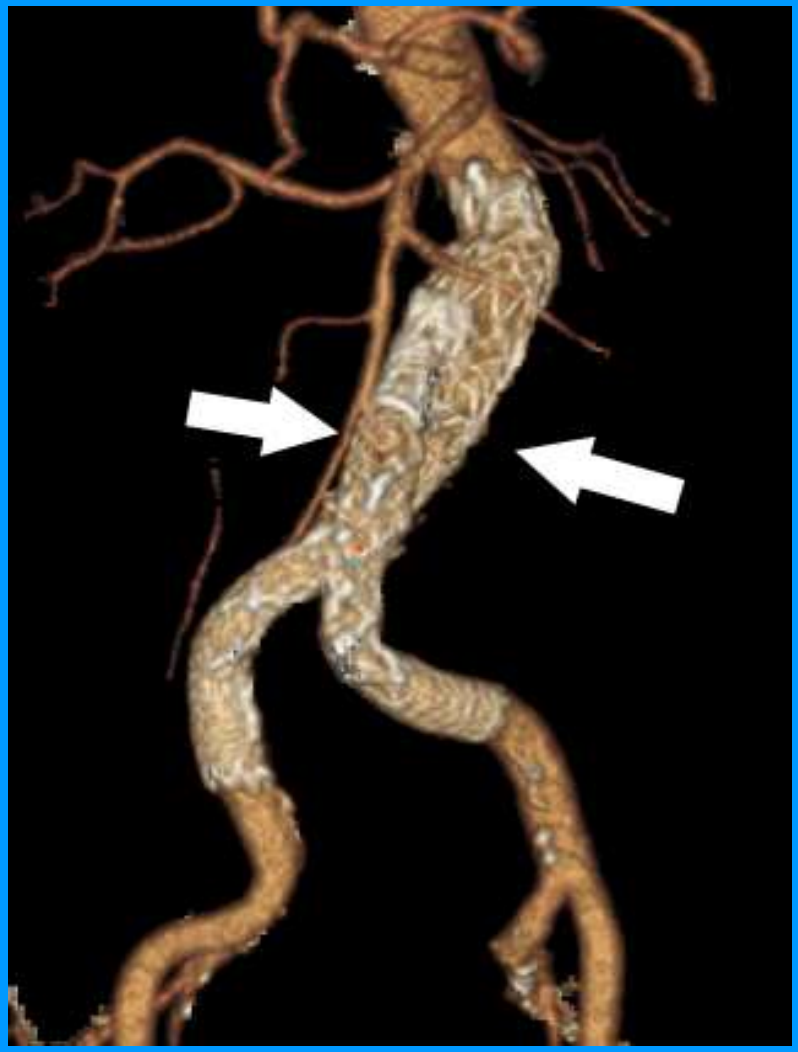


EVAR DEVICES

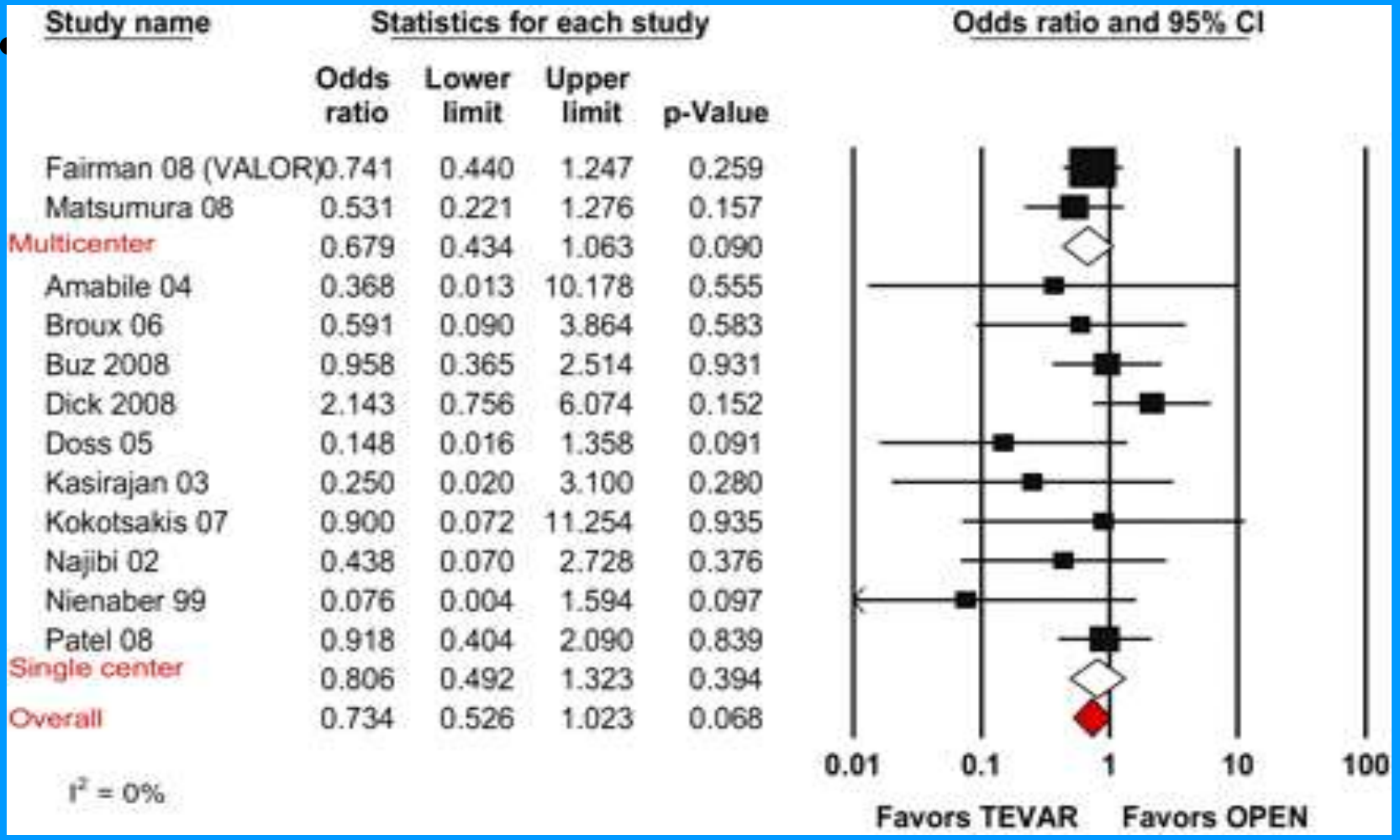


EVAR BEFORE AND AFTER RESULT





1 YEAR SURVIVAL

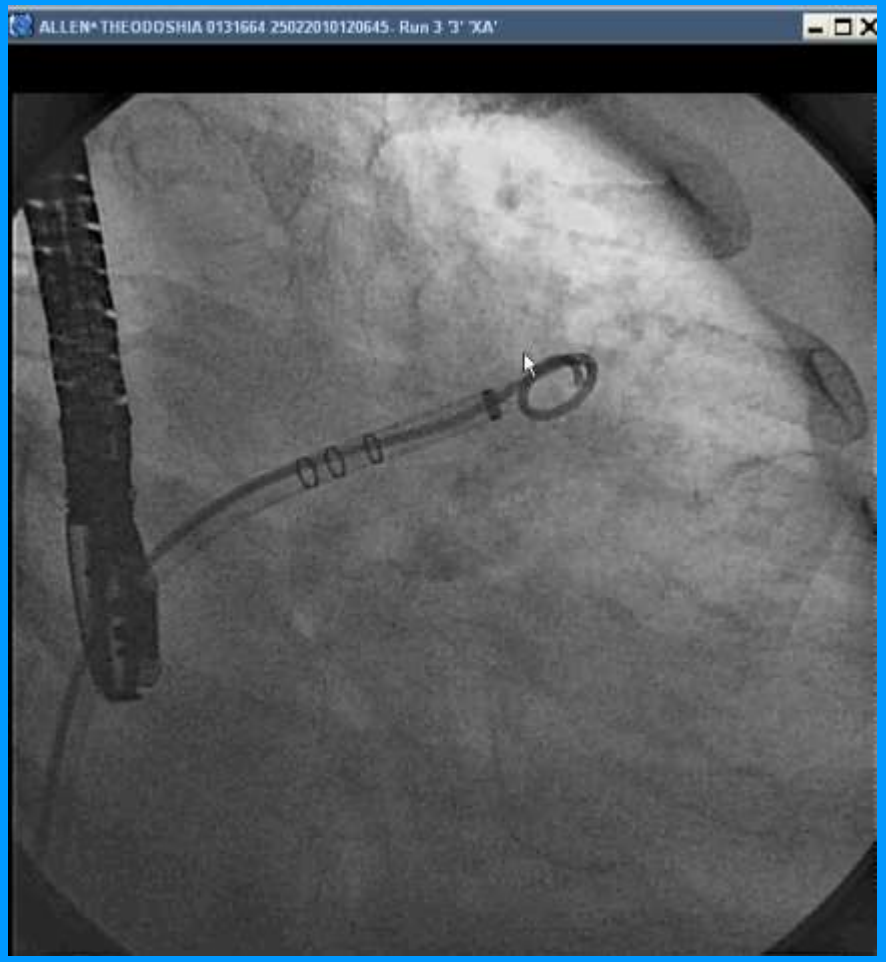


J Am Coll Cardiol, 2010; 55:986-1001

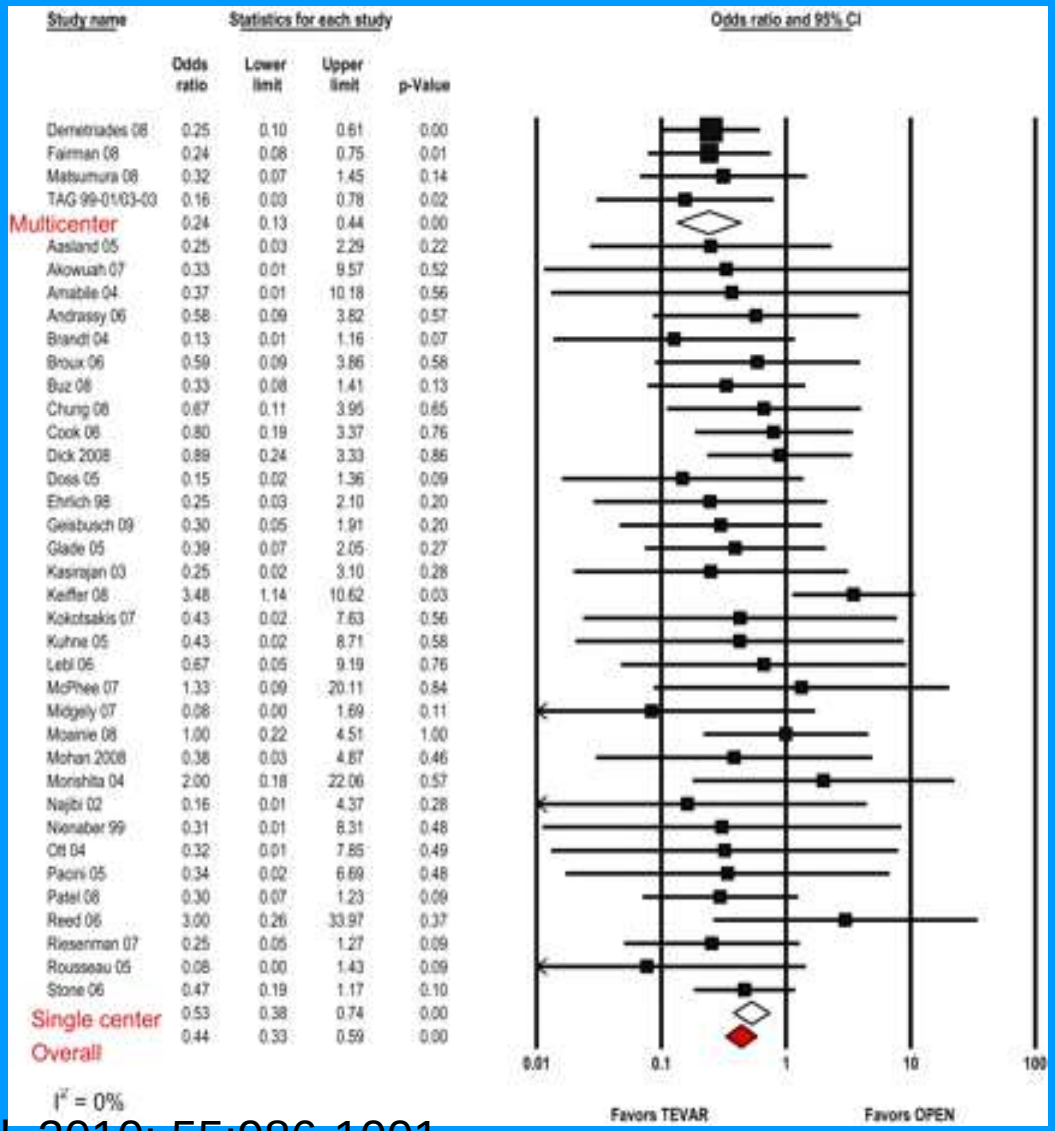
THE END

THANK YOU

LAA CLOSURE

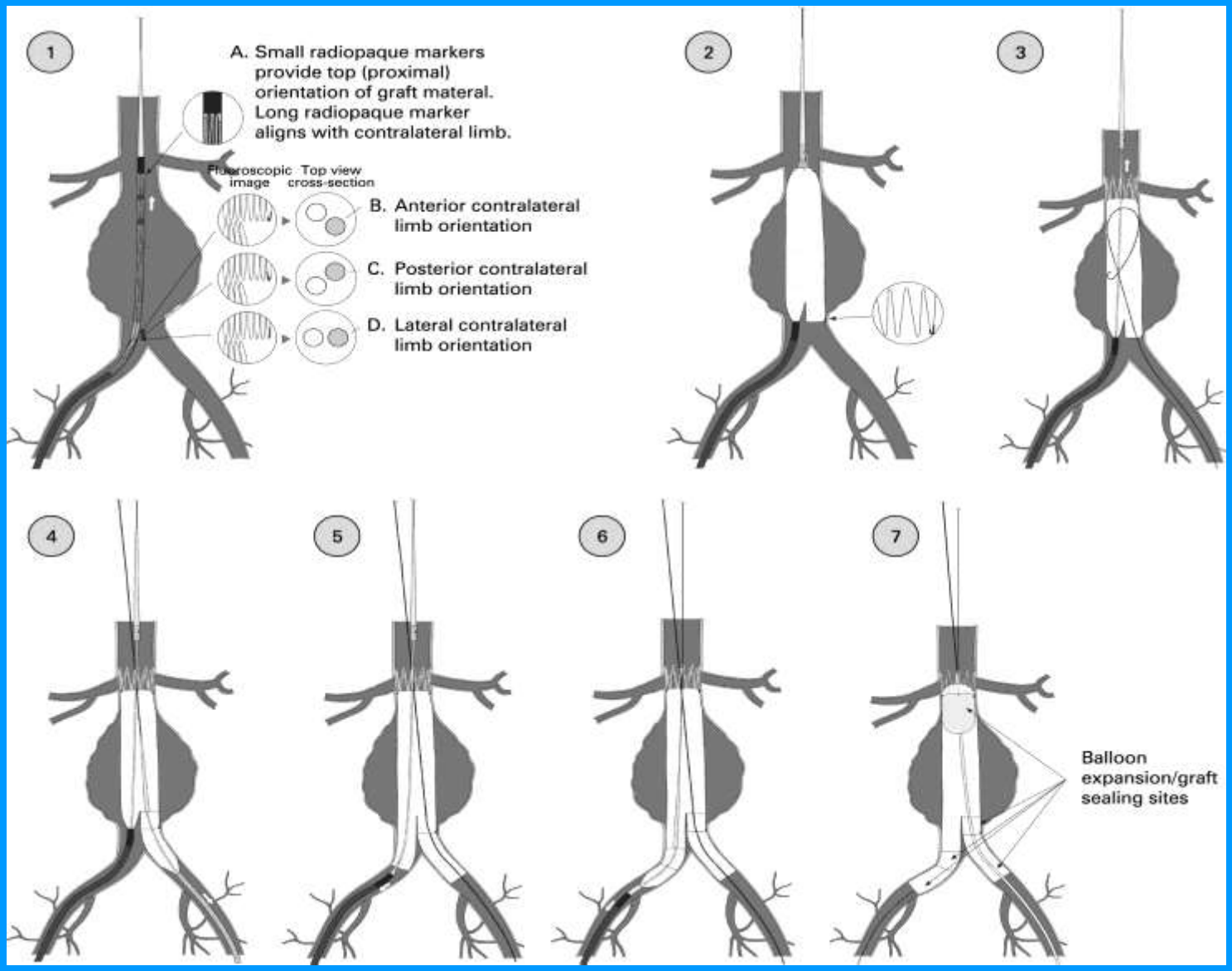


30 DAY SURVIVAL



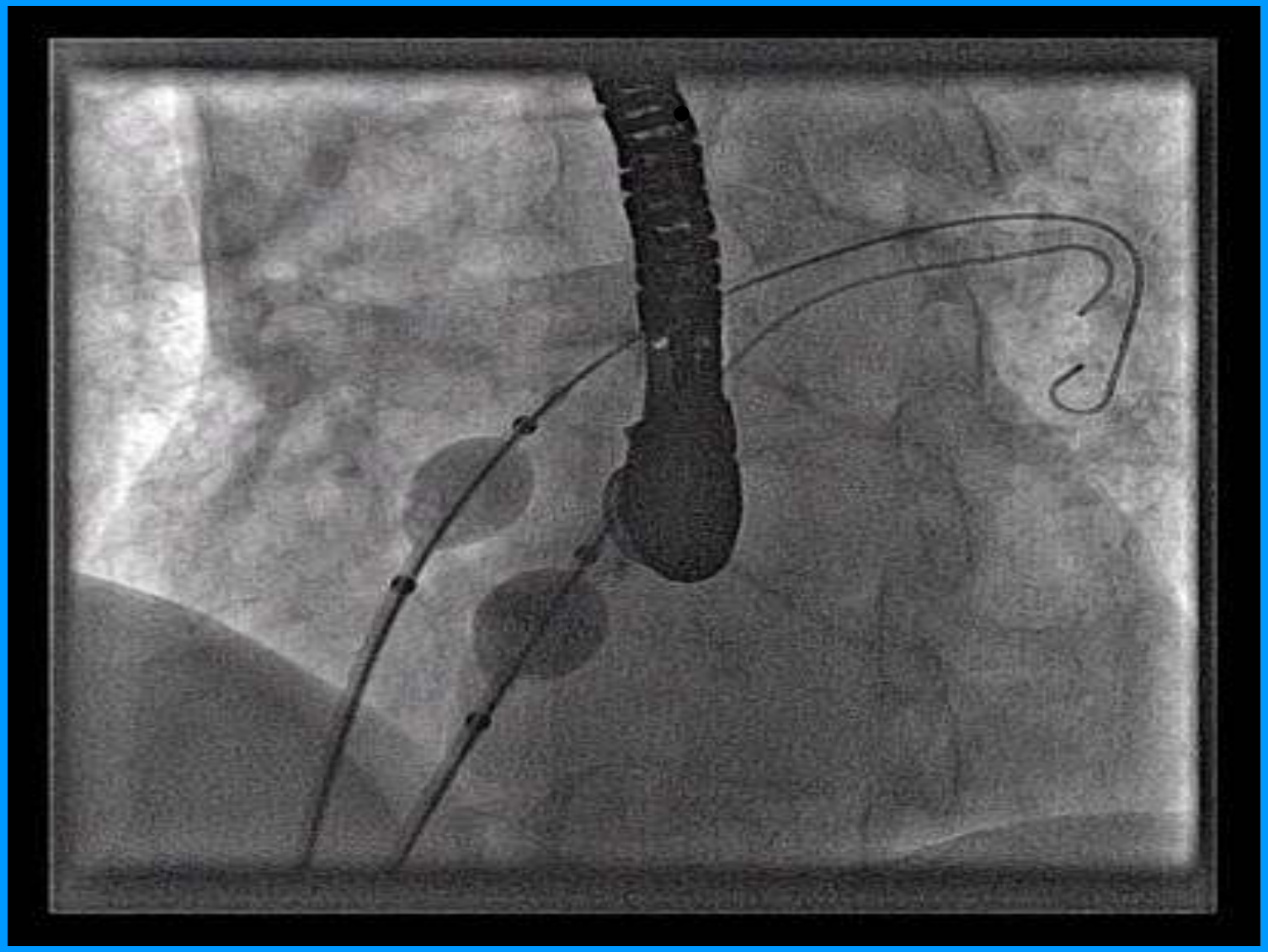
J Am Coll Cardiol, 2010; 55:986-1001

HOW TO FIX AN ANEURYSM

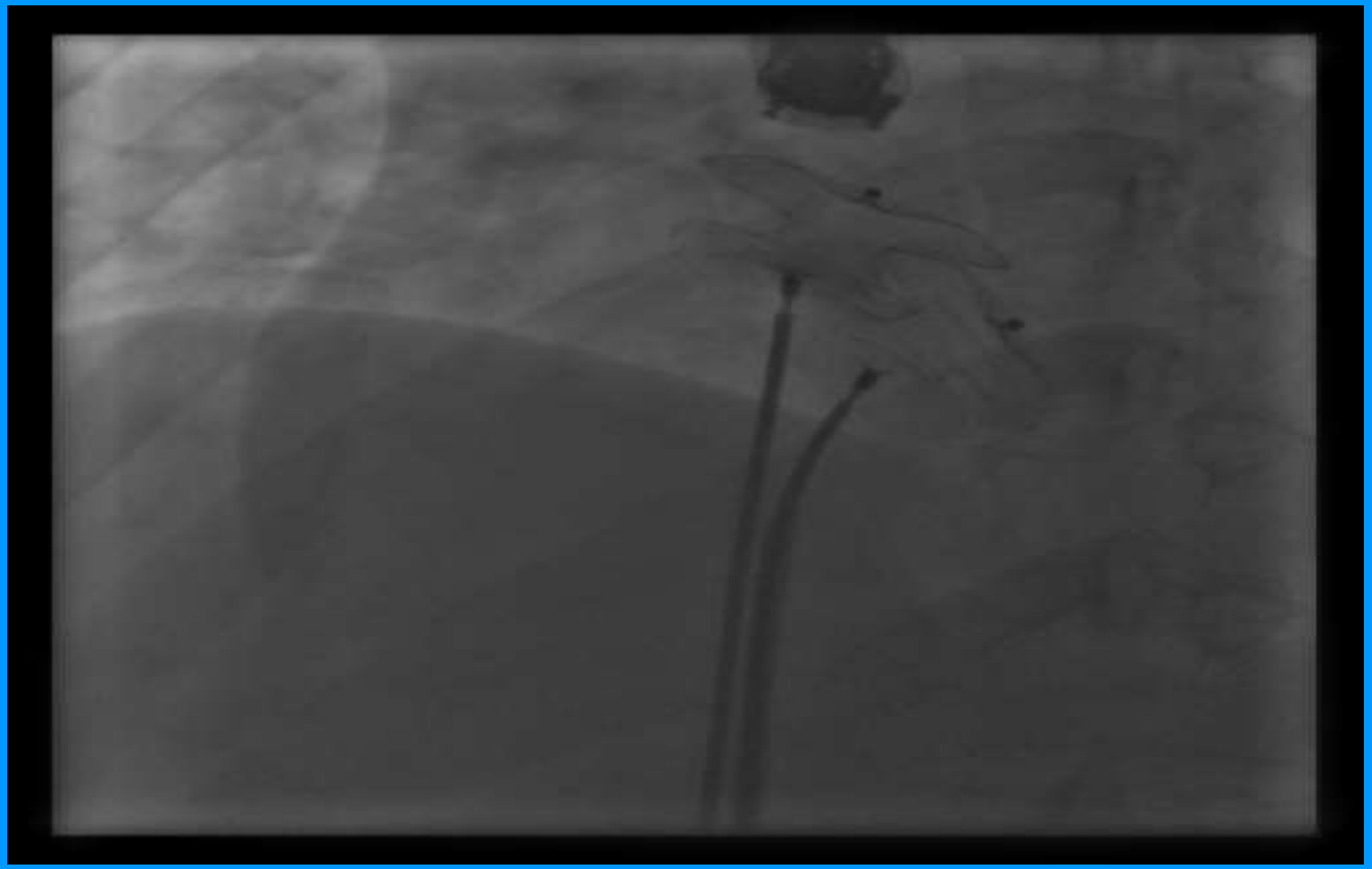



InnoTrak

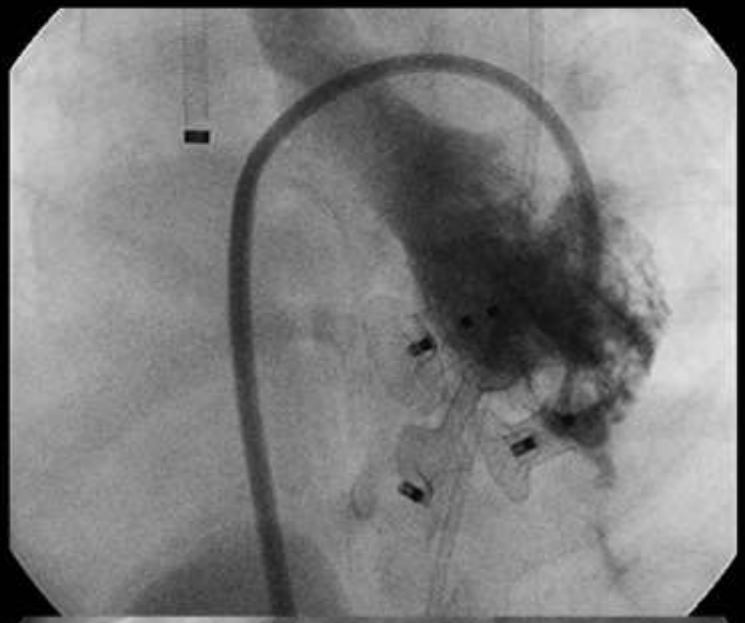
MULTIPLE ASD CLOSURE

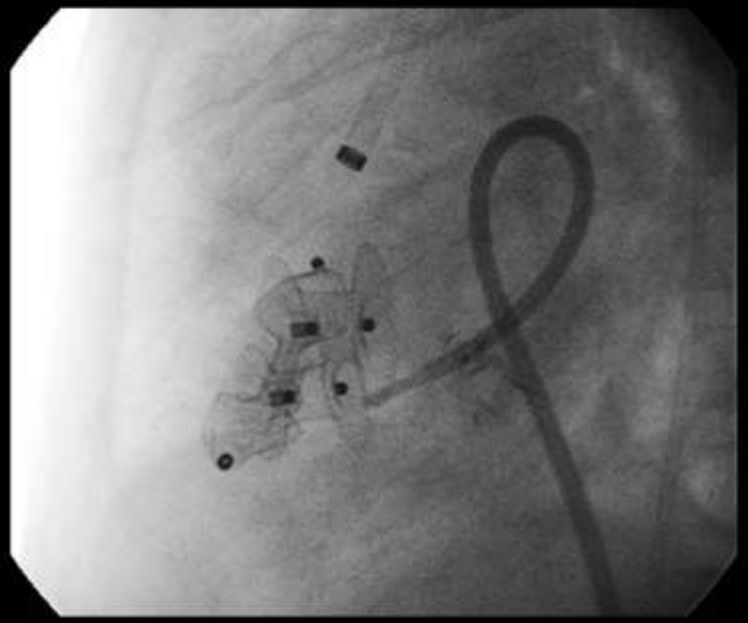


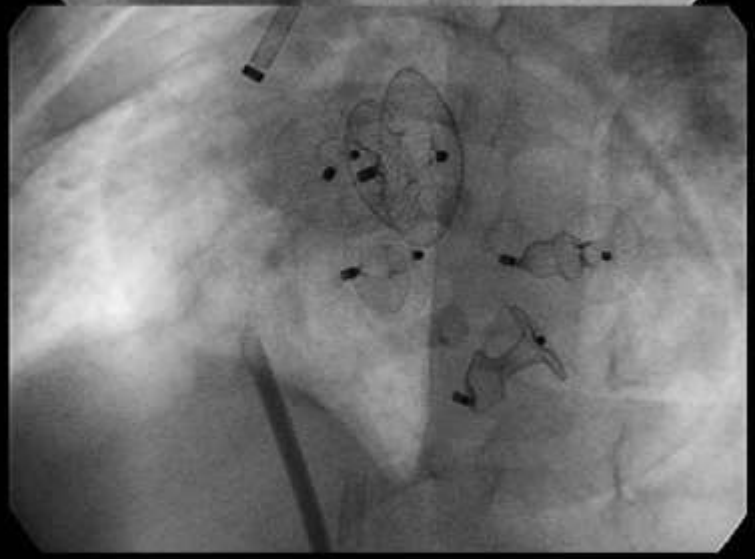
MULTIPLE ASD CLOSURE



Getting Carried Away ???





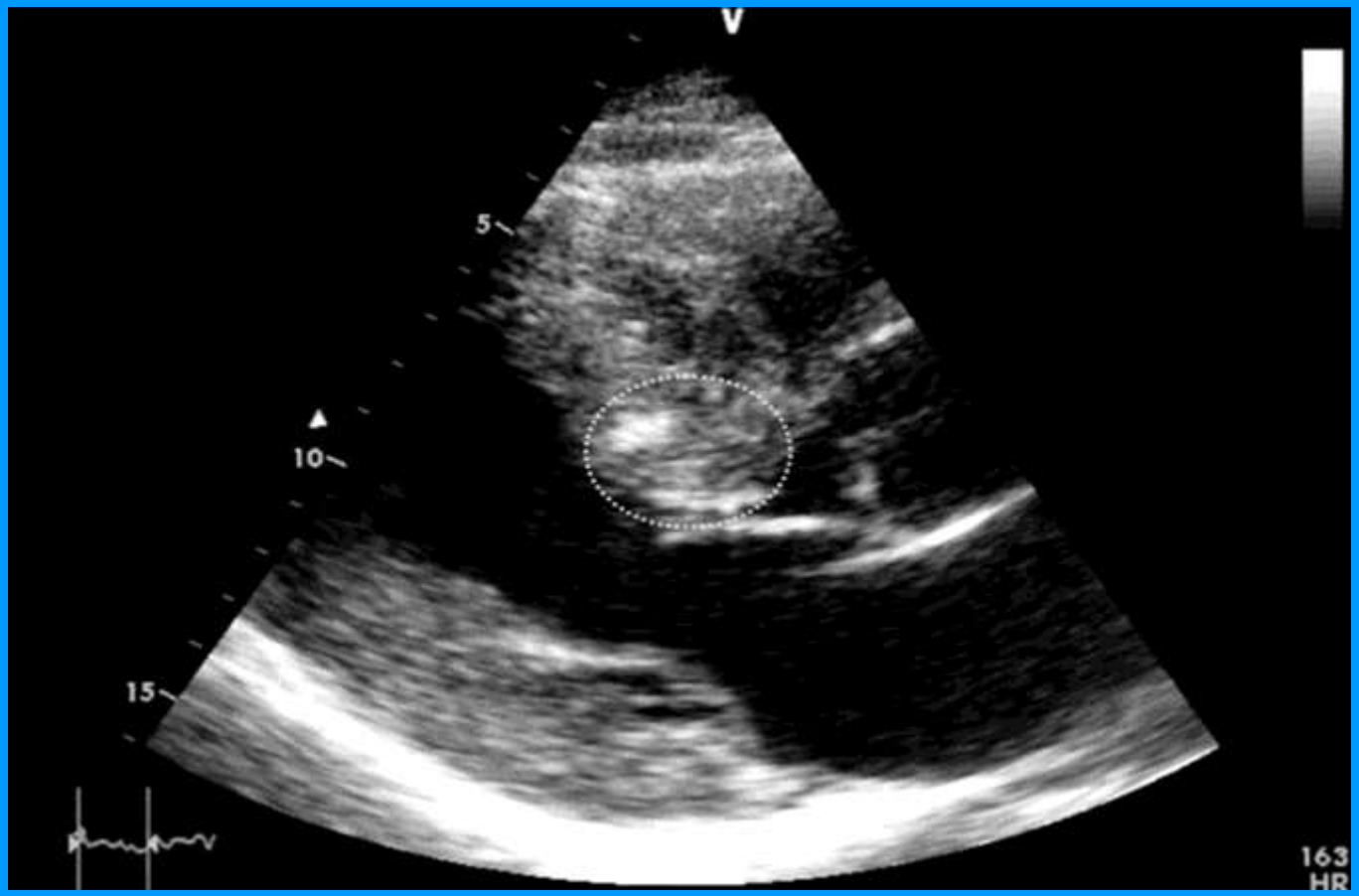


Two infants with Swiss Cheese VSDs

Top Panels: 11 mo/old with 8mm, 6mm, & 8mm AMVSDO

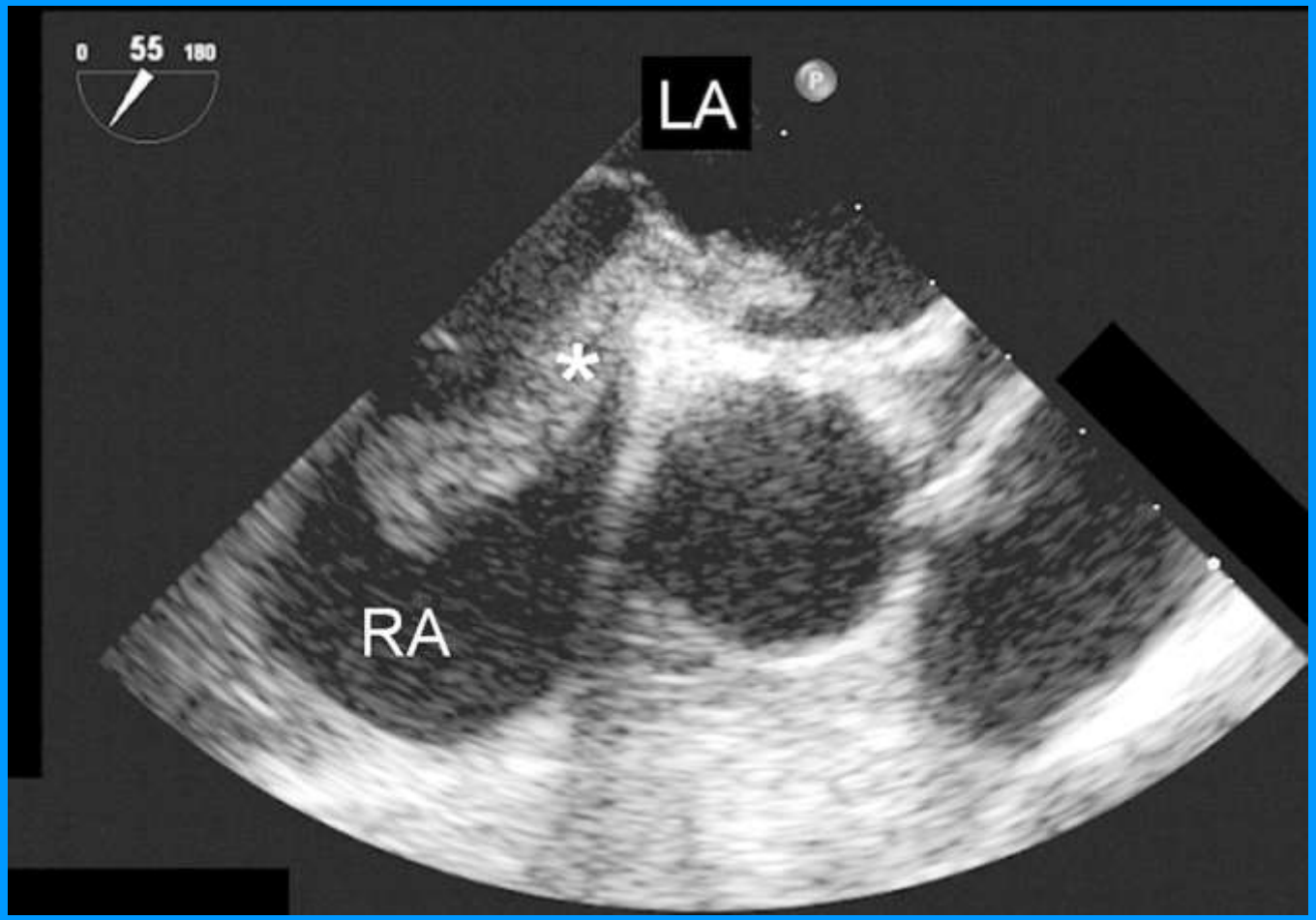
Left Panel: 2 y/o with 6mm & 8mm AMVSDO. Also has 3 ASOs: 11,9,& 6mm

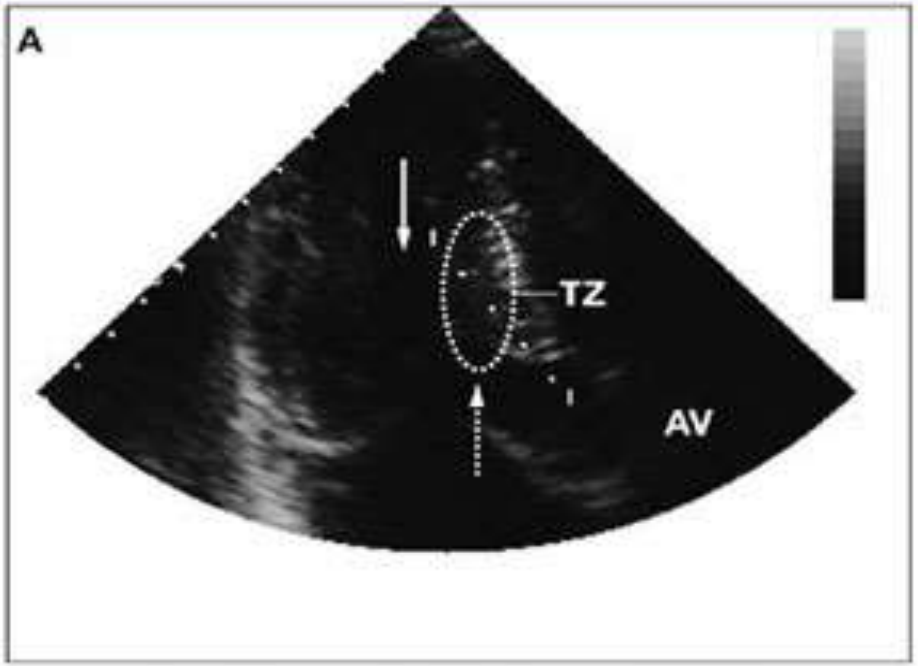
IHSS ECHO

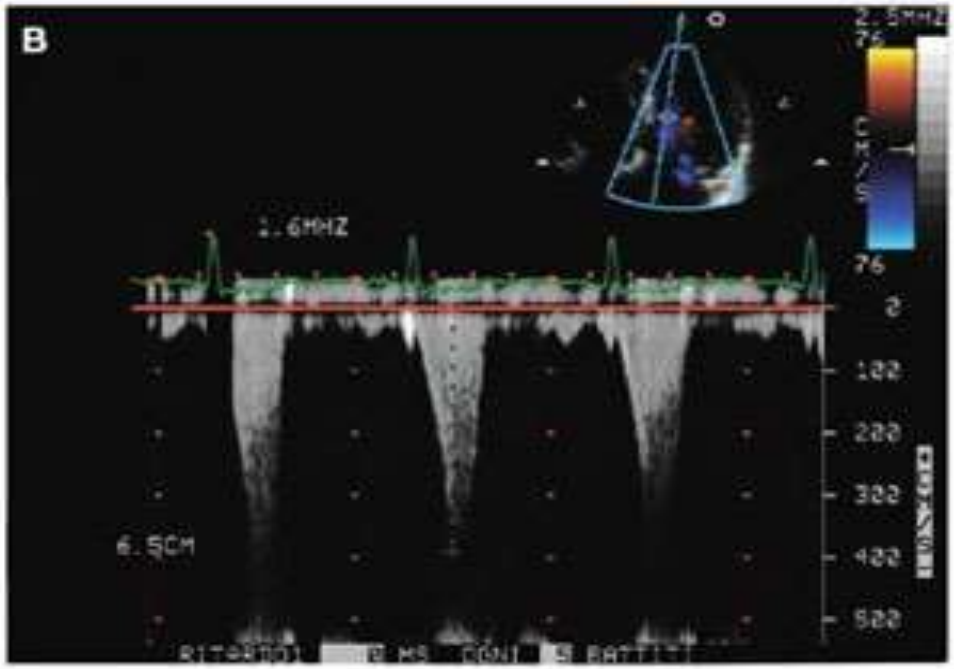


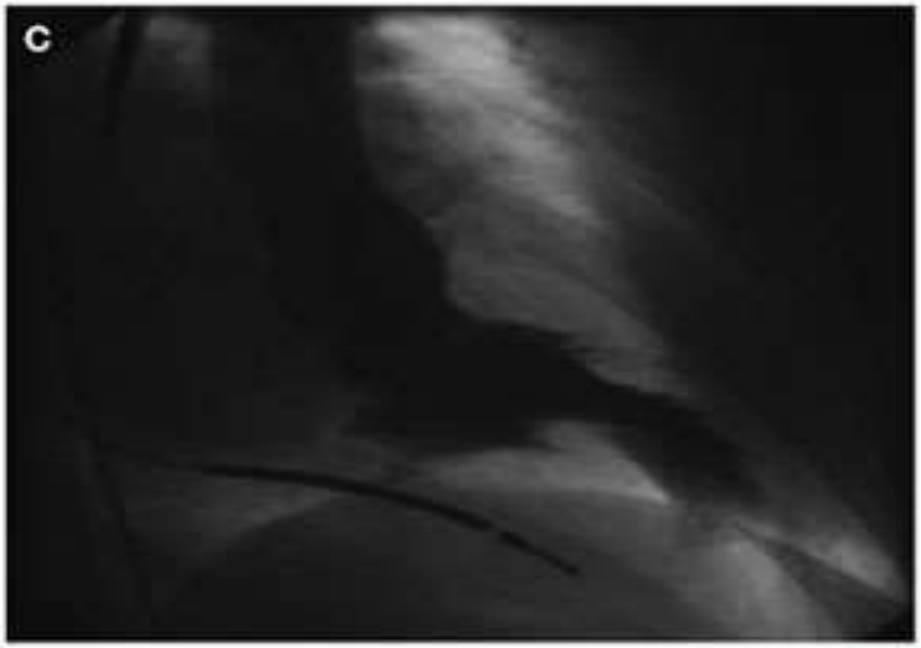
Heart 2006;**92:**1339-1344 doi:10.1136/hrt.2005.063677

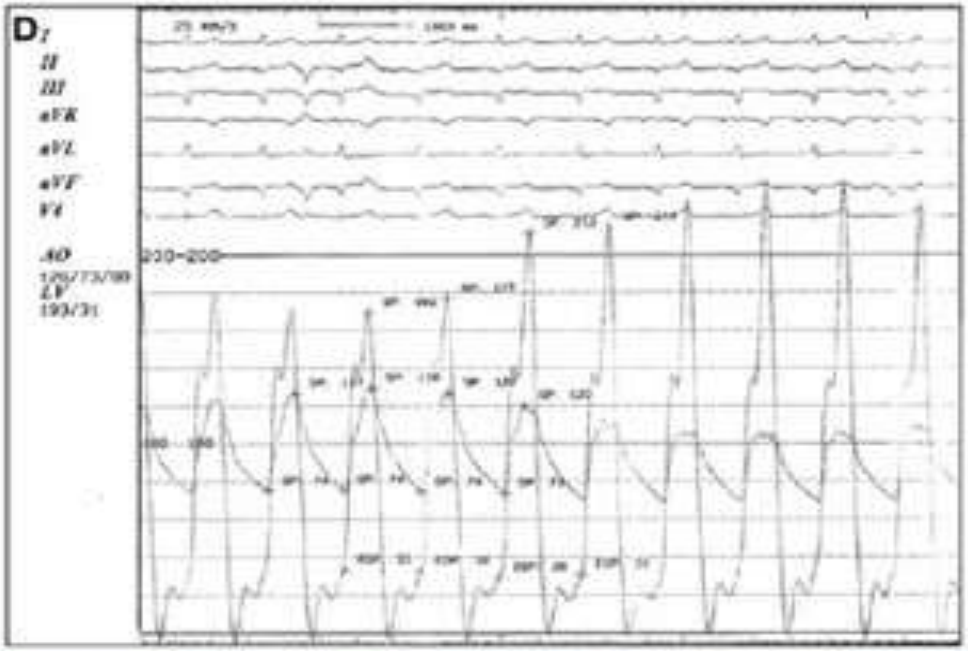
THROMBUS



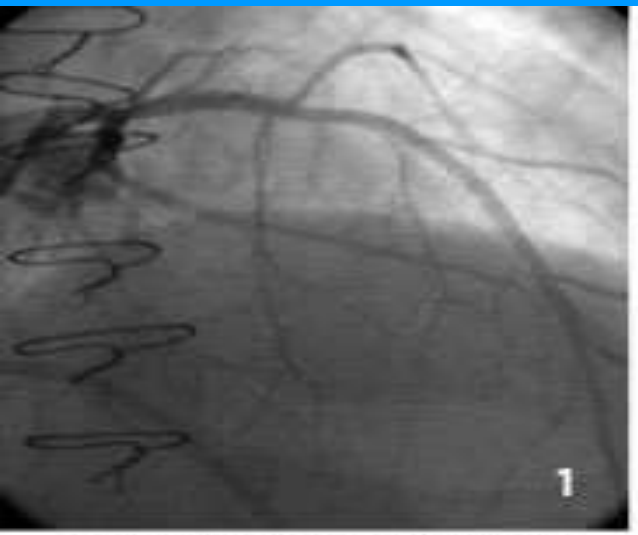




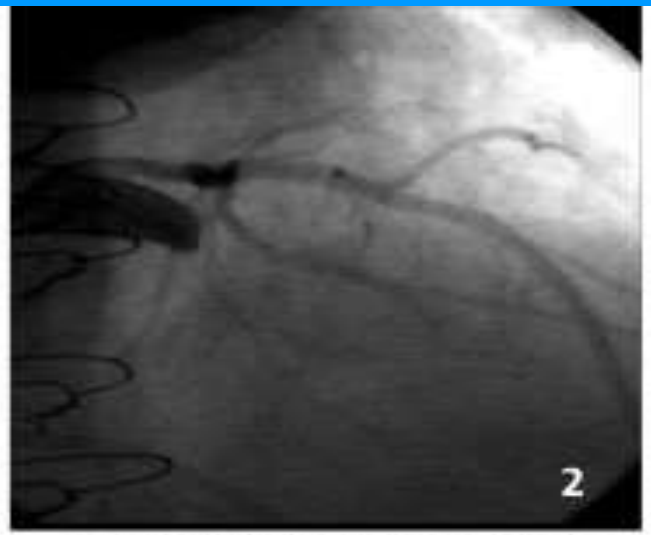




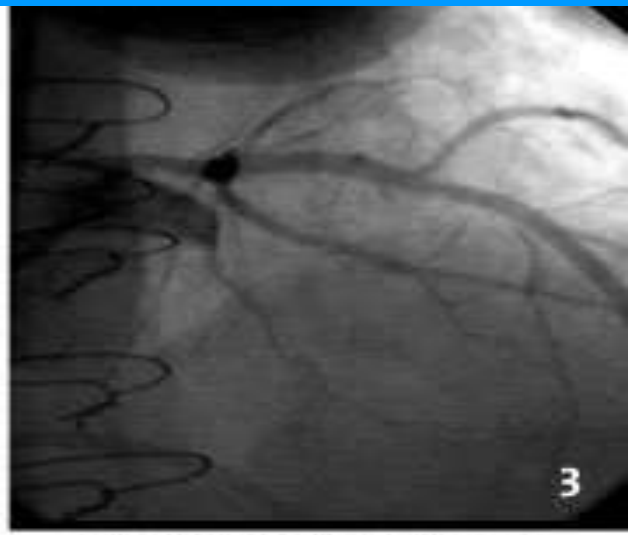
ALCOHOL SEPTAL ABLATION



1: Pre-ablation (septal artery visible)

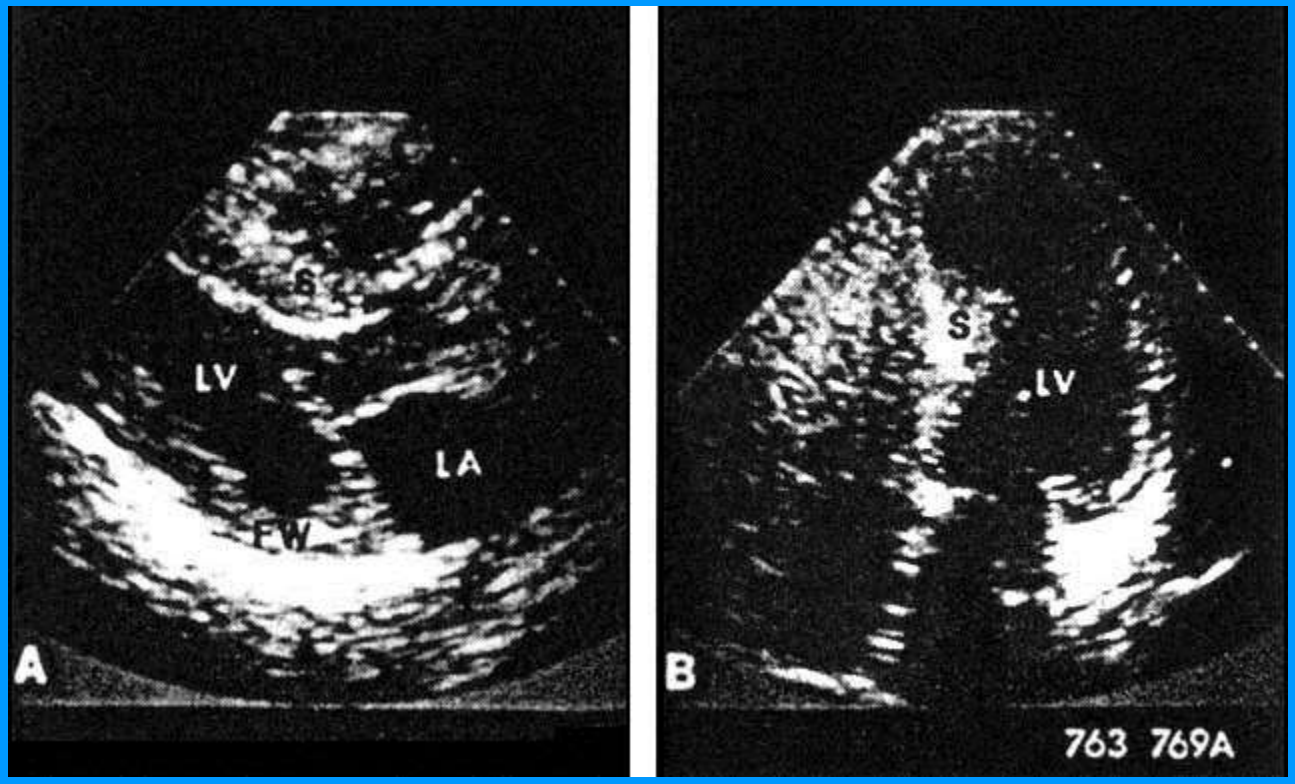


2: Ablation (balloon in septal artery)

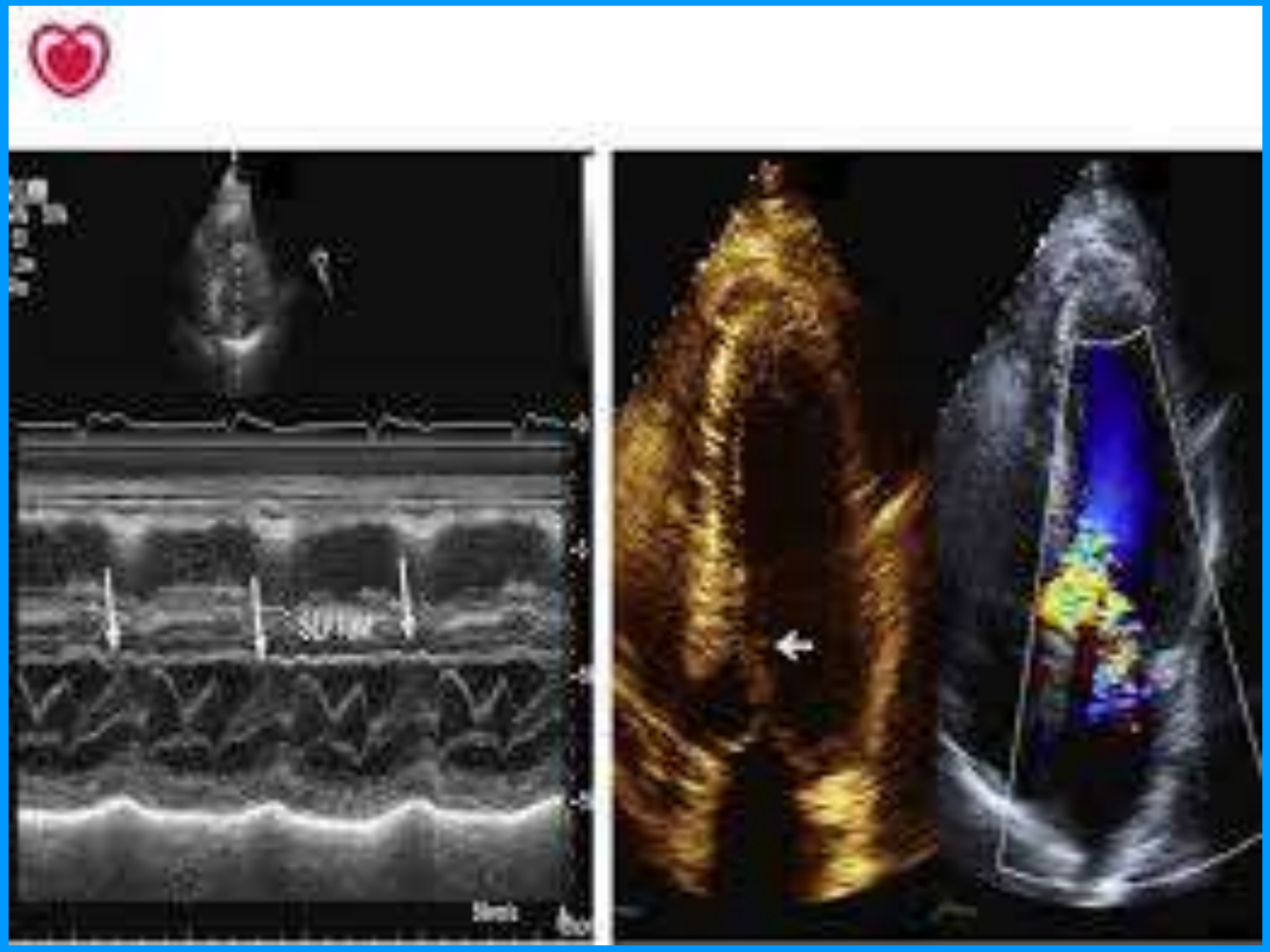


3: Post-ablation (septal artery no longer visible)

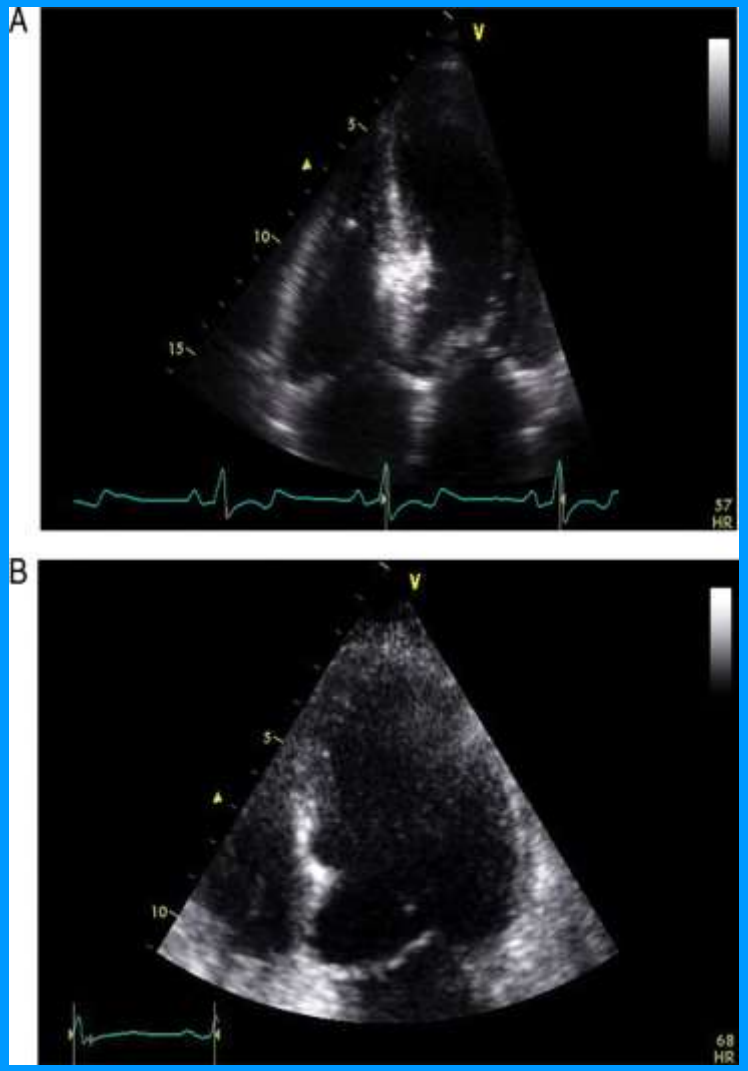
IHSS / SAM



IHSS - SAM

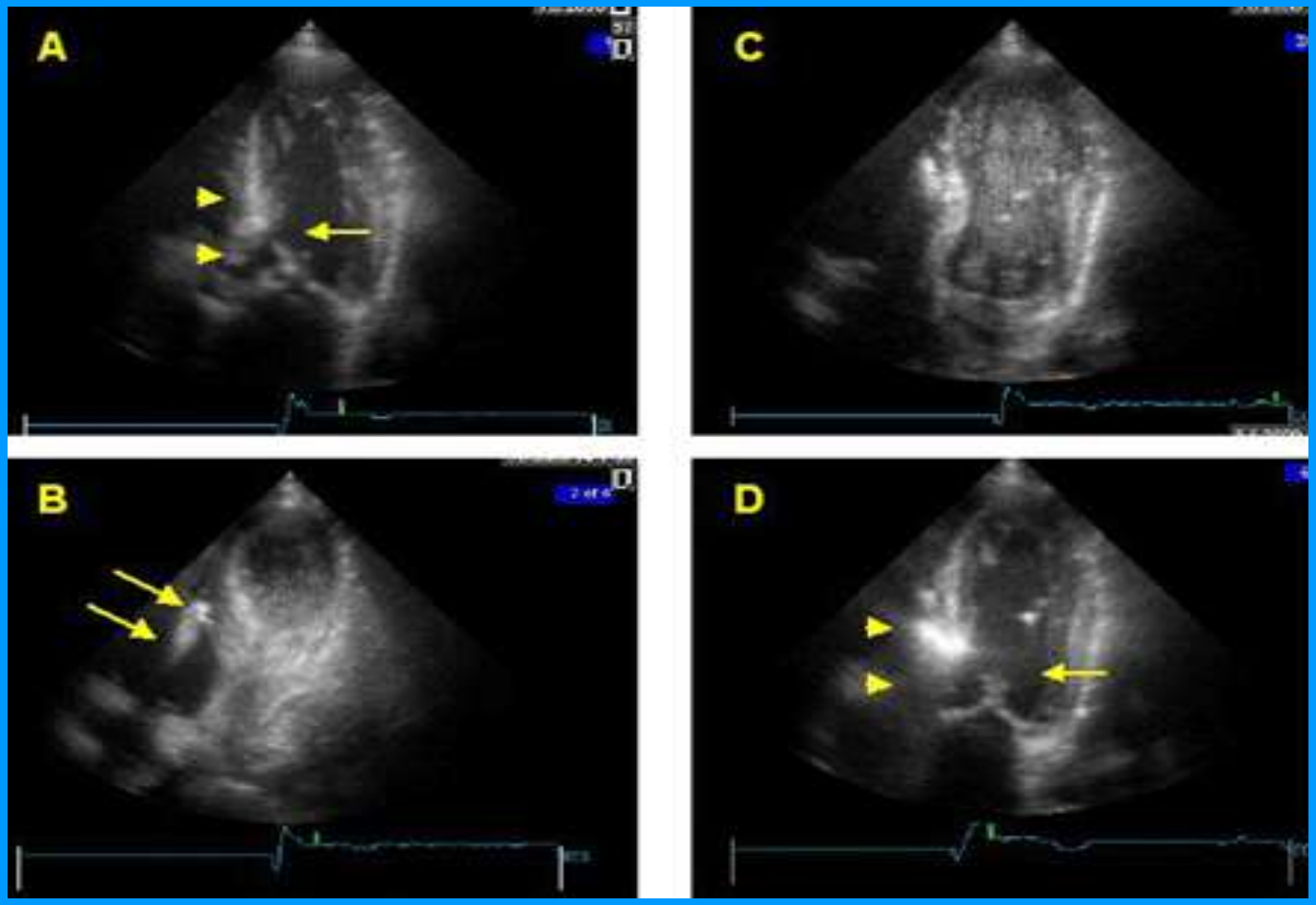


CONTRAST LOCALIZATION IHSS



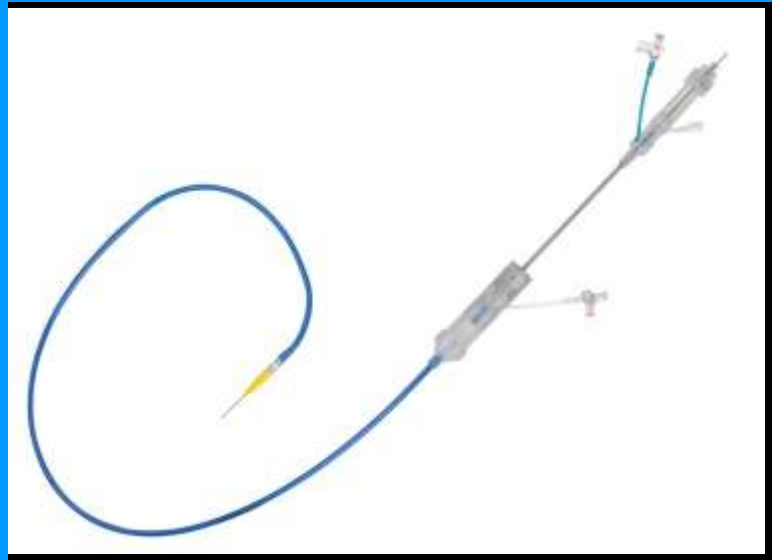
ejechocard.oxfordjournals.org/.../F4.expansion

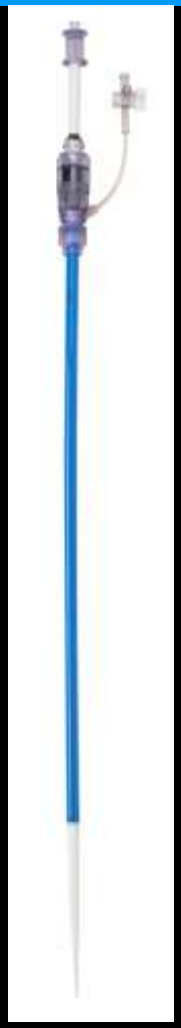
ABNORMAL LOCATION OF CONTRAST IN IHSS

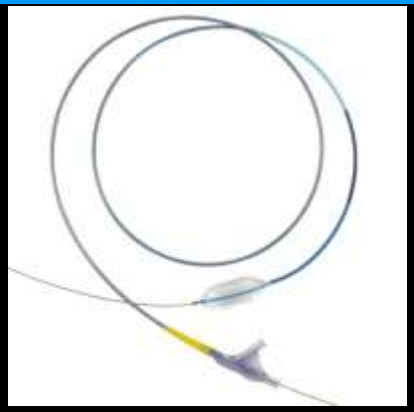


Eur J Echocardiogr October 1, 2004 vol. 5 no. 5 347-355

Edwards Lifesciences
RetroFlex® II
Transfemoral Delivery Kit



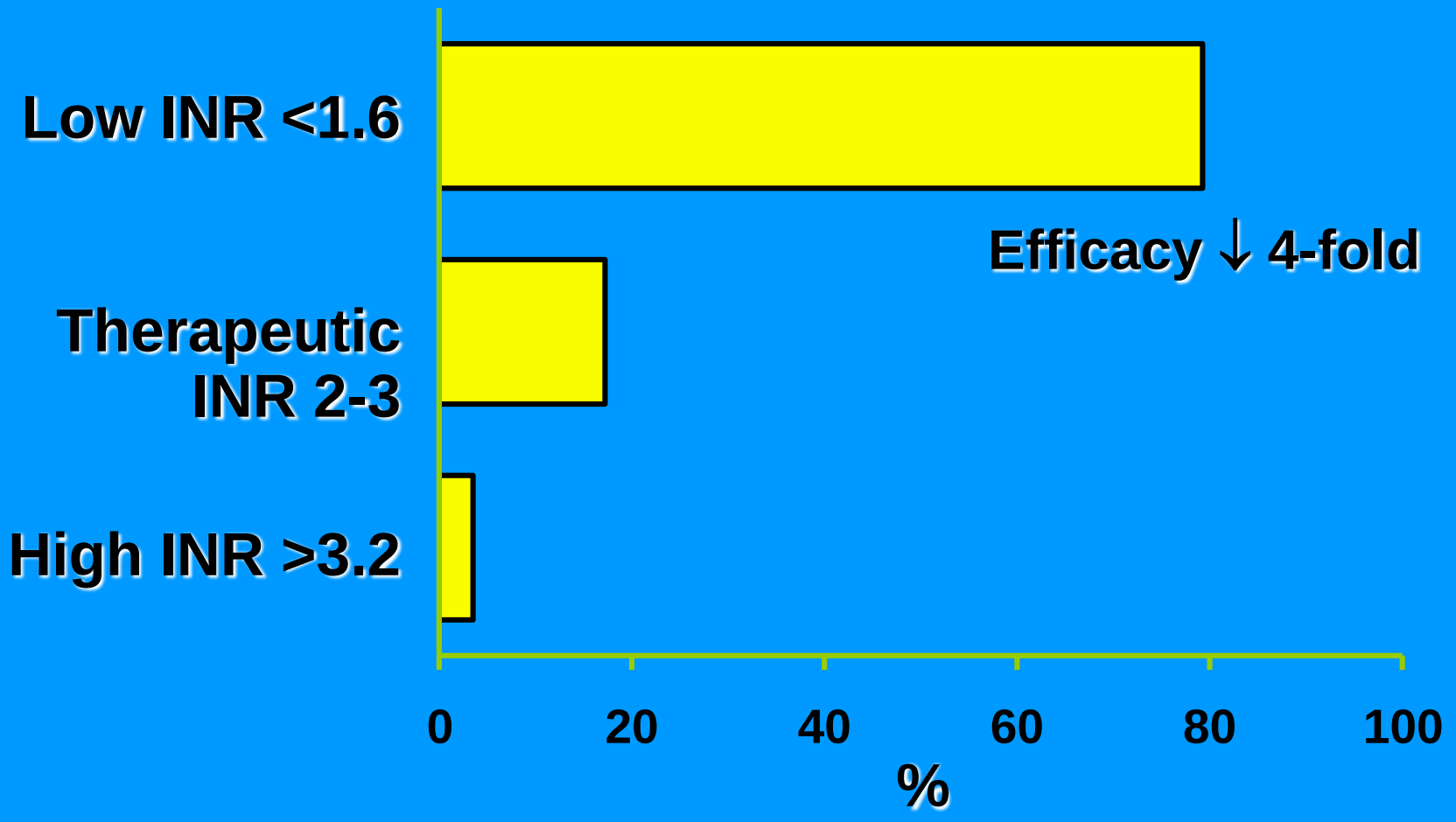




Update SEPT 2008

Non-Valvular Atrial Fibrillation

Adequacy of Anticoagulation in Clinic



Bungard: Pharmacotherapy 20:1060, 2001

Non-Valvular Atrial Fibrillation
Stroke Pathology

- Major fatal bleed with age >75 = 3%/year (30% over 10 years)
- Intracranial hemorrhage
  - 0.3-0.5%/100 patient-years
  - 3% in INR >4.0
  - 10% if INR >4.5

Brass. Stroke 28(12), 1997
VanWalraven: JAMA 288, 2002

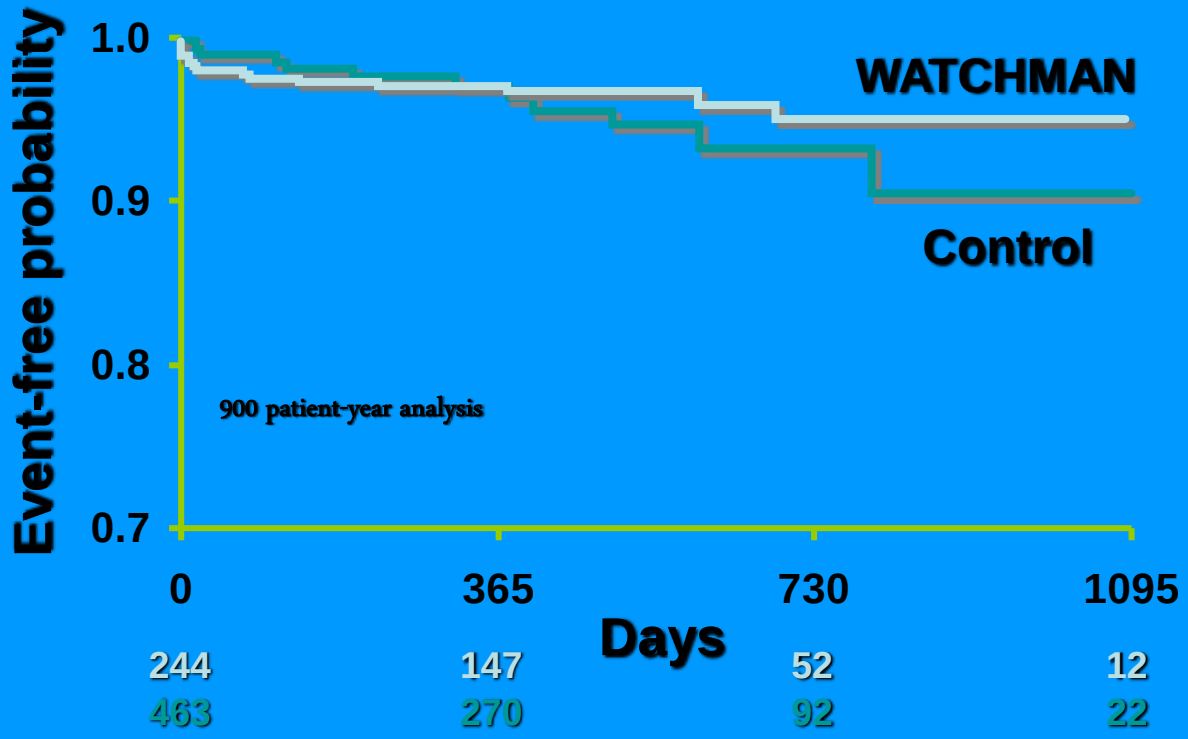
Non-Valvular Atrial Fibrillation
Stroke Pathology

- Insufficient contraction of LAA leads to stagnant blood flow
- Culprit: embolization of LAA clot
- 90% of thrombus found in LAA
- TEE-based risk factors
  - Enlarged LAA
  - Reduced inflow and outflow velocities
  - Spontaneous Echo contrast

Johnson: Eur J Cardiothoracic Surg 17, 2000
Fagan: Echocardiography 17, 2000

Intent-to-Treat
All Stroke

	Device			Control				Posterior probabilities	
Cohort	Events eve	Total pt-yr	Rate (95% CI)	Events (no.)	Total pt-yr	Rate (95% CI)	RR (95% CI)	Non-inferiority	Superiority
600 pt-yr	14	409.3	3.4 (1.9, 5.5)	8	223.6	3.6 (1.5, 6.3)	0.96 (0.43, 2.57)	0.927	0.488
900 pt-yr	15	582.9	2.6 (1.5, 4.1)	11	318.1	3.5 (1.7, 5.7)	0.74 (0.36, 1.76)	0.998	0.731



Randomization allocation (2 device:1 control)

ITT cohort: Non-inferiority criteria met

PROTECT AF Summary

- PROTECT AF trial was a randomized, controlled, statistically valid study to evaluate the WATCHMAN device compared to warfarin
- hemorrhagic stroke risk is significantly lower with the device (91%).
- All cause stroke and all cause mortality risk are equivalent to that with warfarin (26 and 39%)
- Early safety events, specifically pericardial effusion.

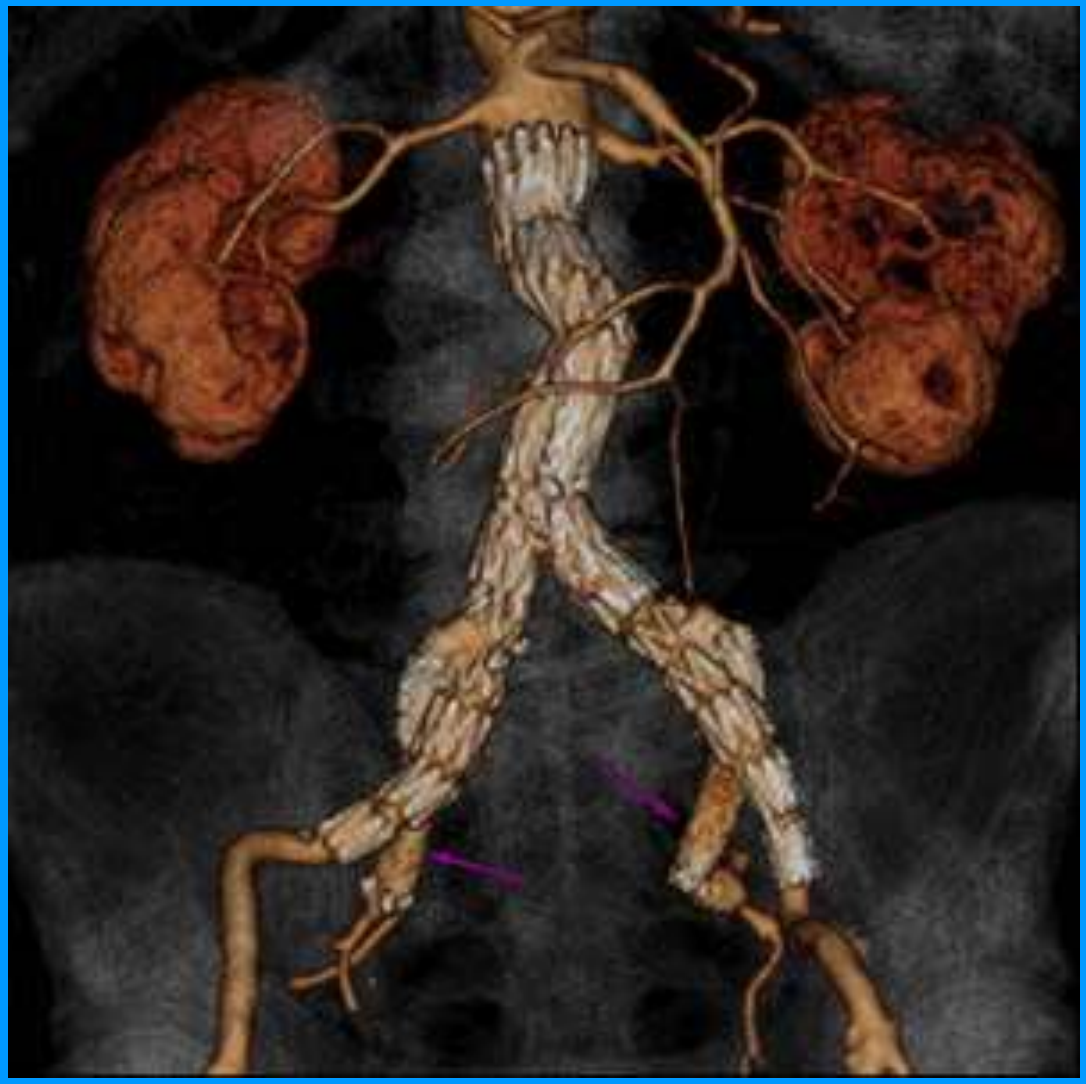
Specific Safety Endpoint Events

- Pericardial effusions – largest fraction of safety events in device group
- Stroke events – most serious fraction of safety events in control group
- Bleeding events were also frequent

FDA SAFETY DATA

- **Major Safety End Points:**
  - **AF (%) CAP (%) p**
- **Procedure/device-related events at 7 d**
  7.7 3.7 .007
- **Serious pericardial effusions at 7 d**
  5.0 2.2 .019
- **Procedure-related stroke**
- 0.9 0.0 .039

EVAR RESULT



EVEREST II Randomized Clinical Trial

Key Inclusion/Exclusion Criteria

Inclusion

- Candidate for MV Surgery
- Moderate to severe (3+) or severe (4+) MR
  - Symptomatic
    - >25% EF & LVESD ≤55mm
  - Asymptomatic with one or more of the following
    - LVEF 25-60%
    - LVESD ≥40mm
    - New onset atrial fibrillation
    - Pulmonary hypertension

ACC/AHA Guidelines
JACC 52:e1-e142, 2008

Exclusion

- AMI within 12 weeks
- Need for other cardiac surgery
- Renal insufficiency
  - Creatinine >2.5mg/dl
- Endocarditis
- Rheumatic heart disease
- MV anatomical exclusions
  - Mitral valve area <4.0cm^2
  - Leaflet flail width (≥15mm) and gap (≥10mm)
  - Leaflet tethering/coaptation depth (>11mm) and length (<2mm)

EVEREST II Randomized Clinical Trial

Primary Endpoints

Safety

- Major Adverse Event Rate at 30 days
- Per protocol cohort
- Superiority hypothesis

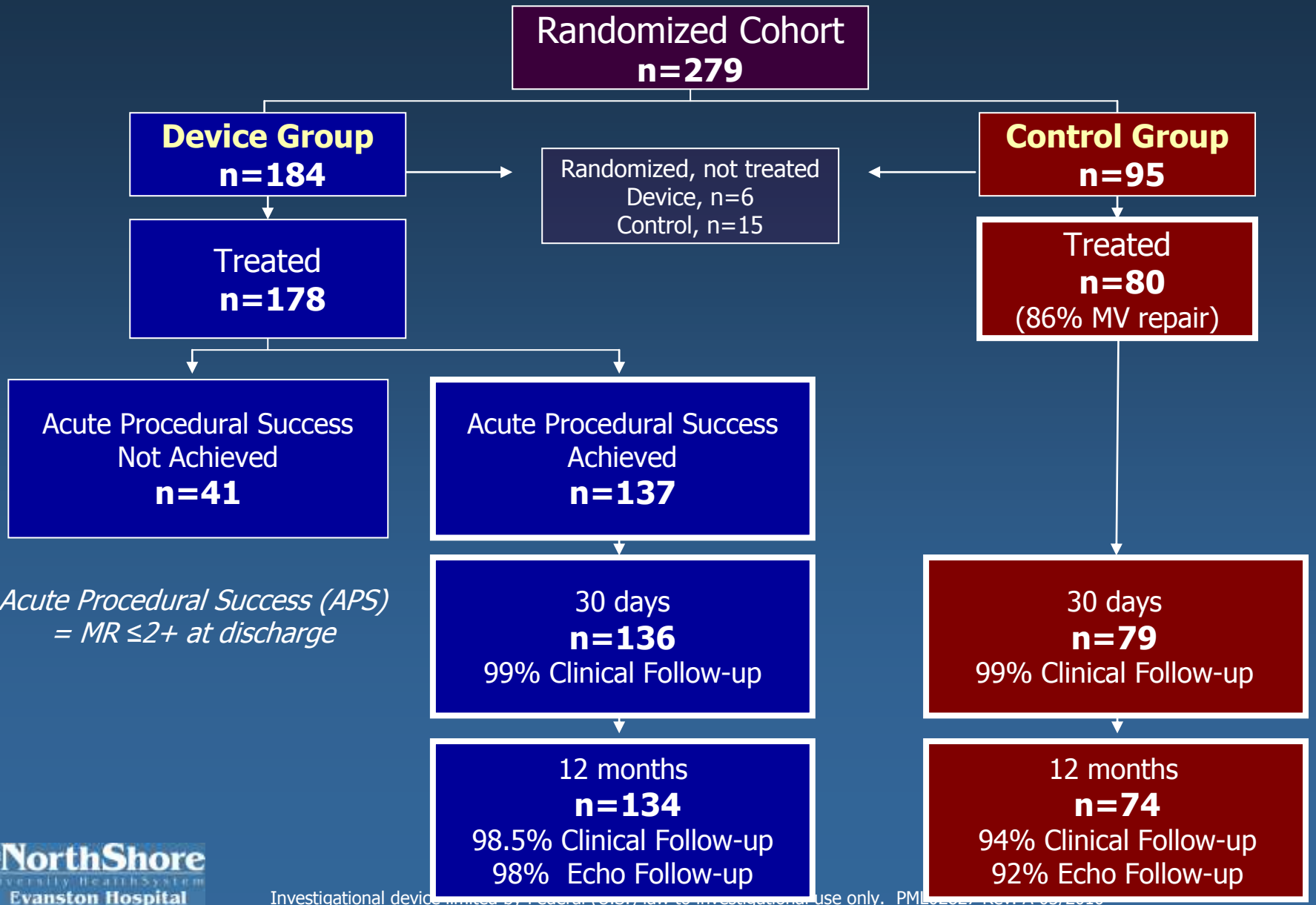
Effectiveness

- Clinical Success Rate
  - Freedom from the combined outcome of
    - Death
    - MV surgery or re-operation for MV dysfunction
    - MR >2+ at 12 months
- Per protocol cohort
- Non-inferiority hypothesis

Pre-Specified MAEs
Death
Major Stroke
Re-operation of Mitral Valve
Urgent / Emergent CV Surgery
Myocardial Infarction
Renal Failure
Deep Wound Infection
Ventilation >48 hrs
New Onset Permanent Atrial Fib
Septicemia
GI Complication Requiring Surgery
All Transfusions ≥2 units

EVEREST II RCT: Patient Flow

Per Protocol Cohort: Analysis of Device Performance



Acute Procedural Success (APS)
= MR ≤2+ at discharge

EVEREST II RCT: Summary

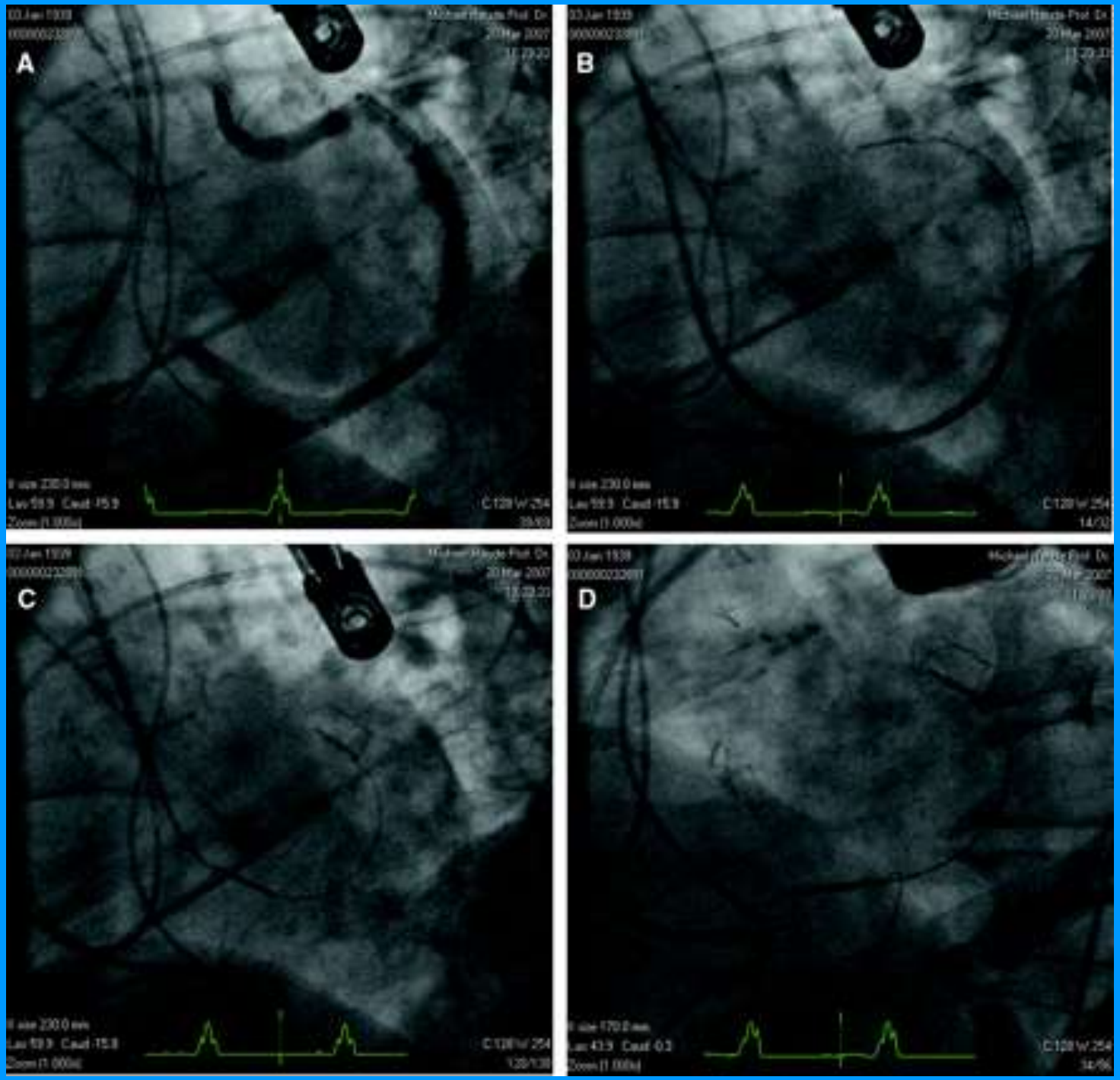
- Safety & effectiveness endpoints met
  - Safety: MAE rate at 30 days
    - MitraClip device patients: 9.6%
    - MV surgery patients: 57%
  - Effectiveness: Clinical Success Rate at 12 months
    - MitraClip device patients: 72%
    - MV Surgery patients: 88%
- Clinical benefit demonstrated for MitraClip System and MV surgery patients through 12 months
    - Improved LV function
    - Improved NYHA Functional Class
    - Improved Quality of Life
- Surgery remains an option after the MitraClip procedure

MITRAL ANNULOPLASTY

- Percutaneous Mitral Annuloplasty for Functional Mitral Regurgitation: **:**
- **This was a single-arm evaluation of percutaneous mitral annuloplasty performed via the coronary sinus with the CARILLON Mitral Contour System.**
- **Patients with dilated cardiomyopathy, moderate to severe functional mitral regurgitation (MR), an ejection fraction <40%, and a 6-minute walk distance between 150 and 450 m were enrolled in the study.**
- **The outcome measures were echocardiographic MR grade, exercise tolerance, New York Heart Association class, and quality of life, and they were assessed at baseline and 1 and 6 months.**

- *Circulation 2009;120:326-333.*

MITRAL ANNULOPLASTY RING


A
B
C
D

MITRAL ANNULOPLASTY

- **The study enrolled 48 patients,**
- **18 did not receive the device.**
- **Of the 18 patients, 3 had coronary sinus perforation or dissection. In 13 patients, the device was recaptured due to slippage of the distal anchor (n = 3) and due to coronary artery compromise or insufficient reduction in MR (n = 10).**
- **1 patient died during follow-up and there were 3 myocardial infarctions in the periprocedural phase. No device migration or late infarctions were seen. The major adverse event rate was 13% at 30 days.**
- **At 6 months, the severity of MR reduction on quantitative echocardiographic measures ranged from 22% to 32%. There was significant improvement in the 6-minute walk distance (from 307 m at baseline to 403 m at 6 months, $p < 0.001$) and quality of life, measured by the Kansas City Cardiomyopathy Questionnaire (47 ± 16 points at baseline to 69 ± 15 points at 6 months, $p < 0.001$).**

MITRAL ANNULOPLASTY

- **The study demonstrates safety, efficacy, and feasibility of percutaneous mitral annuloplasty.**
- **The initial enthusiasm for coronary sinus–based percutaneous mitral annuloplasty waned once the variability in the relation of coronary sinus to the mitral annulus and the risk of coronary artery compromise were recognized .**
- **This study is provocative since the procedure was performed with reasonable safety, and there are some data to suggest efficacy in reducing MR and improvement in clinical status. This is a rapidly evolving field, and further refinement in the device and better preprocedural imaging will further improve safety and reduce the number of unsuccessful procedures. Larger controlled studies will be warranted to confirm the clinical improvement and assess long-term implications of percutaneous mitral annuloplasty before it can be used in routine clinical practice.**