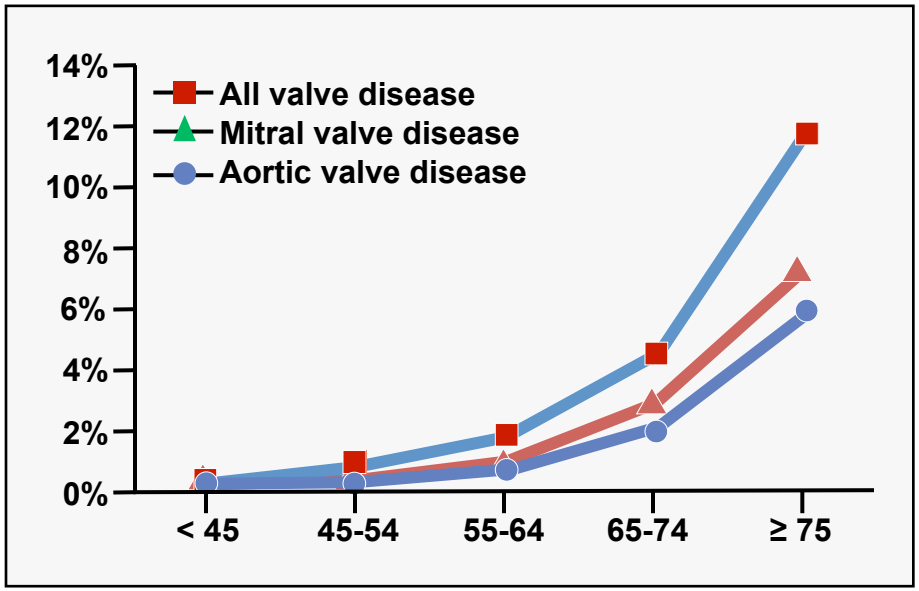
Cardiologie Structurelle Valvulaire Aortique et Mitrale MitraClip AsPeCAF 2017

Prof. Patrizio LANCELLOTTI , MD, PhD, FESC

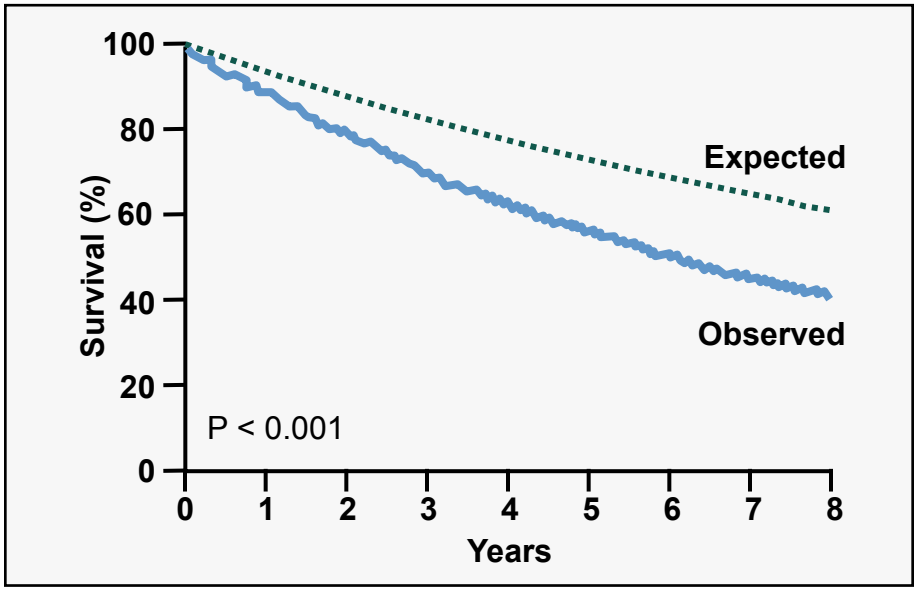
Chef du Service de Cardiologie, CHU Sart Tilman, Liège

The Burden of Valve Disease Increases

Prevalence



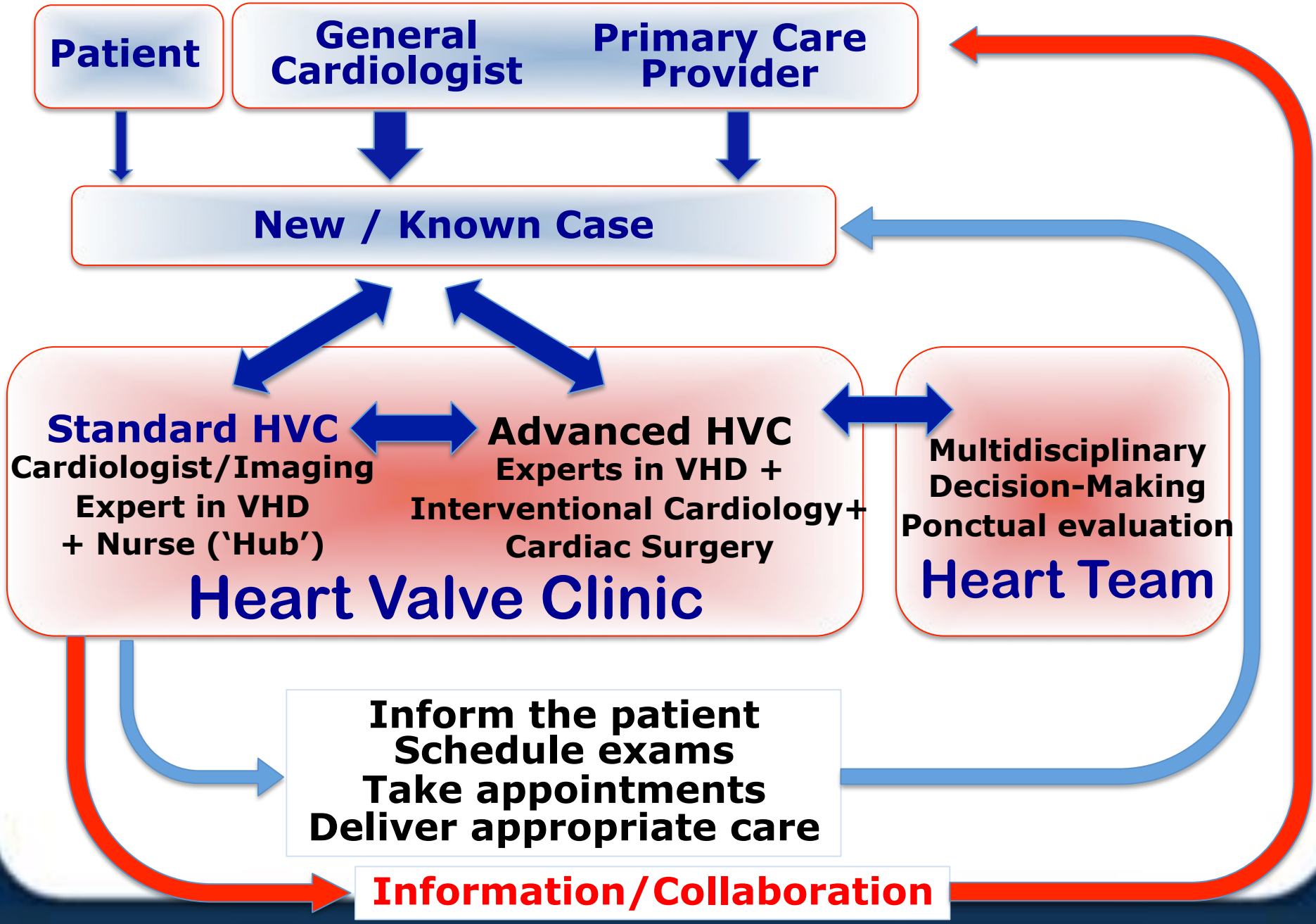
Survival



Nkomo. *Lancet* 2006;368:1005–1011

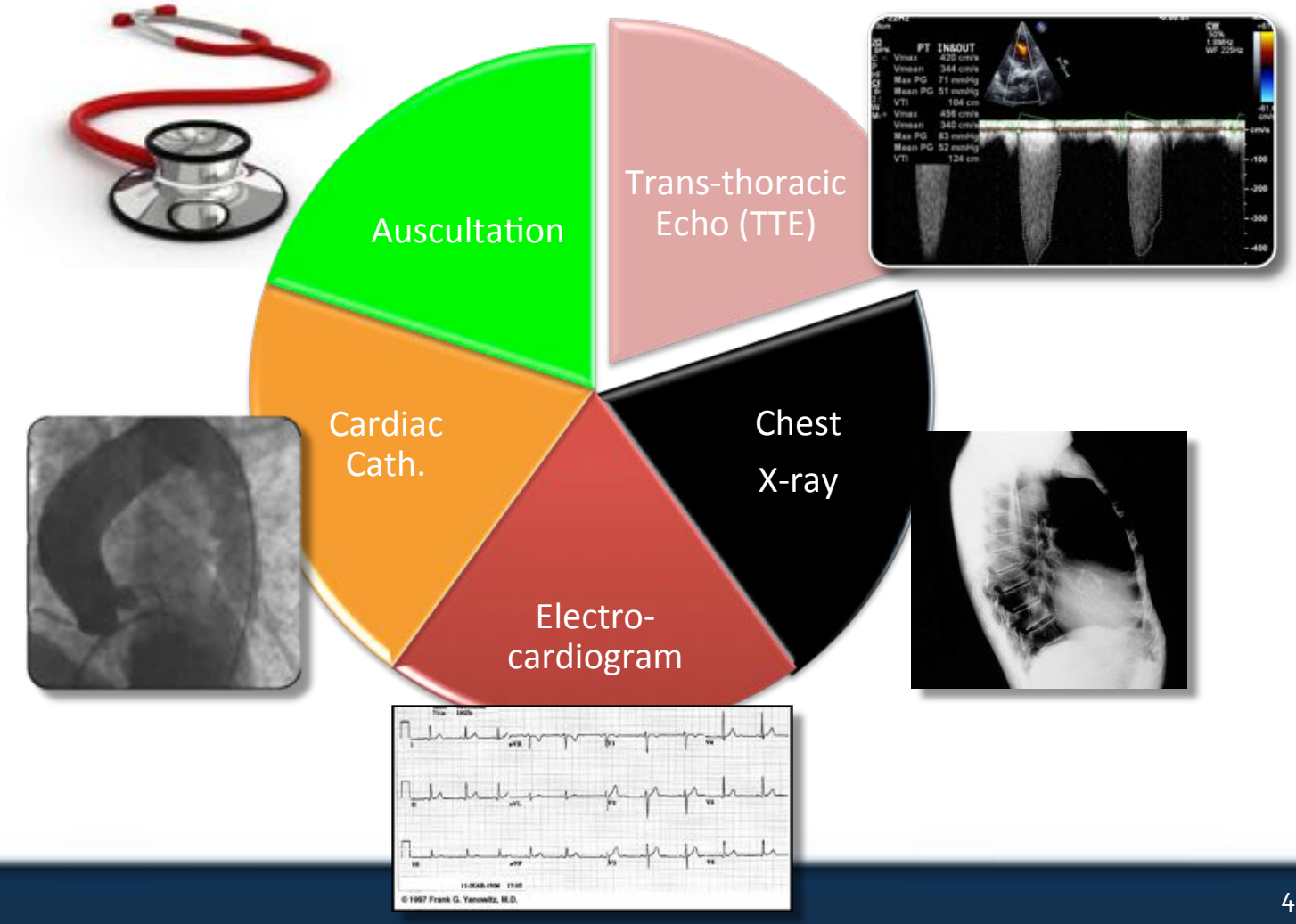
Many of these patients

- do not receive a correct diagnosis
- do not have optimized care according to current guidelines

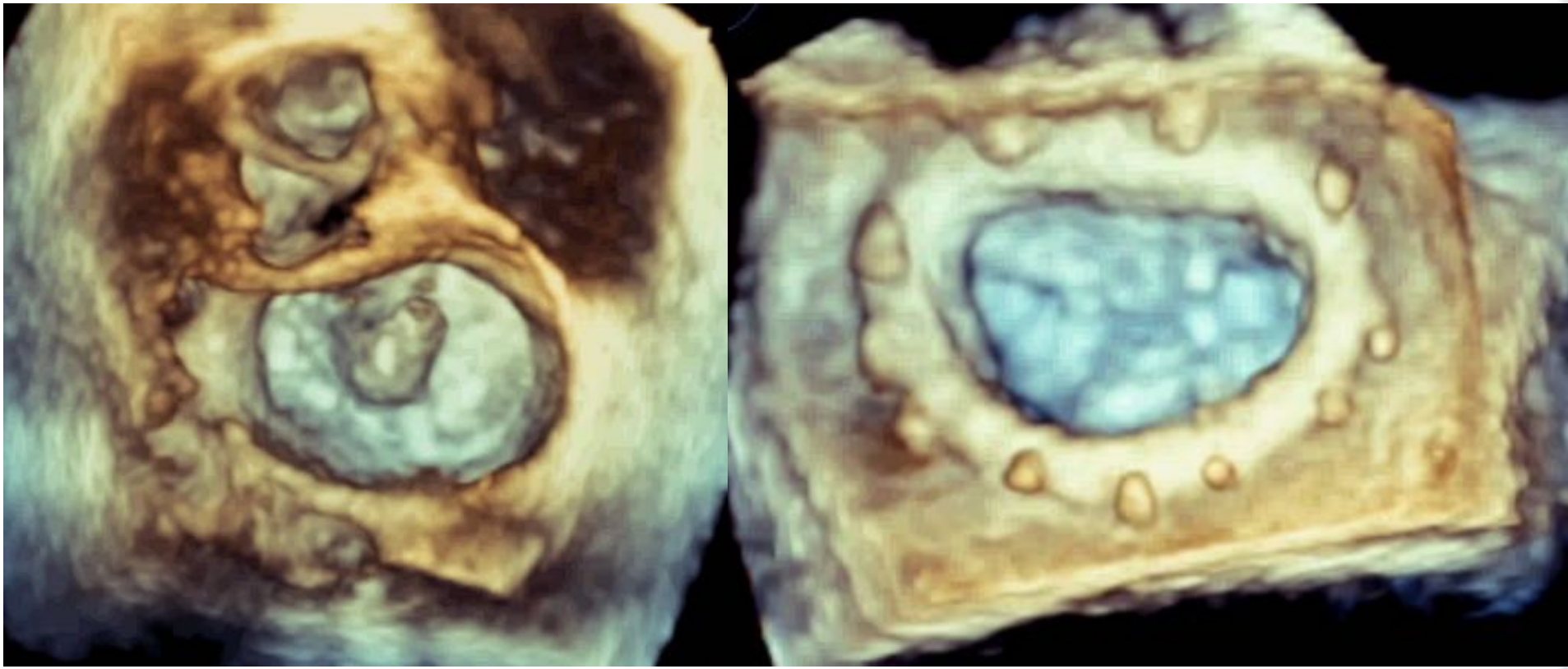


Lancellotti et al., Eur Heart J. 2013

Multiple Modalities May Be Used to Diagnose Severe Aortic Stenosis6

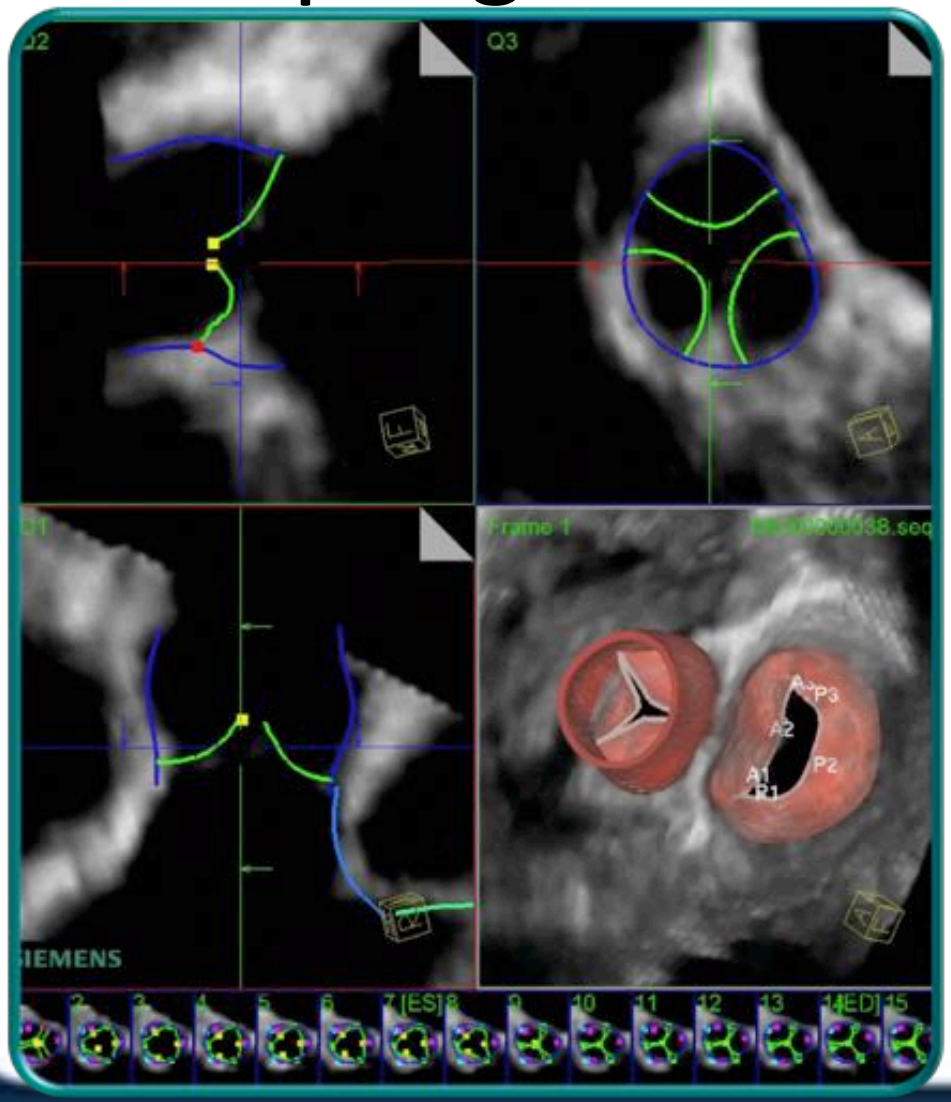


3D echo-morphology



Mitral Valve Repair

3D Quantification of Mitral-Aortic Coupling – commercial software



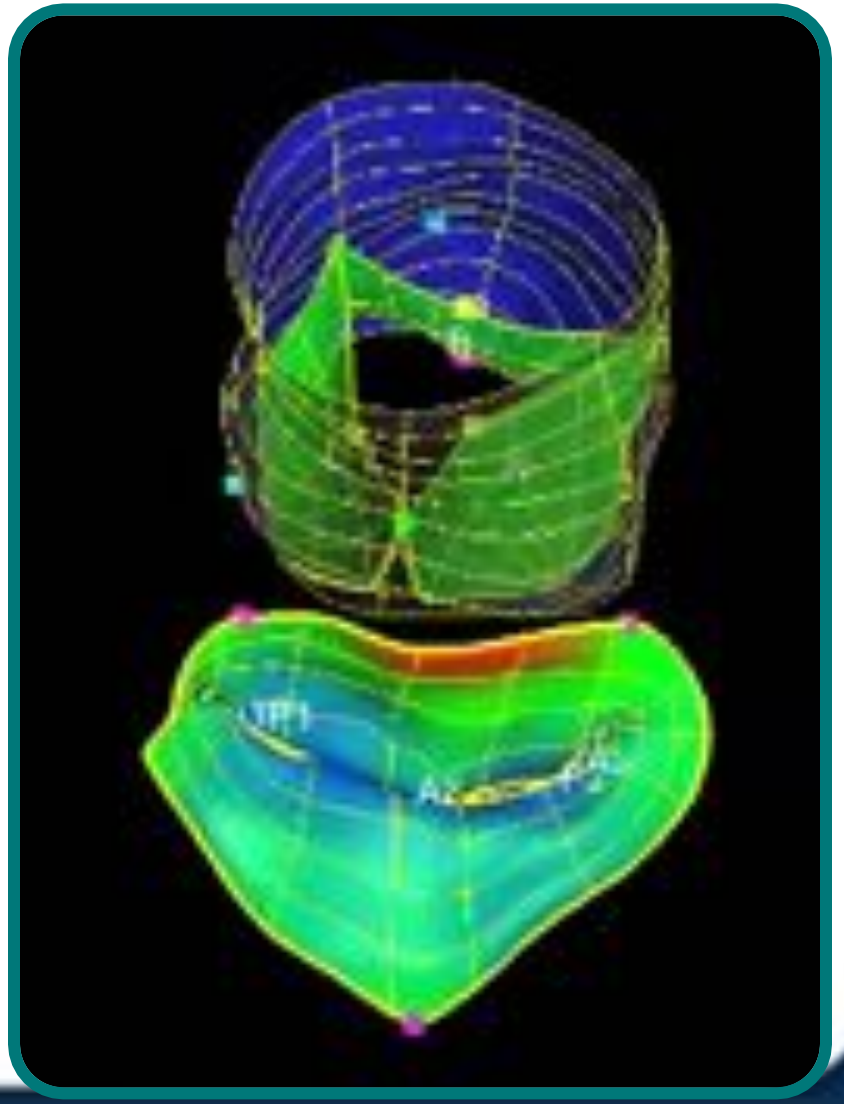
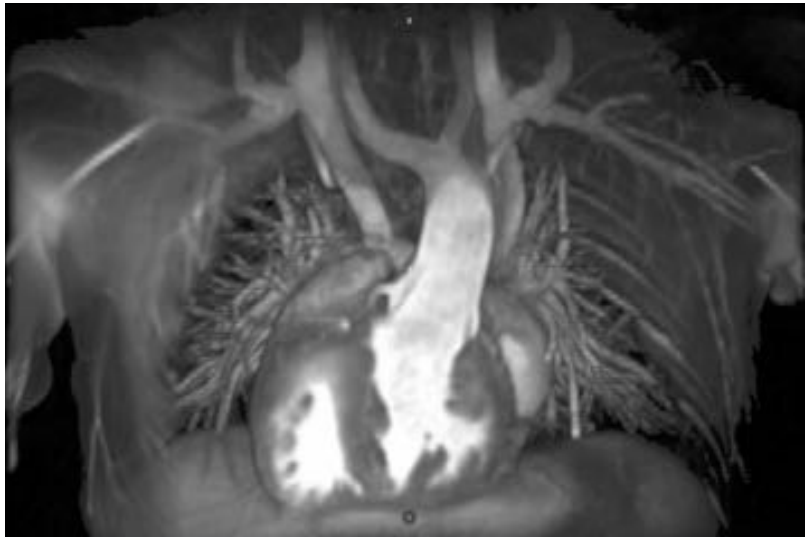
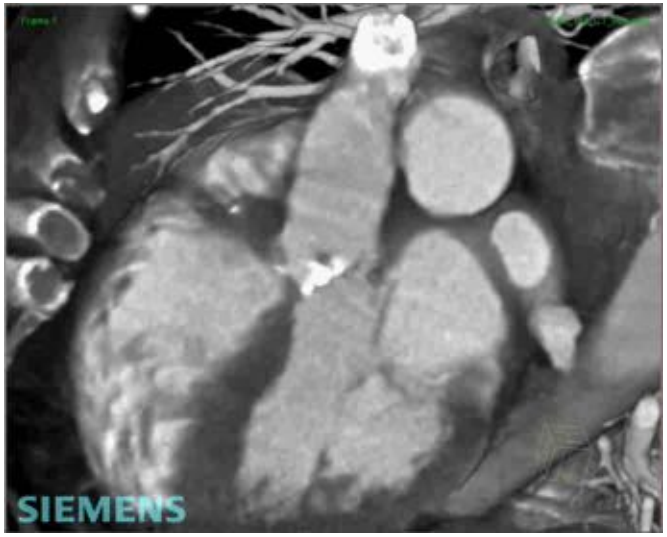


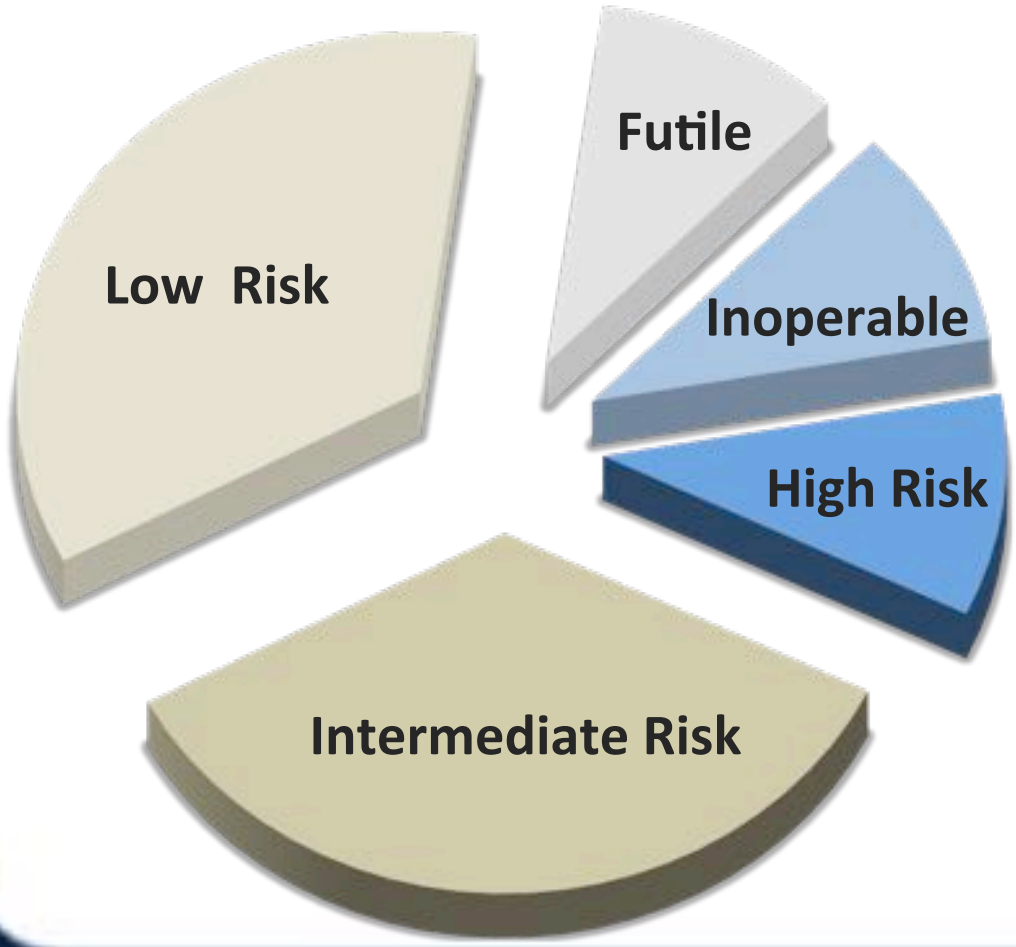
Image-based computer simulation (TAVIguide) Predicts Valve Morphology and Calcium Displacement





3D cardiac anatomy, function, and flow in 1 free-breathing, 8 min scan

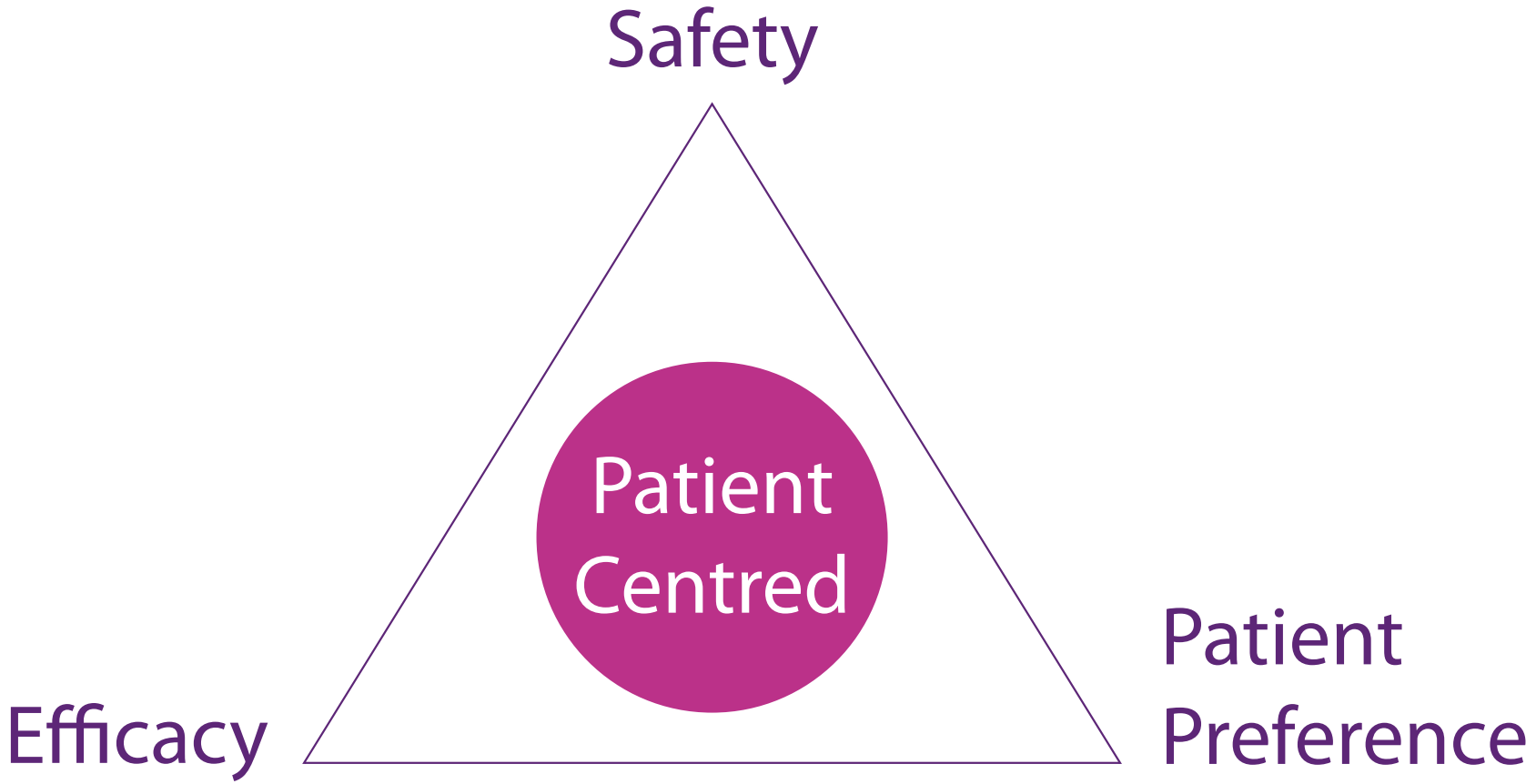
Clinical Risk: Heart Team Approach Interventional Cardiology + Surgeons



www.euroscore.org/calc.html

http://209.220.160.181/STSWebRiskCalc261/de.aspx

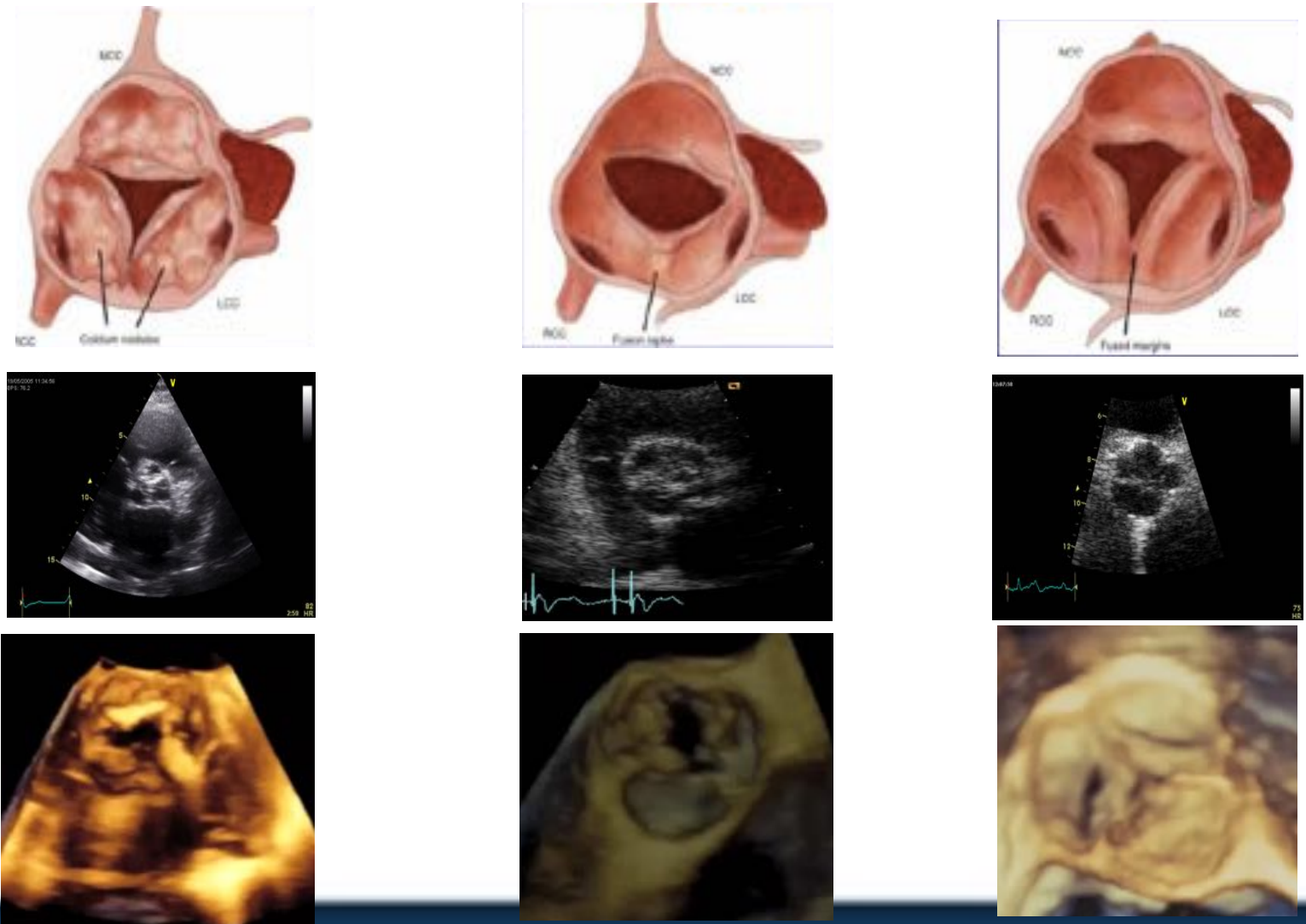
Adoption of Interventional Procedures



Aortic Stenosis

Aortic Stenosis

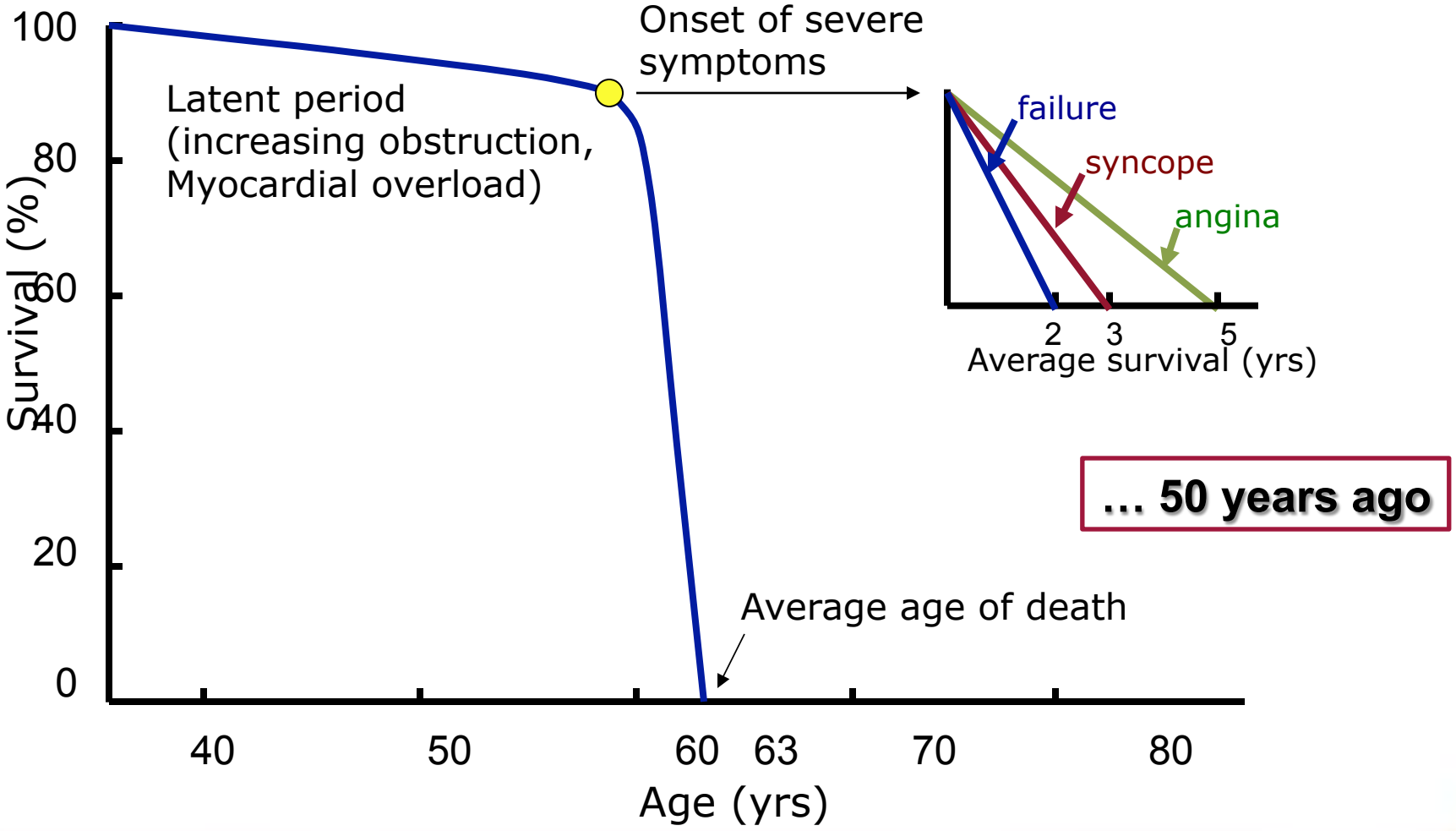
Degenerative: 50 % *Bicuspid: 40 %* *Rheumatic 10 %*



Roberts & Ko. Circulation. 2005; 111: 920-5

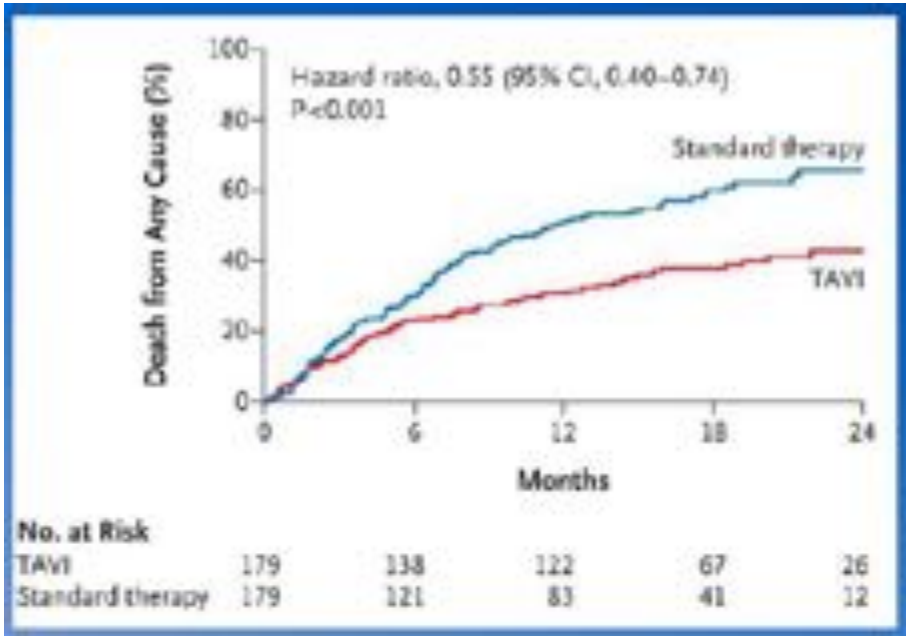
Severe Aortic Stenosis

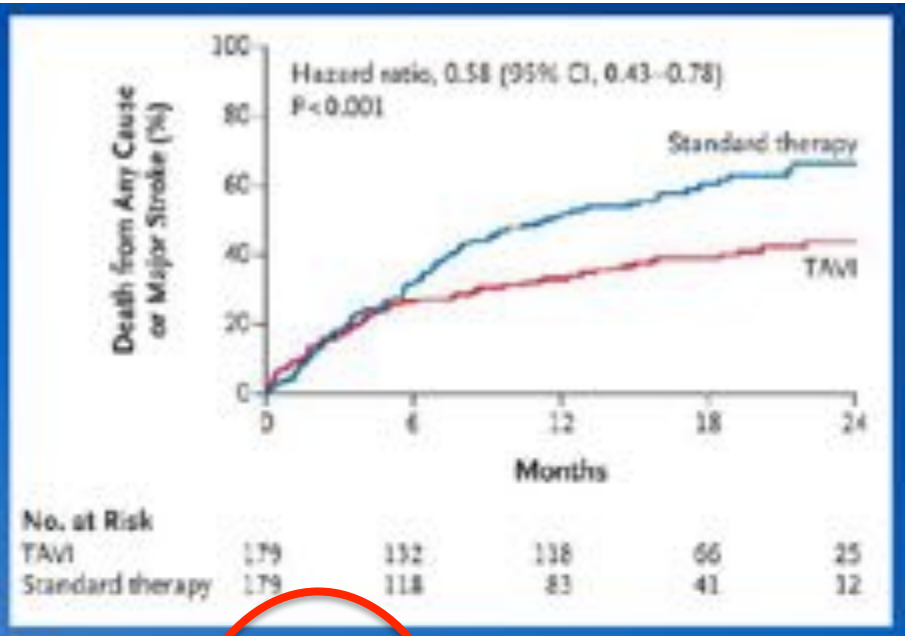
Prognosis of Symptomatic Patients



Ross, Braunwald
Circulation 1968

TAVI vs. Medical RX: Partner Cohort B

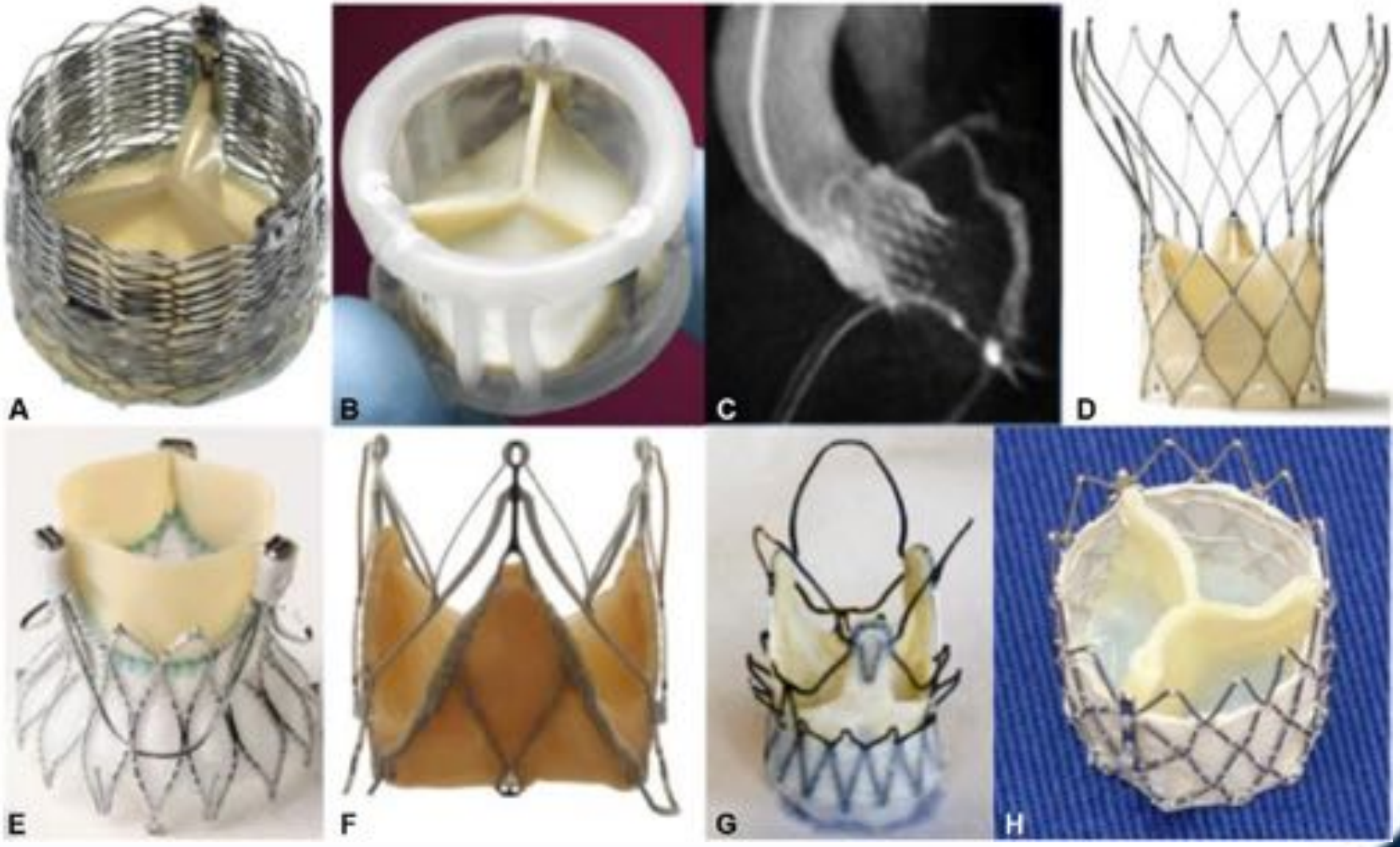


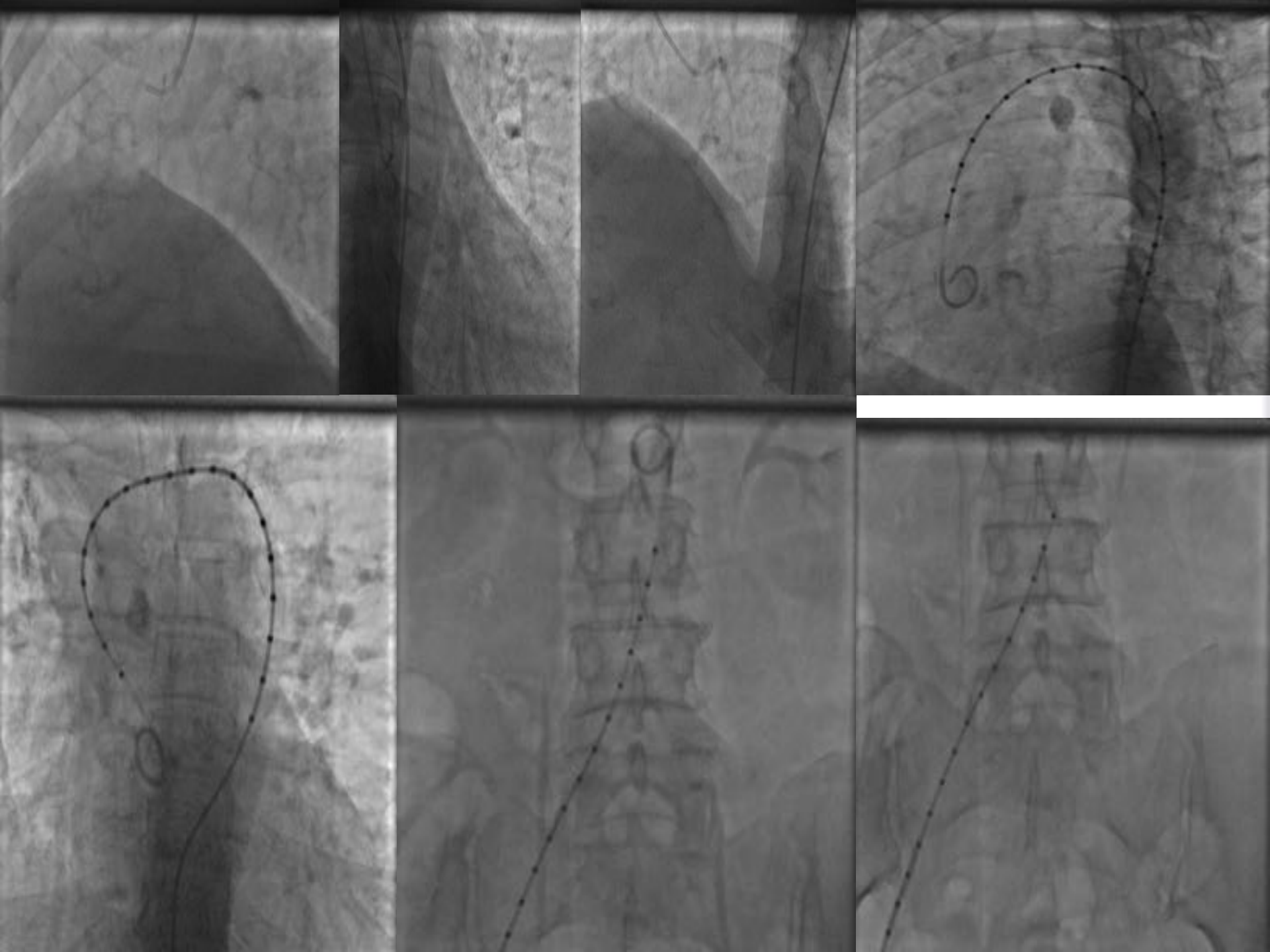


	TAVI	Medical Rx (37% with BAV, 10% AVR)	p
Mortality (1 yr)	31%	50%	<.001
Hospitalization	22%	44%	<.001
Stroke/TIA	10.6%	4.5%	0.04
Major Vasc Comp.	16.8%	2.2%	<.001

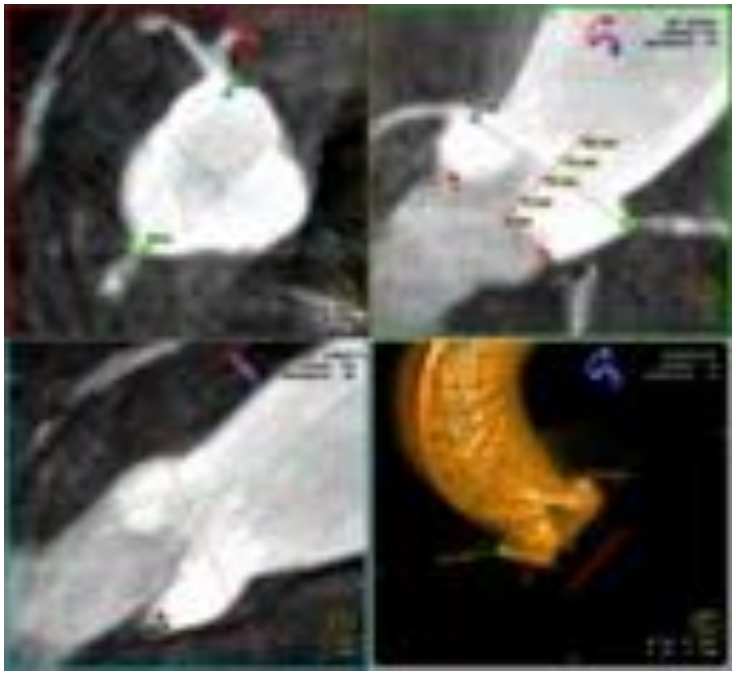
Leon M et al. New Engl J Med 2010

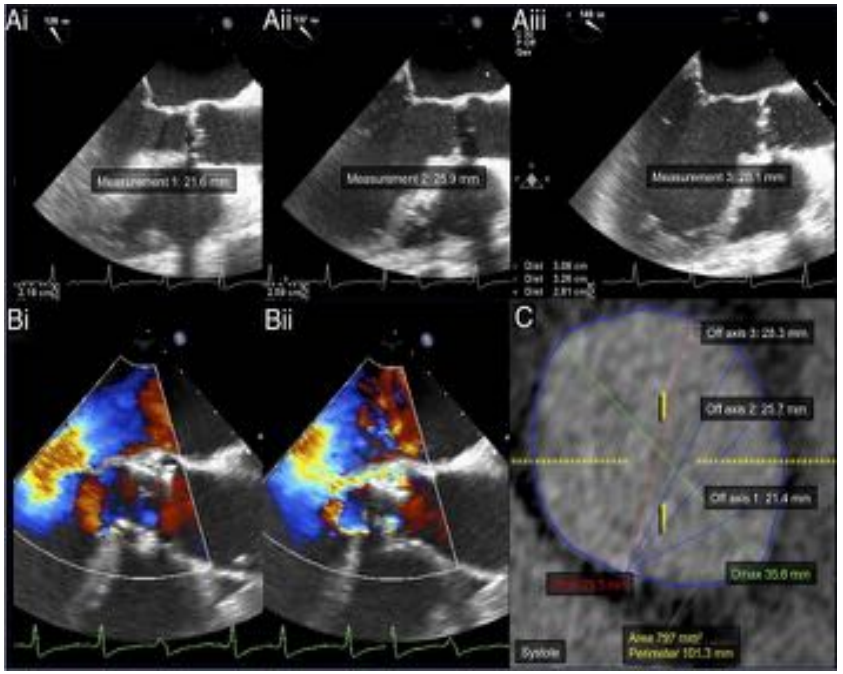
Transcatheter Aortic Valve Implantation

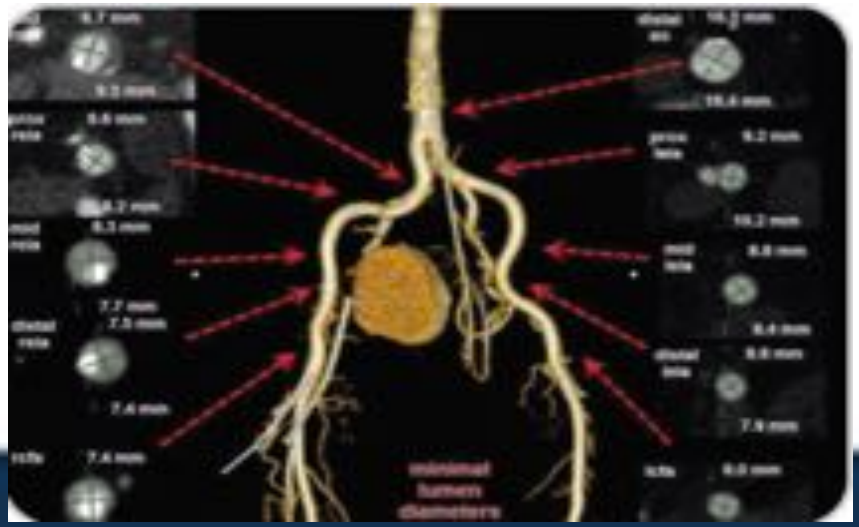


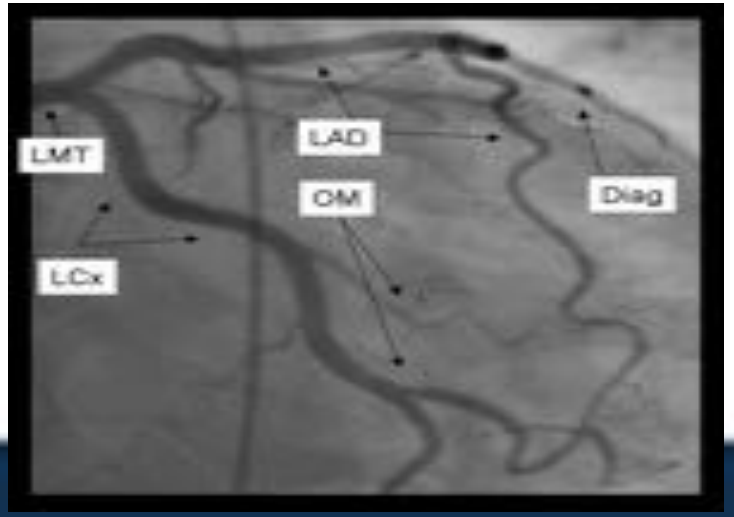


TAVR Multimodality imaging

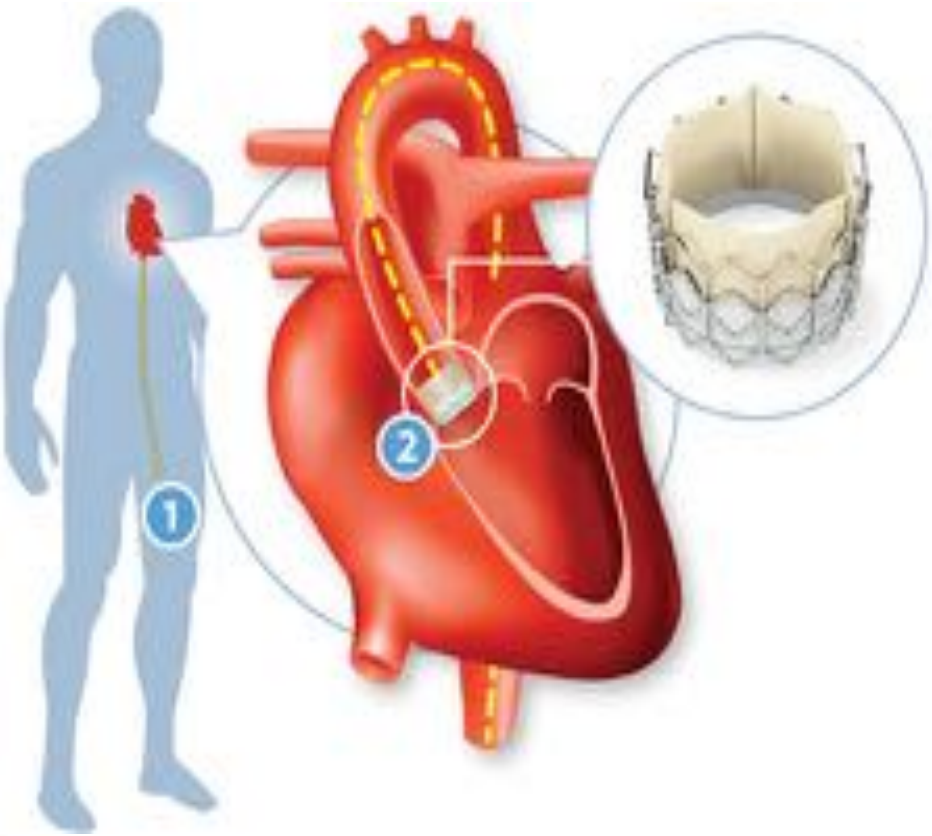


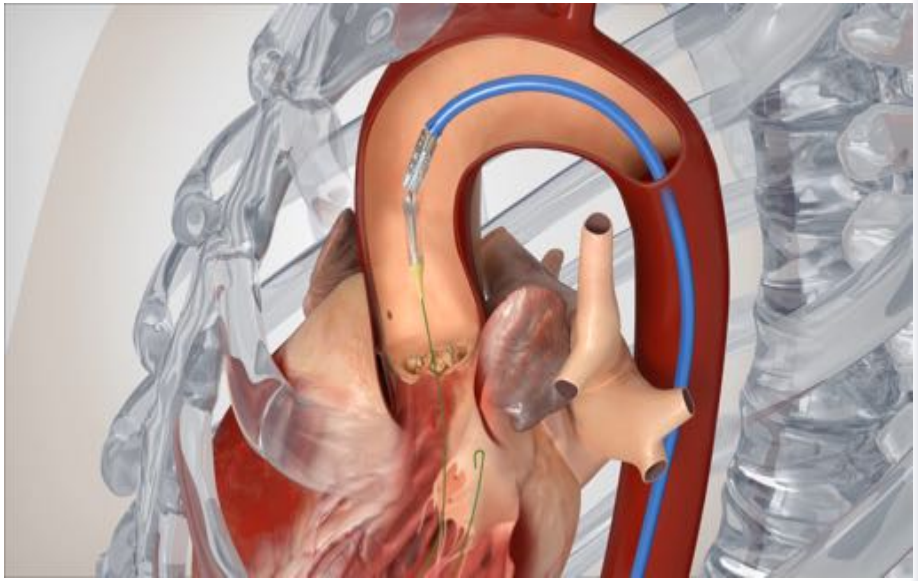




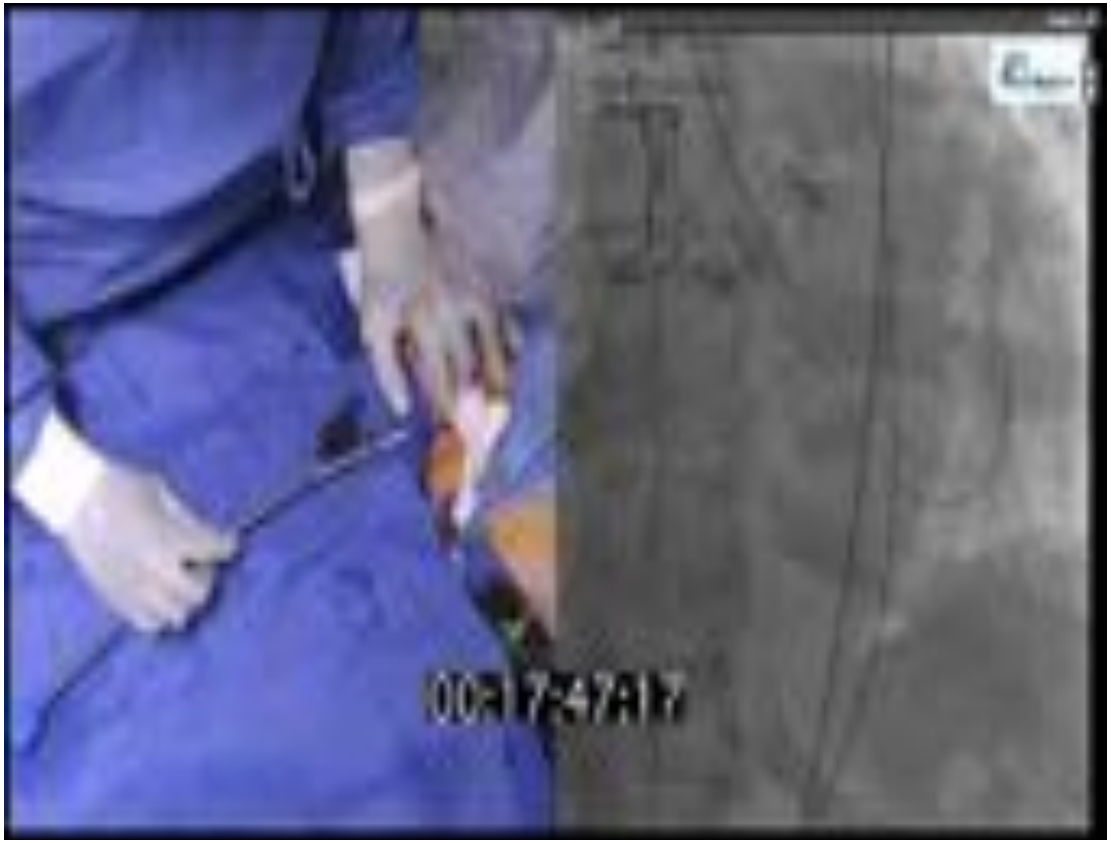


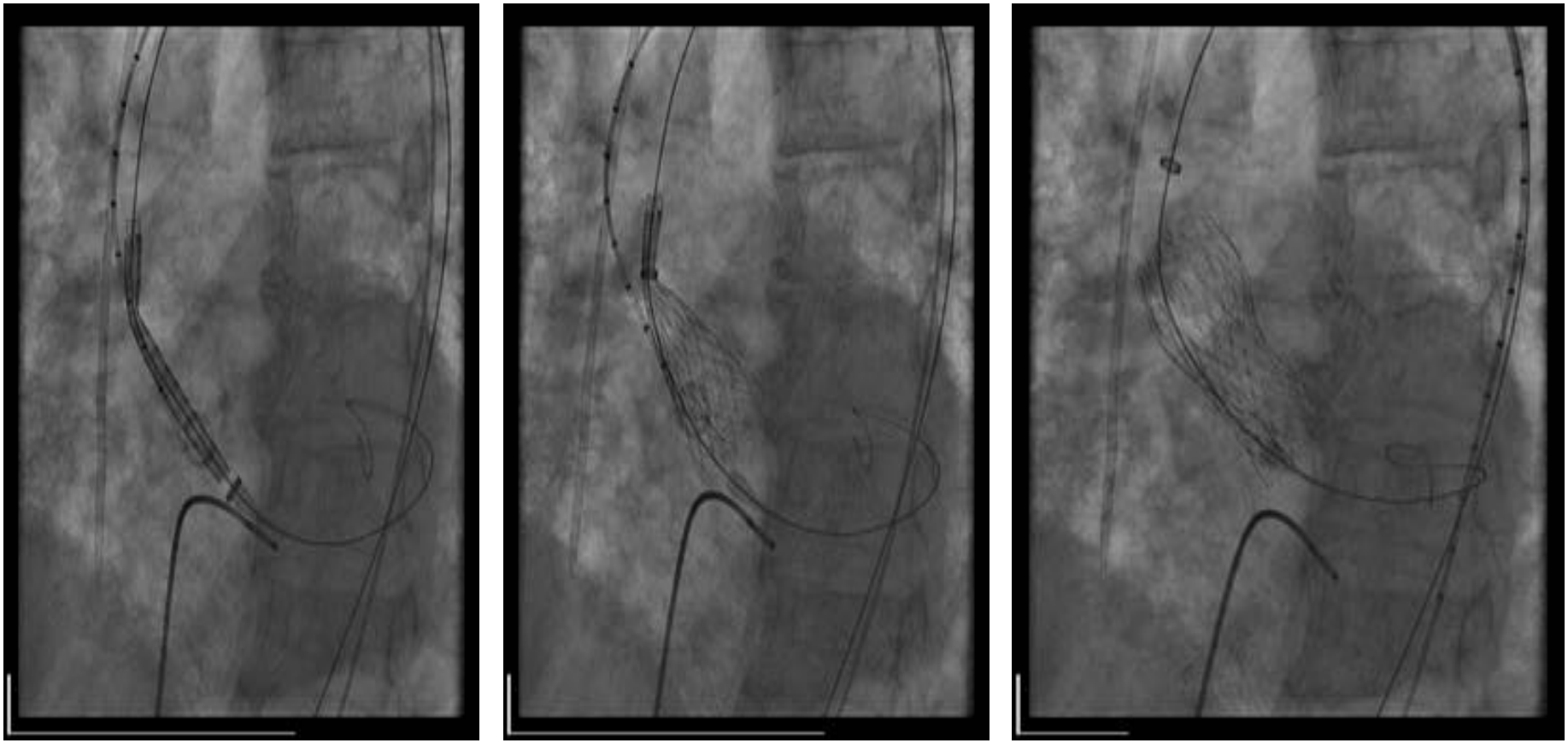
Transcatheter Aortic Valve Replacement



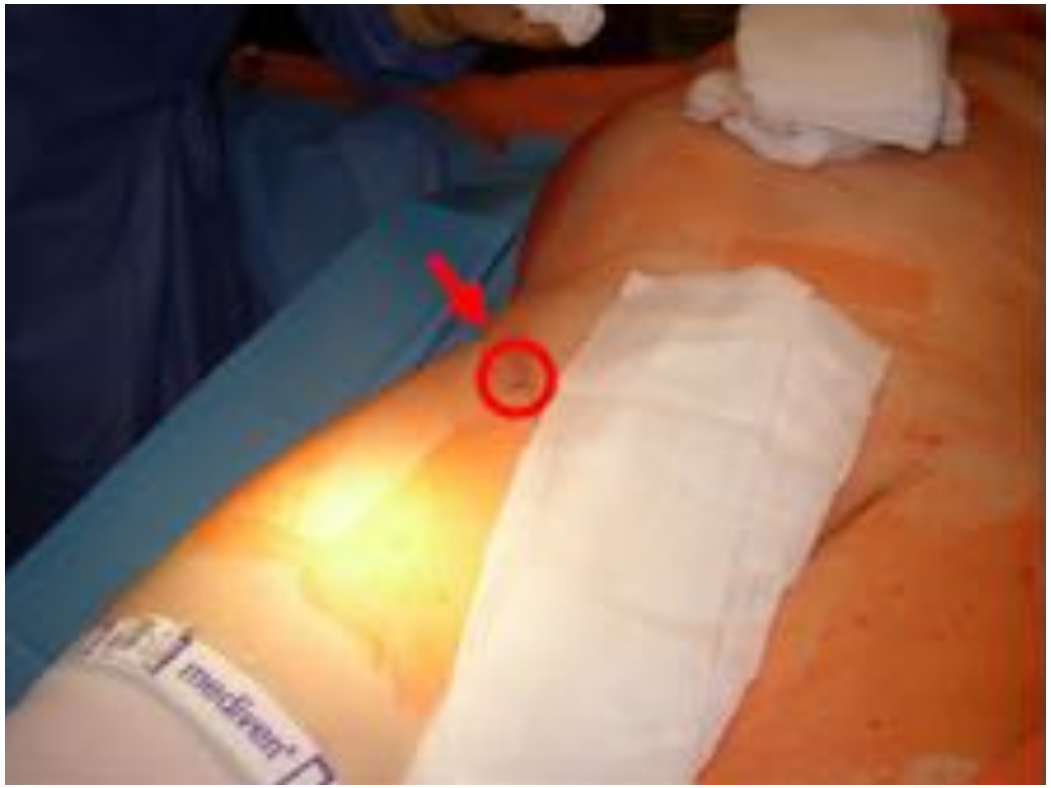


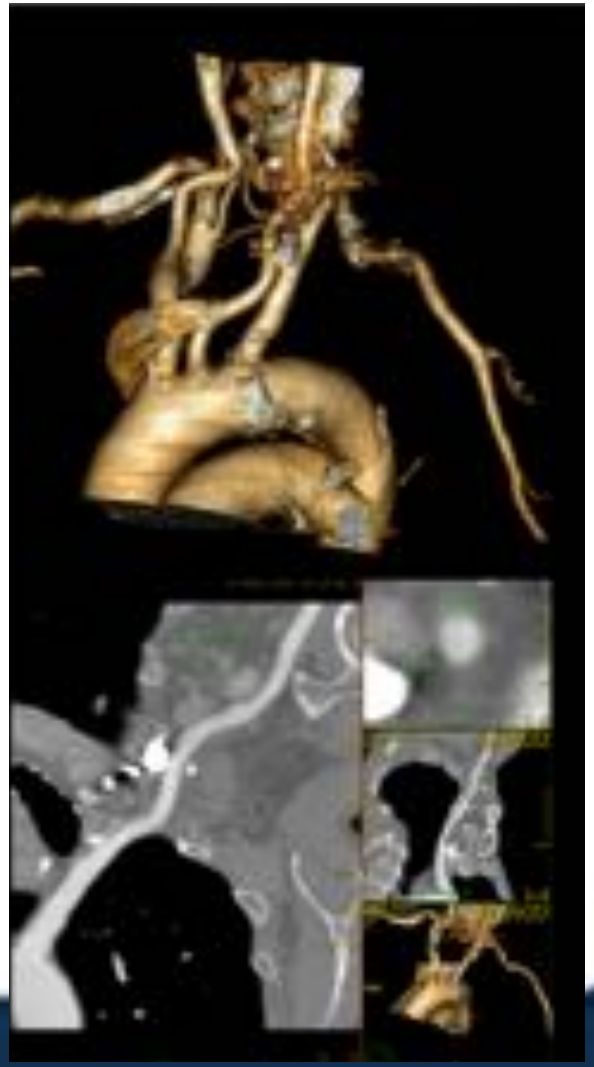
Evolut R and Enveo delivery catheter



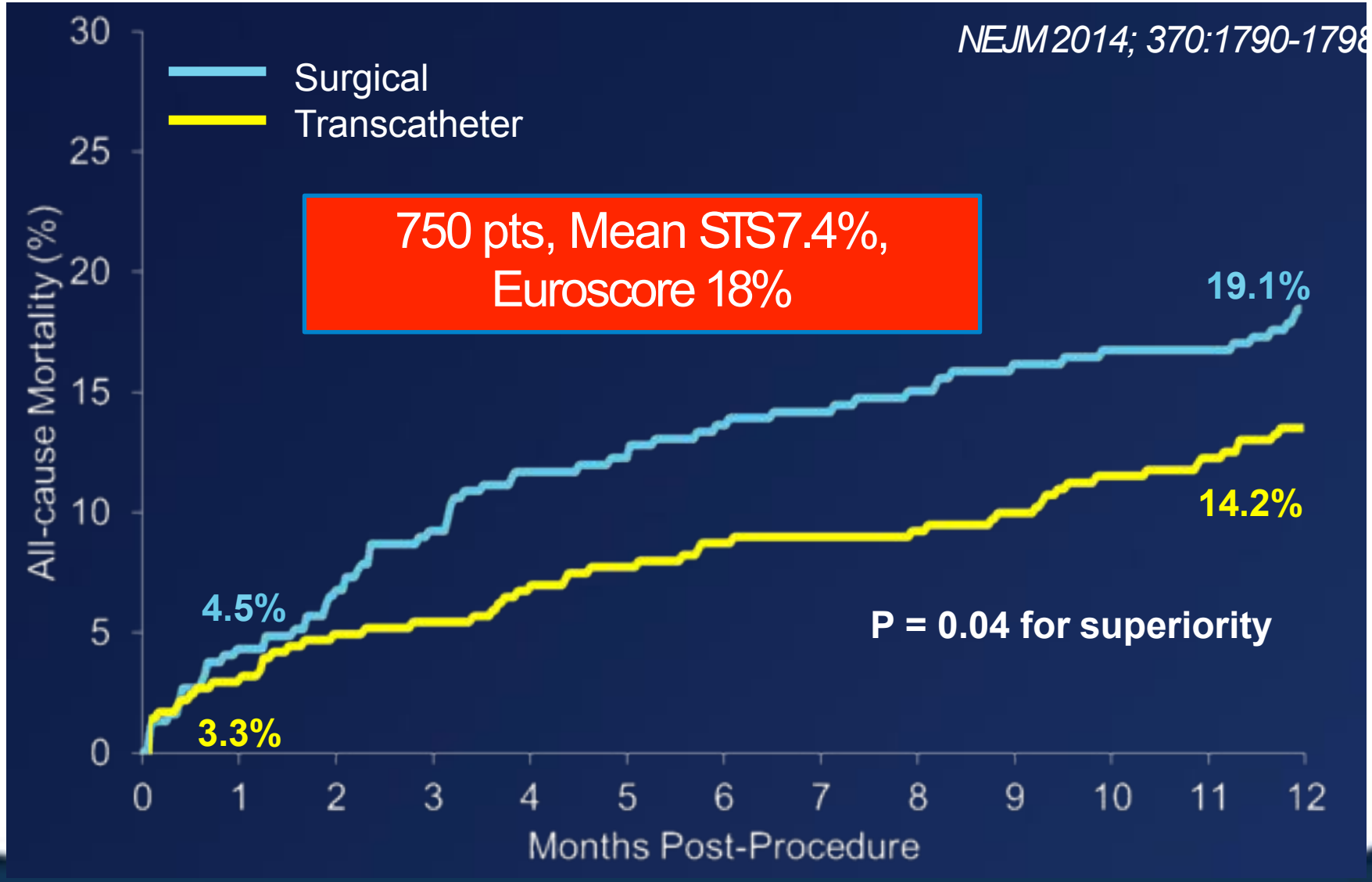


Transfemoral Approach: *First choice if possible.*
Alternatives: *Transapical or Subclavian Access*





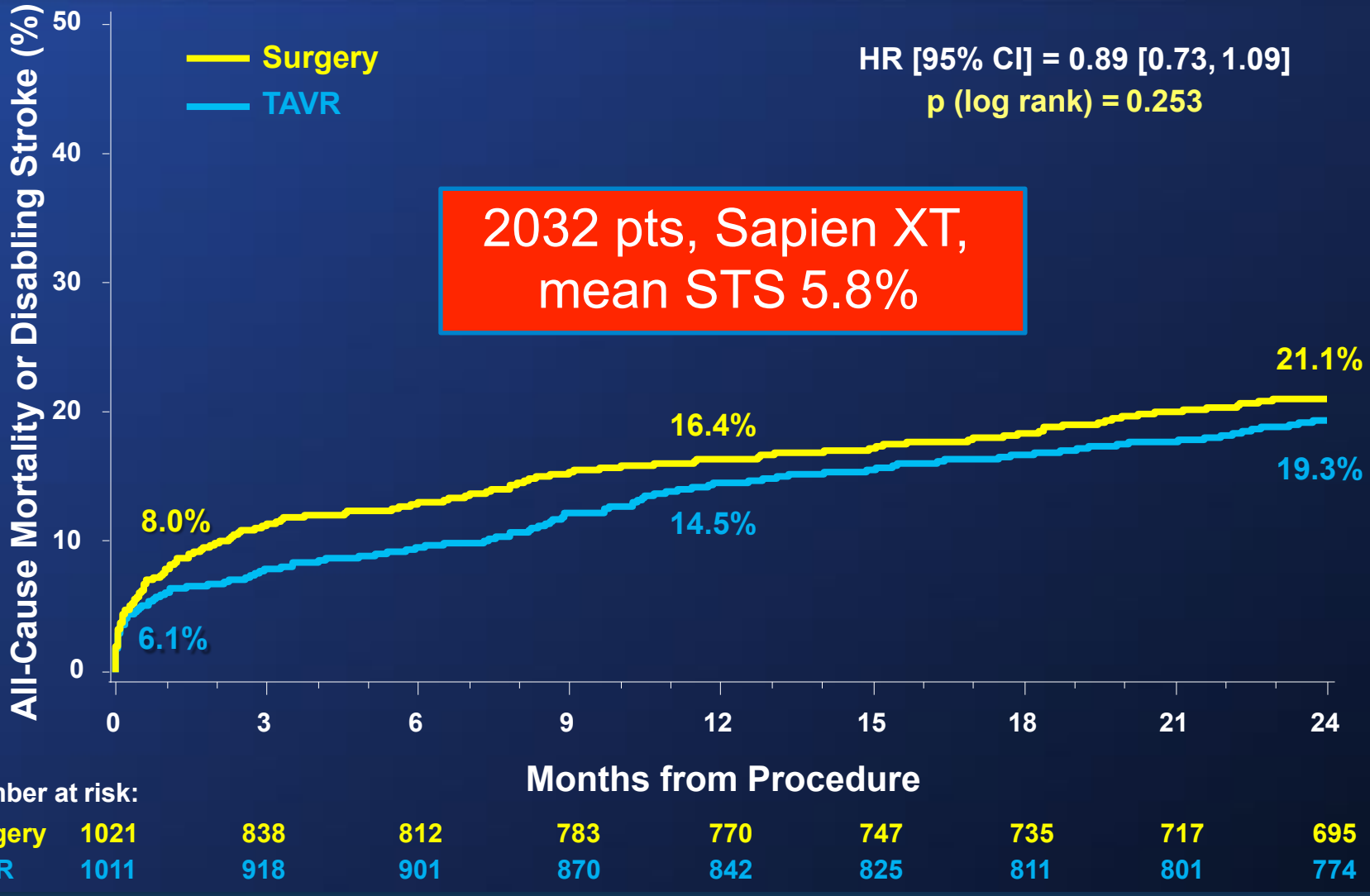
Primary Endpoint: 1 Year All-cause Mortality (Partner Cohort A)



Primary Endpoint (ITT)

All-Cause Mortality or Disabling Stroke

THE PARTNER II TRIAL



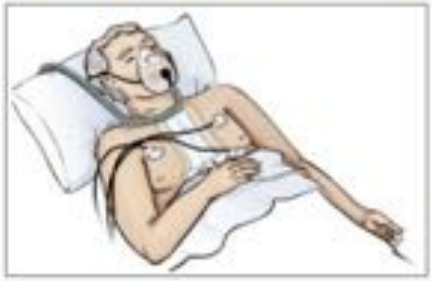
Number at risk:

Surgery	1021	838	812	783	770	747	735	717	695
TAVR	1011	918	901	870	842	825	811	801	774

Advantages of TAVI vs. Surgical aortic valve replacement (SAVR)

PROCEDURE

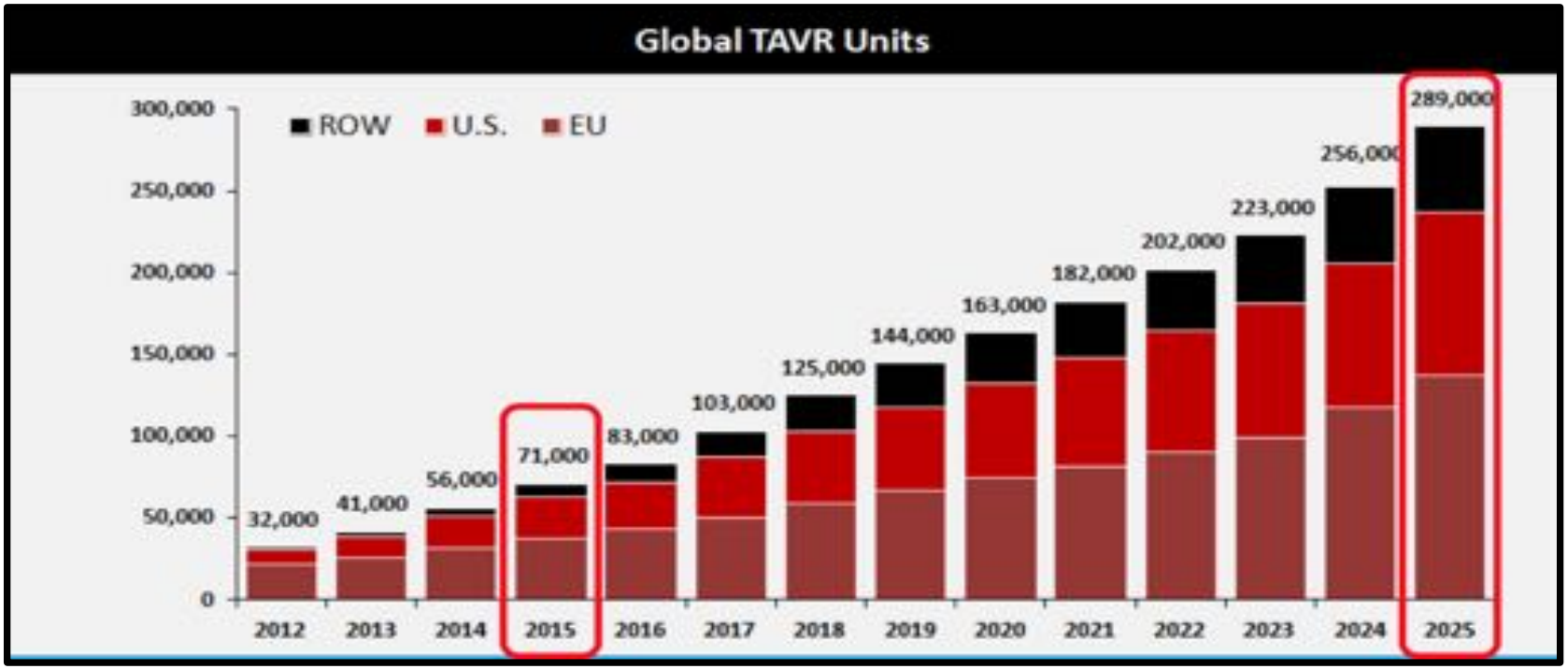
EARLY PERI-PROCEDURE



INVASIVENESS
CARDIOPULMONARY BYPASS
INFECTION
STERNAL WOUND DEHISCENCE
PROLONGED VENTILATION

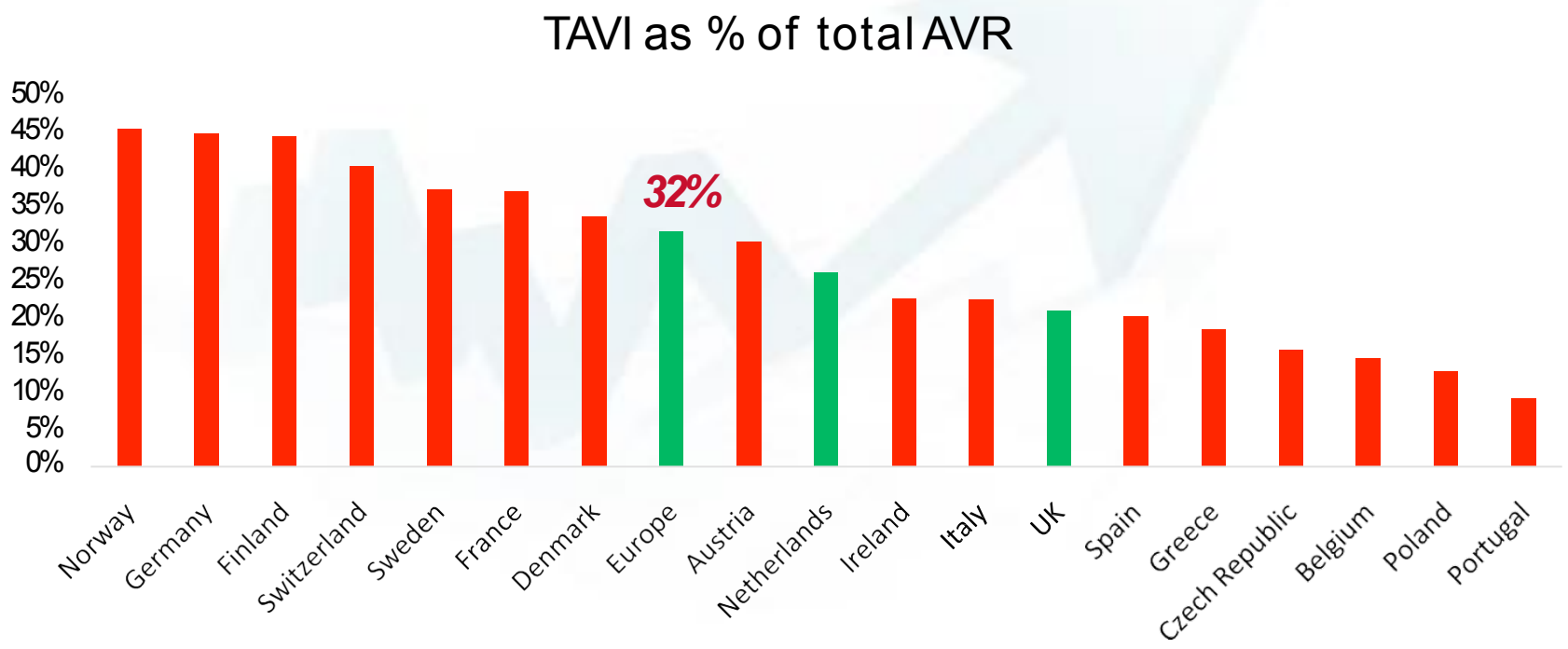
TAVI vs. SAVR

Estimated global TAVI market procedure growth



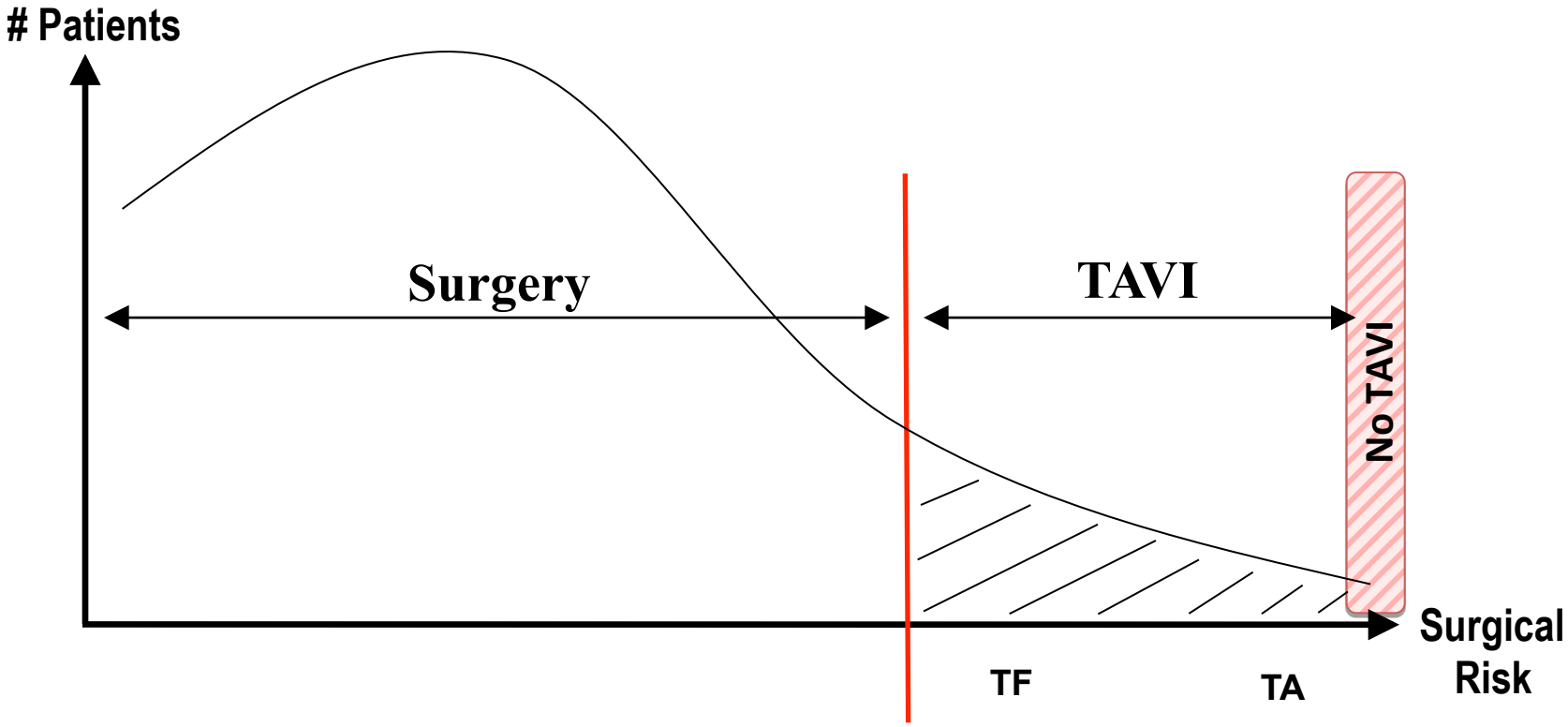
In the next 10 years, TAVI procedures are predicted to increase 4-fold

TAVI penetration continues to increase



*Includes all AVR: surgical isolated, combined with CABG and multiple valve procedures and TAVI.

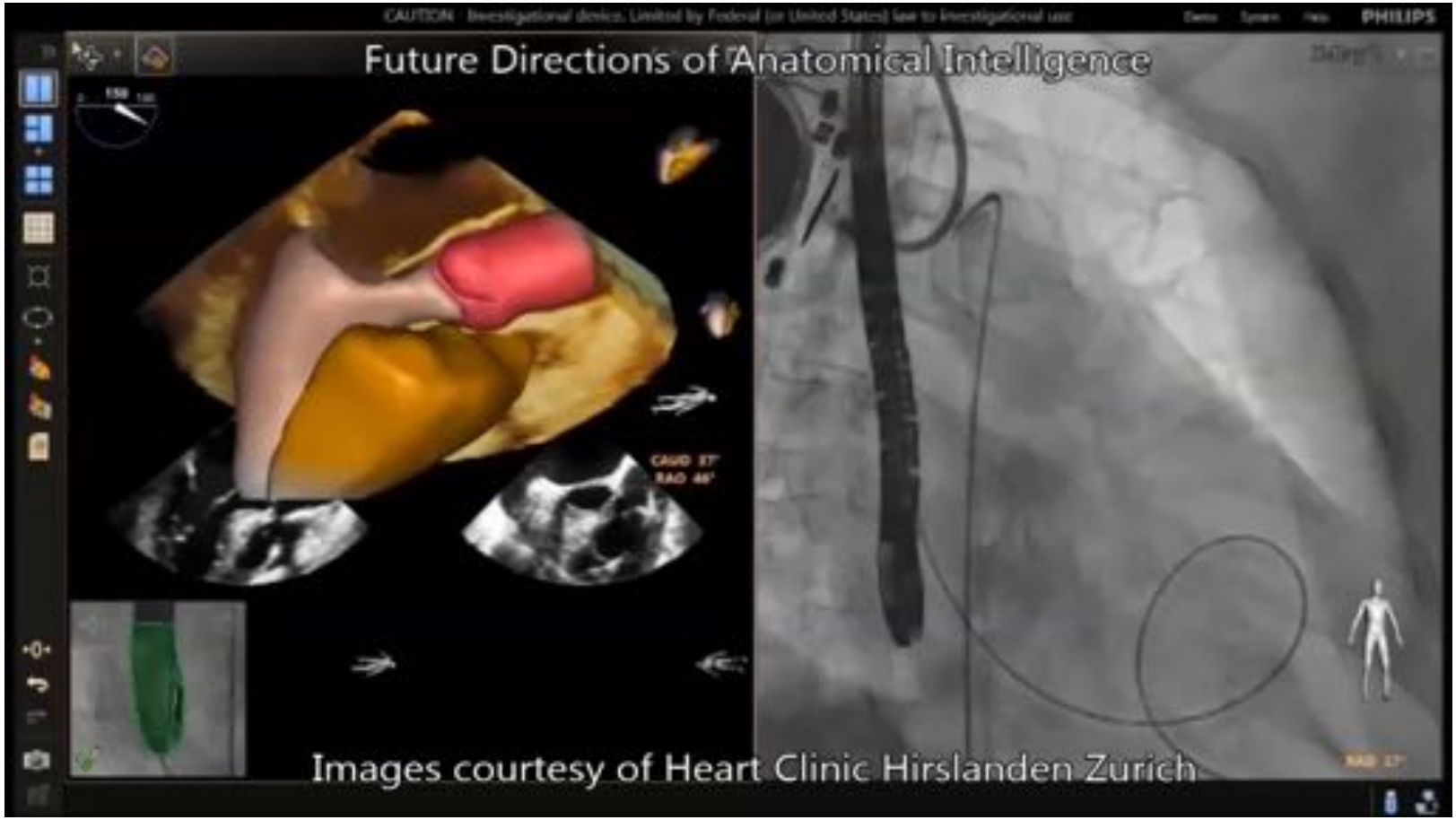
Evolving Patient Selection for TAVI



What is required to expand TAVI to moderate/low risk and younger patients?

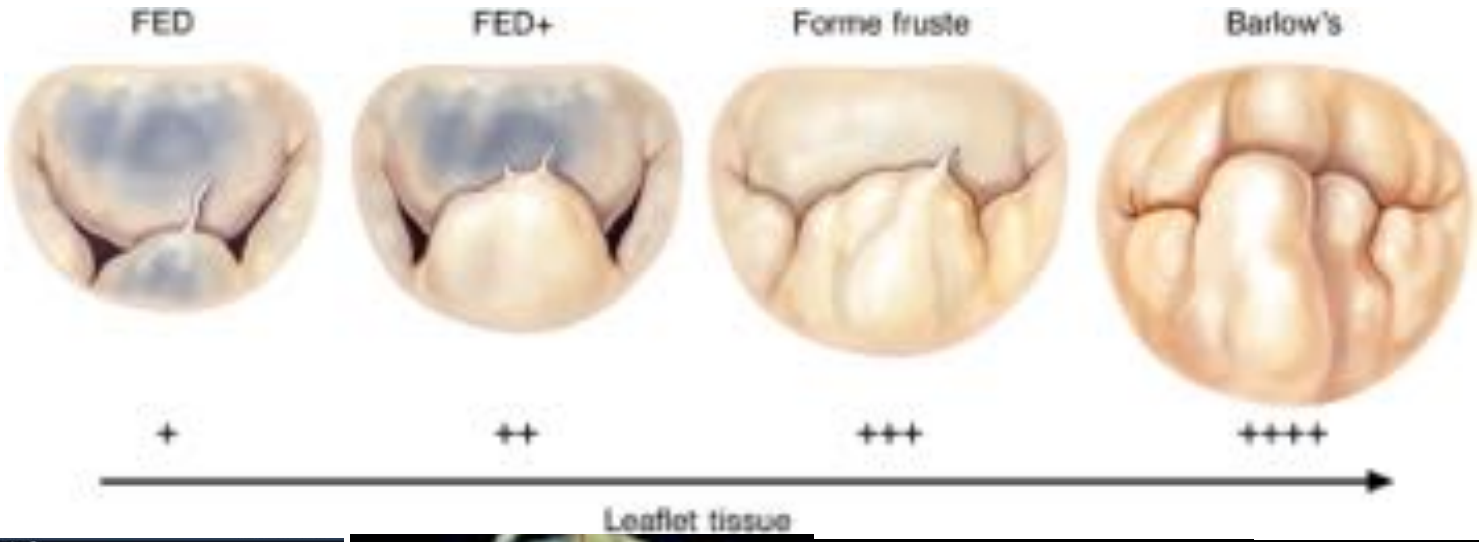
- **Outcomes** need to be equal or better than SAVR
  - Mortality
    - Acute i.e. in-hospital/30-day
    - Long-term i.e. 1-2 years
  - Stroke
- **Patient preference** for TAVI
  - Morbidity, recovery time, patient experience
- **Valve durability** comparable to surgery
- **Affordable**
  - Cheaper and/or more cost-effective

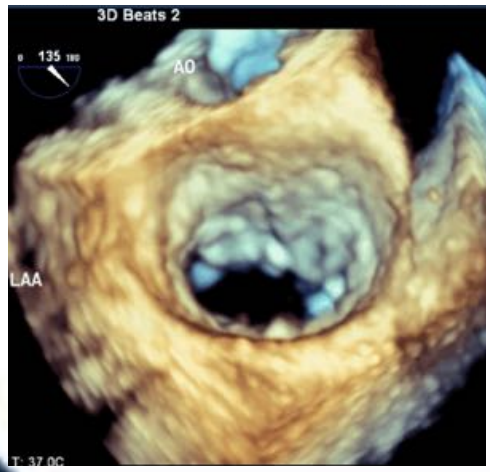
EchoNavigator and Image Fusion (Automatic quantification)

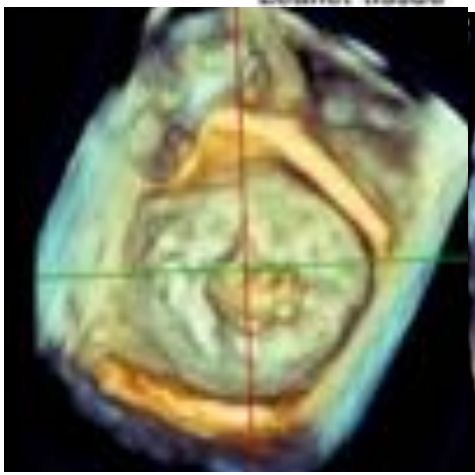


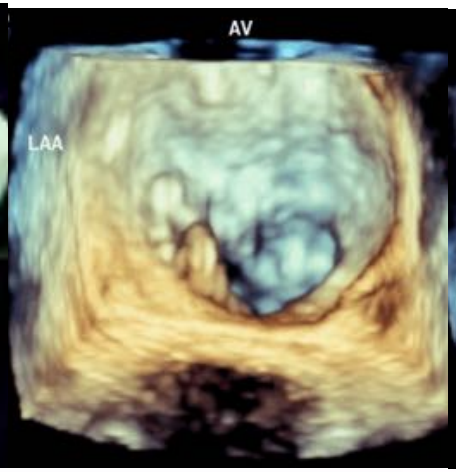
Mitral Regurgitation

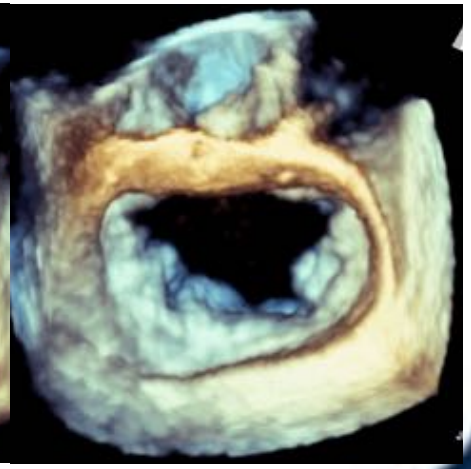
Mitral Regurgitation
Spectrum of Degenerative Disease





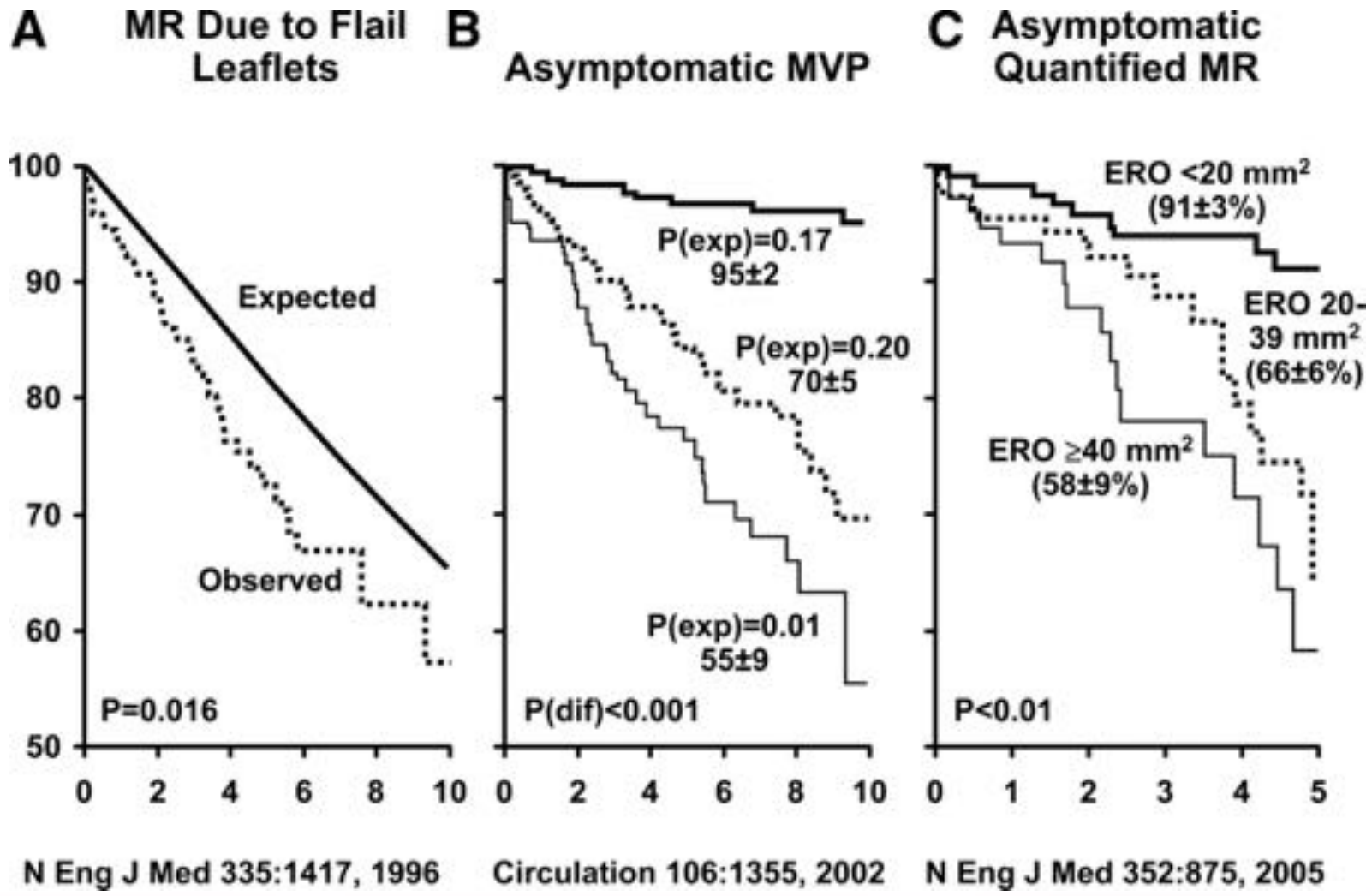






Adams et al EHJ 2010

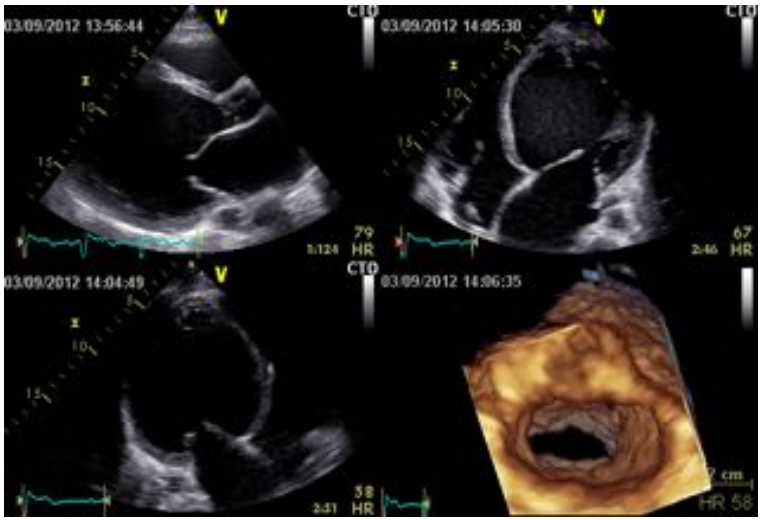
When present, MR impacts survival

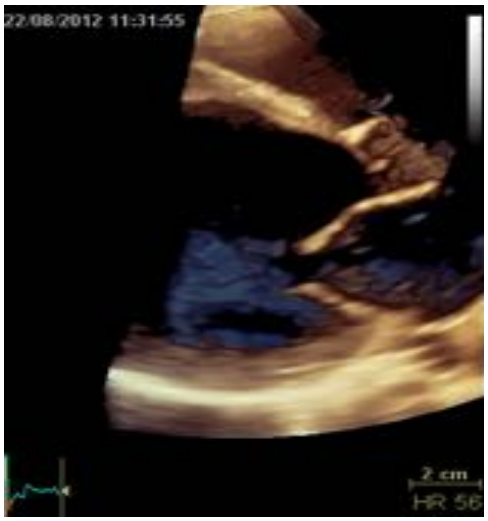


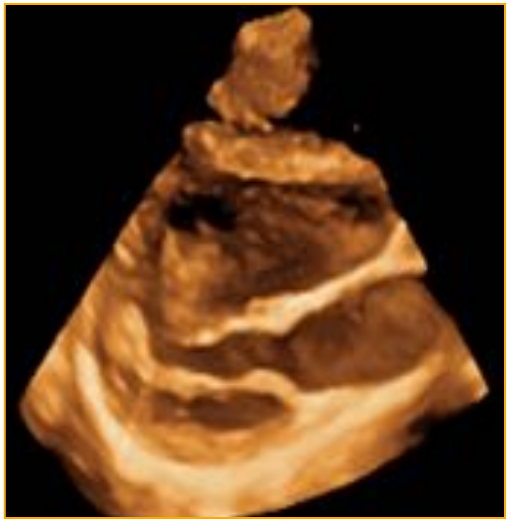
Secondary MR

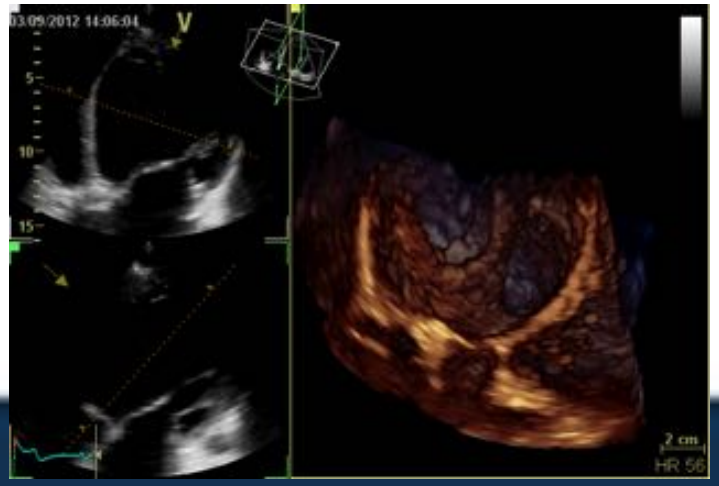
Normal leaflets, Annular dilation, LV dilation + spherical +

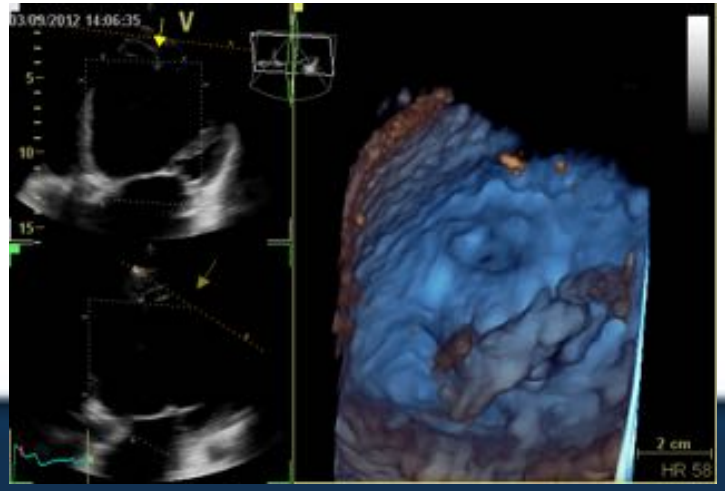
Altered geometry + PMs displacement + WM abnormalities



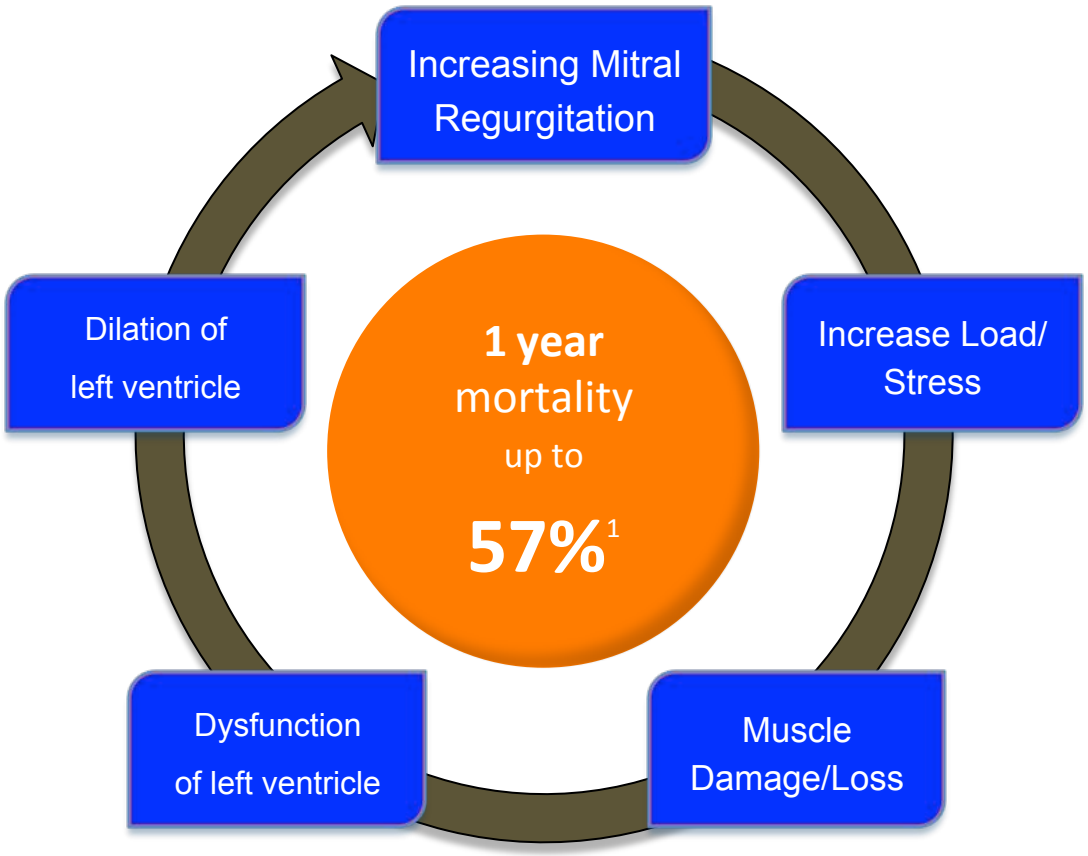








MR Progresses to Heart Failure



MR initiates a cascade of events progressing to heart failure, then death, if untreated [2,3]

[1] Markwick et al. Prognostic Implications of Moderate and Severe Mitral Regurgitation in Contemporary Clinical Care. TCT 2012
[2] Trichon BH et al. Am J Card. 2003,91:538-43
3 Lancellotti et al. Circulation 2003; 108: 1713-1717

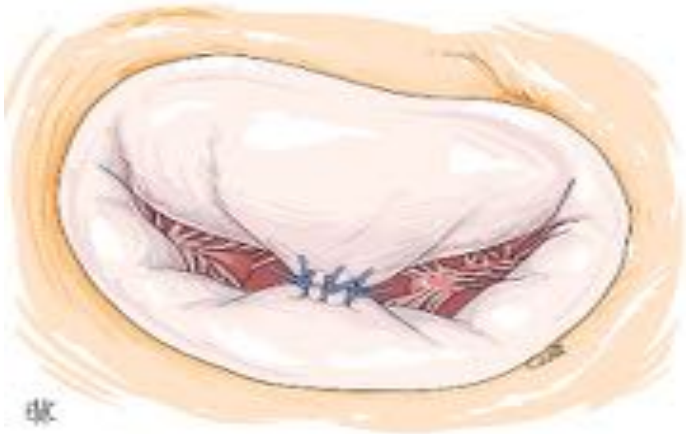
The expanding portfolio of transcatheter mitral repair and replacement

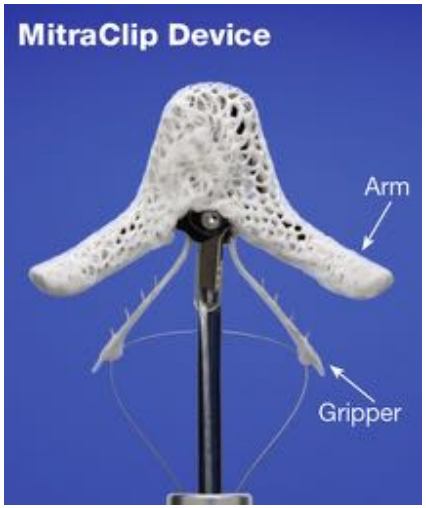
MitraClip
Neochord
Harpoon
Chordart
....

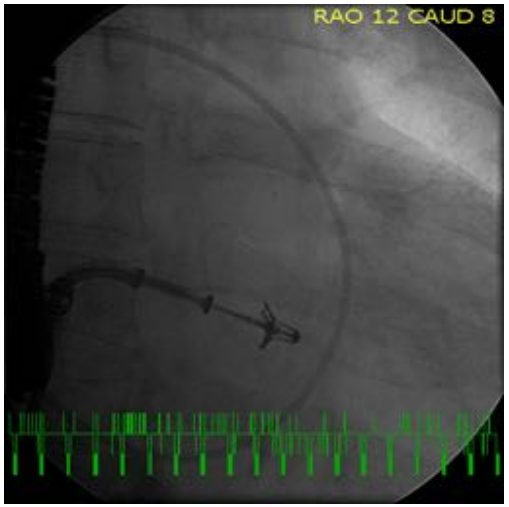
Cardioband
Mitralign
Carillon
Millipede
....

Tendyne
Neovasc
CardiaQ
Twelve
....

Aim of the MitraClip therapy
- abolish severe MR -







MitraClip indication ?

II b, level C
DMR & FMR

Severe mitral regurgitation

Symptomatic

High or prohibitive surgical risk

Technically feasible (echo)

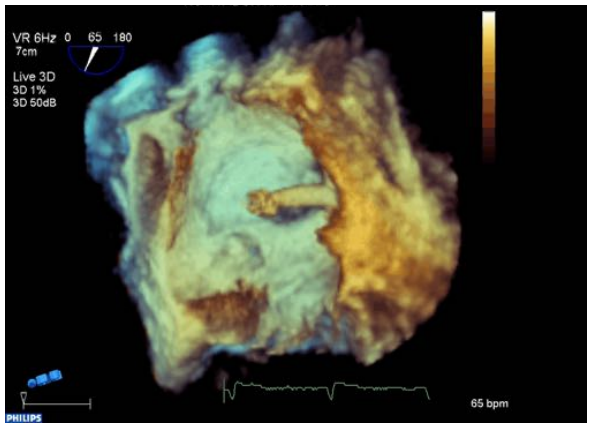
MitraClip: Peri-procedural Echo

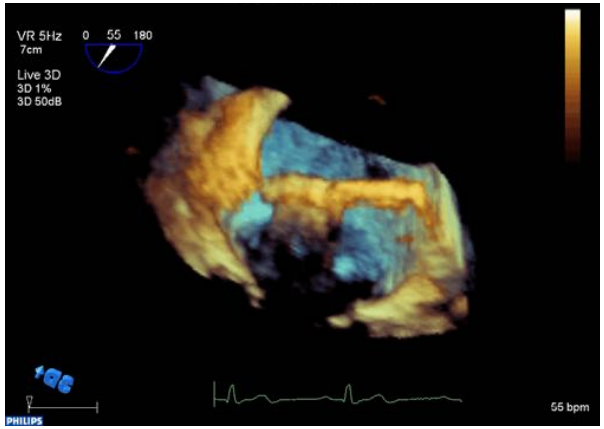
A- Transseptal catheterization (help in guiding the clip)

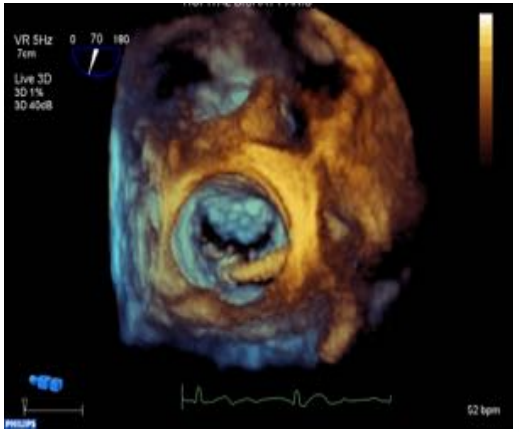
B- Advancing the clip delivery system towards the mitral leaflets

C- Positioning the clip and orientation of the clip arms

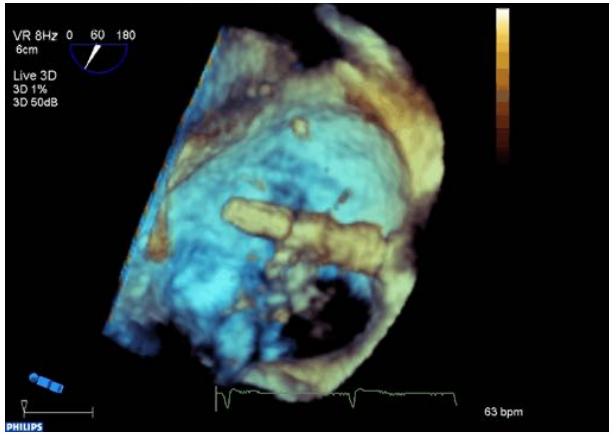
- Guide Crossing

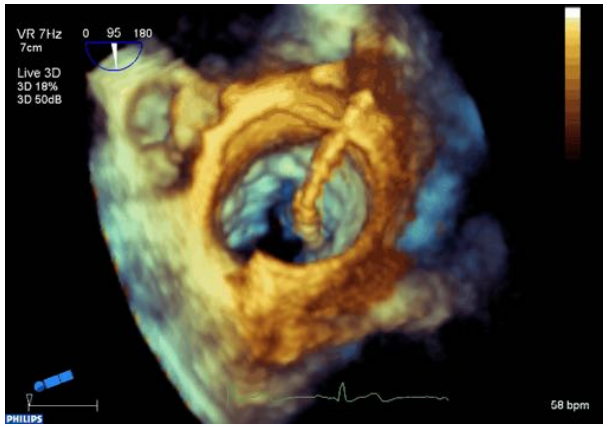


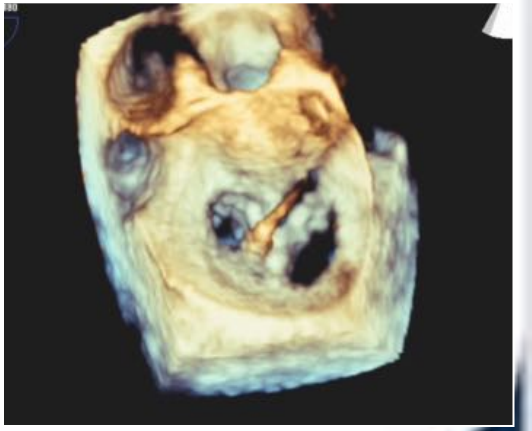




- Clip Crossing



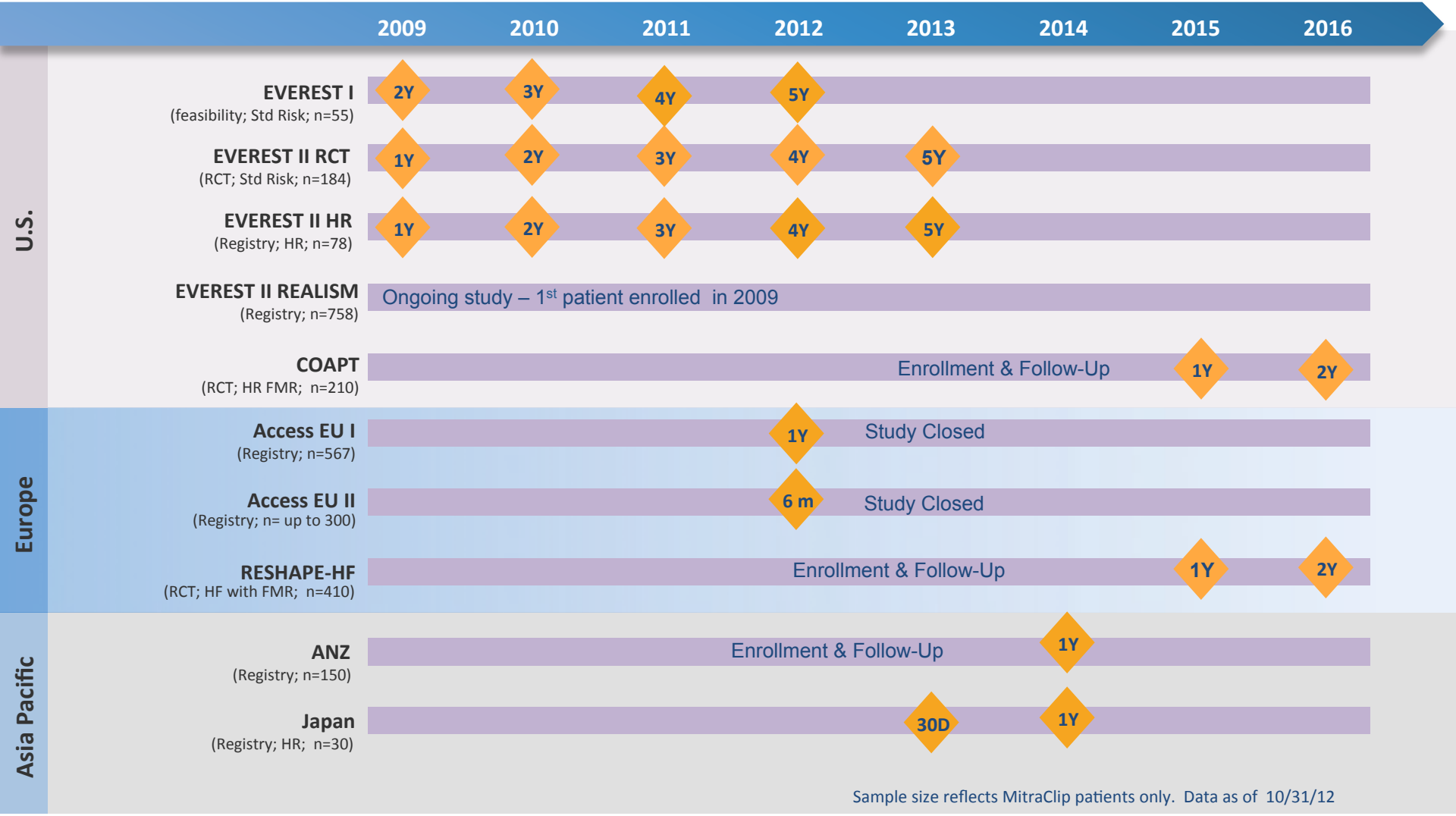




The mitral clip delivery system is angled down towards the mitral leaflets, aiming for A2P2

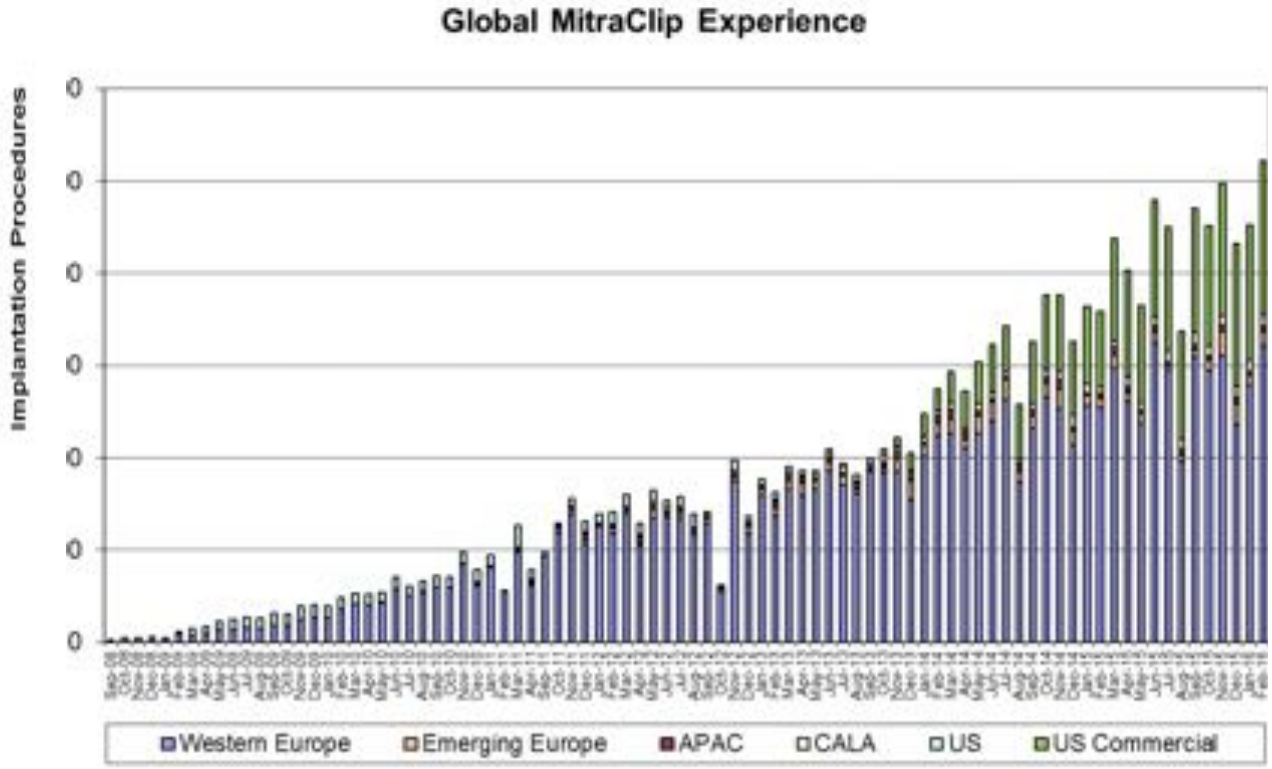
E. Brochet

Clinical Trial Program



Sample size reflects MitraClip patients only. Data as of 10/31/12

Global Mitraclip Procedure ≈40,000



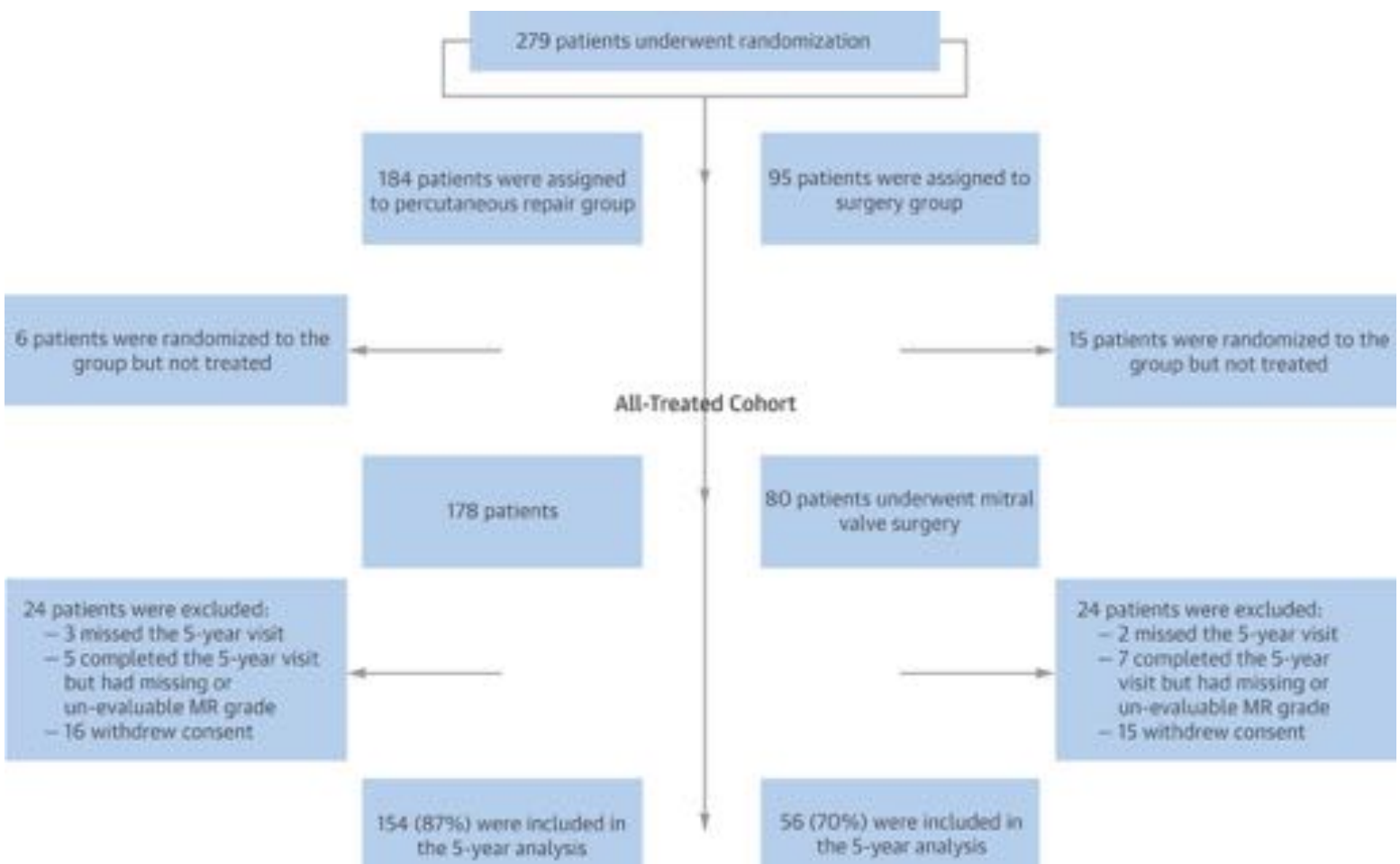
Includes clinical and commercial procedures as of 02/29/2016. Source: Abbott Vascular

Registries on MitraClip

	Age (yrs)	DMR	MR ≤2	In-hospital death
• STS/ACC TVT (US)	83	86%	93%	2.3%
• SENTINEL (EU)	74	28%	95%	2.9%
• ACCESS (EU)	74	23%	91%	
• TRAMI (DE)	75	29%	95%	2.9%
• MitraSwiss (CH)	77	38%	85%	4.0%
• France (FR)	73	23%	88%	3.3%
• GRASP (IT)	72	24%	100%	
• Netherlands (NL)	73	18%	93%	
• MARS (Asia)	71	46%	94%	4.2%
• EVEREST I	71	79%	74%	0.9%
• EVEREST II RCT	67	51%	77%	1.1%
• EVEREST II HRS	76	30%	86%	2.6%

Sorajja et al J Am Coll Cardiol. 2016;67:1129–40

Everest II RCT



Feldman et al, JACC 201

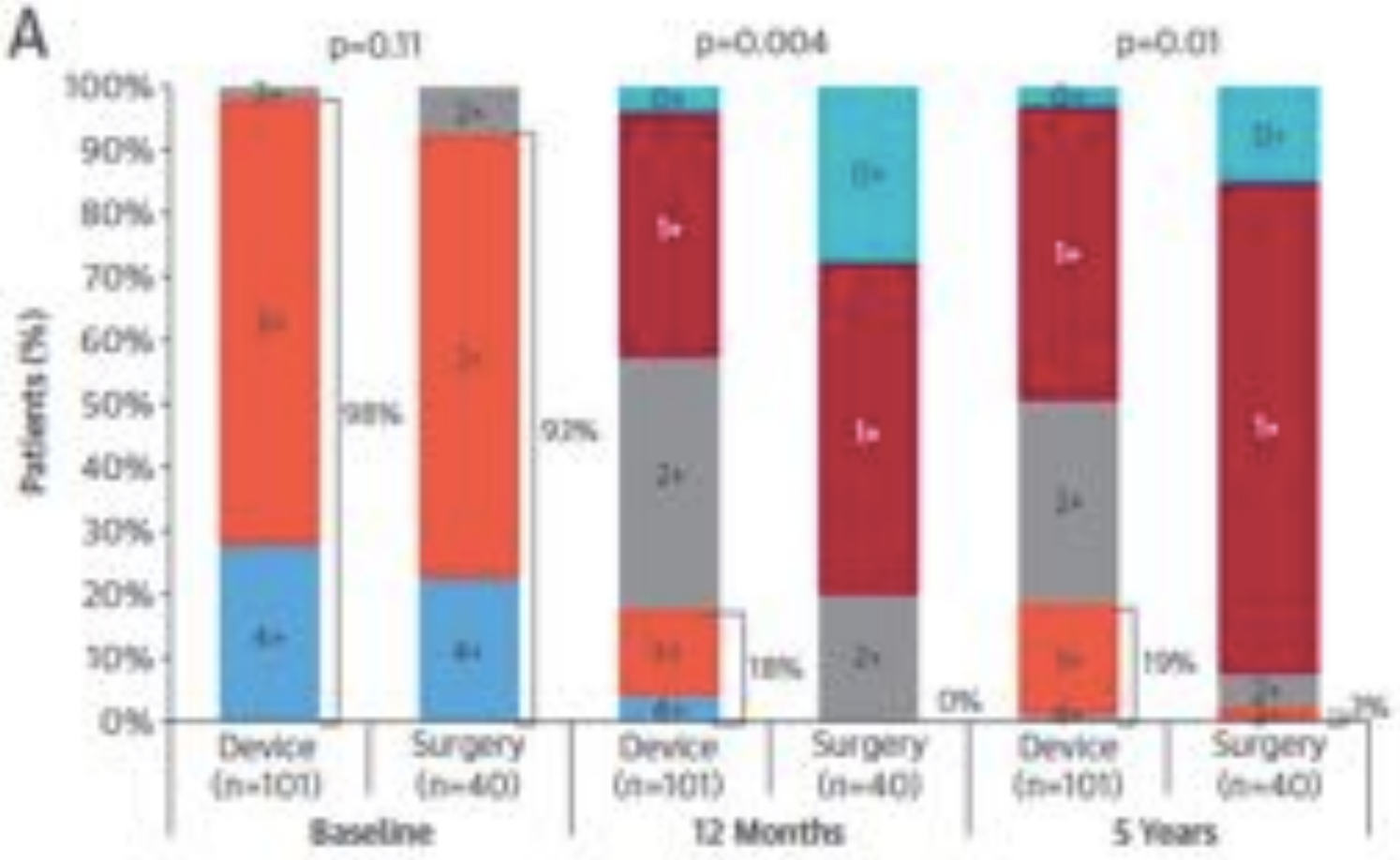
Safety Endpoint: 30 Day MAE

EVEREST II Randomized Controlled Trial (RCT)

30 Day MAE	# (%) Patients experiencing event	
	Percutaneous (N=180)	Surgery (N=94)
Death	2 (1.1%)	2 (2.1%)
Major Stroke	2 (1.1%)	2 (2.1%)
Re-operation of Mitral Valve	0	1 (1.1%)
Urgent / Emergent CV Surgery	4 (2.2%)	4 (4.3%)
Myocardial Infarction	0	0
Renal Failure	1 (0.6%)	0
Deep Wound Infection	0	0
Ventilation > 48 hrs	0	4 (4.3%)
New Onset Permanent Atrial Fib	2 (1.1%)	0
Septicemia	0	0
GI Complication Requiring Surgery	2 (1.1%)	0
Transfusions ≥ 2 units	24 (13.3%)	42 (44.7%)
TOTAL % of Patients with MAE	**15.0%**	**47.9%**
	Difference (Percutaneous – Surgery) = -32.9%	
	p<0.001; (95% CI: -20.7%, -45.0%)	

(Feldman T, N Engl J Med 2011;364:1395 – 1406)

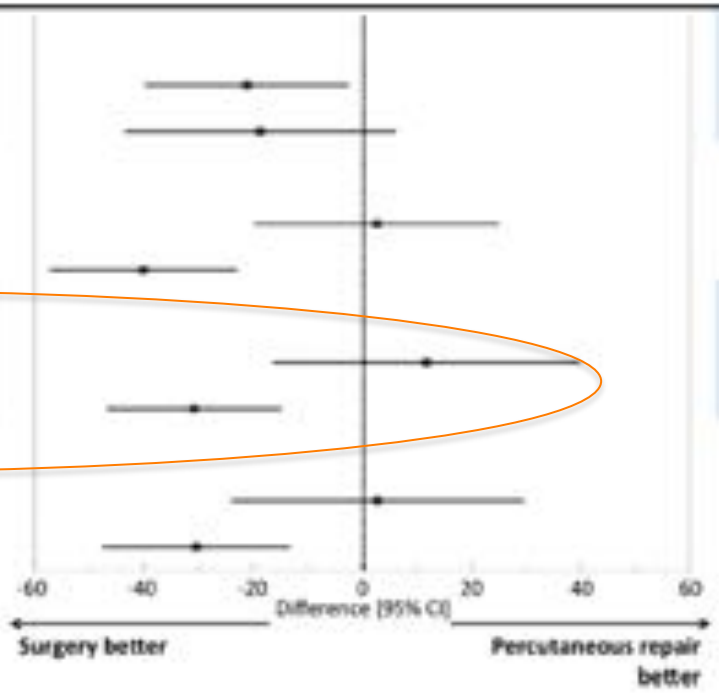
Mitral Regurgitation Grade EVEREST II RCT. 5 years results



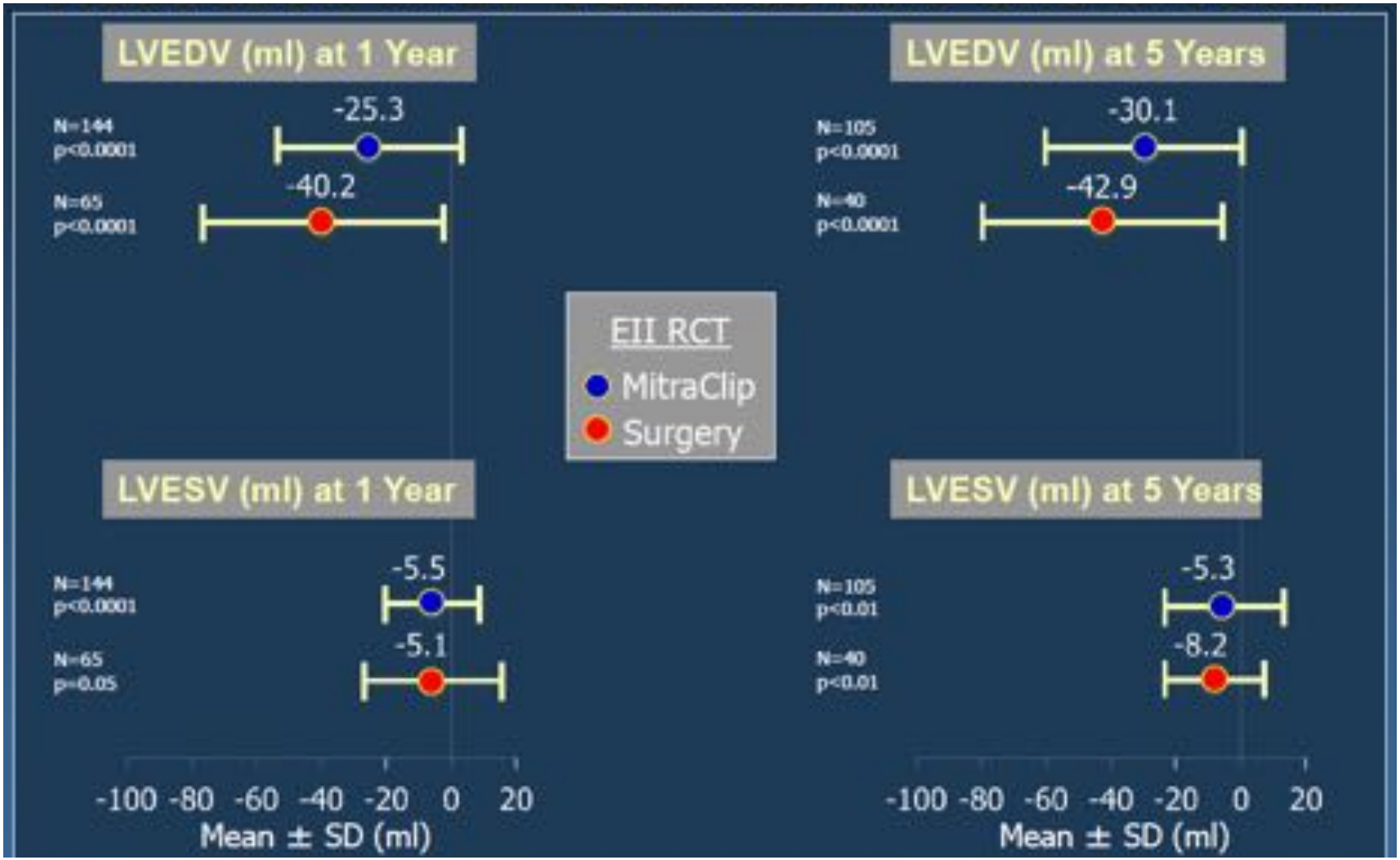
Feldman T et al. J Am Coll Cardiol 2015;66:2844–54

Freedom From Death, MV Surgery or Reoperation, and 3. or 4. MR at 5 Years

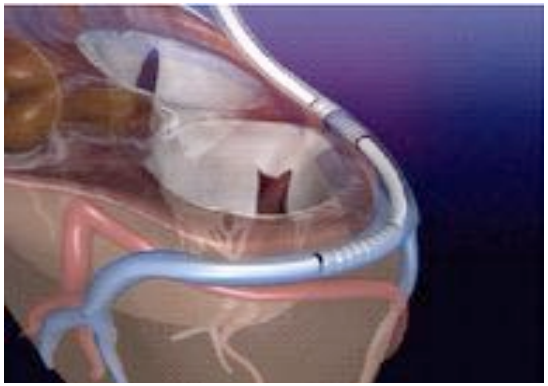
Subgroup	Percutaneous Repair	Surgery	Difference (95% CI)	p value	Interaction p value
Sex					0.89
Male	42.9 (42/98)	63.9 (23/36)	-21.0% (-39.5% to -2.5%)	0.03	
Female	46.4 (26/56)	65.0 (13/20)	-18.6% (-43.2% to 6.1%)	0.15	
Age					0.005
Age ≥70 yrs	45.1 (32/71)	42.3 (11/26)	2.8% (-19.5% to 25.0%)	0.81	
Age <70 yrs	43.4 (36/83)	83.3 (25/30)	-40.0% (-57.0% to -22.9%)	<0.001	
Type of MR					0.02
Functional MR	40.5 (17/42)	28.6 (4/14)	11.9% (-16.0% to 39.8%)	0.43	
Degenerative MR	45.5 (51/112)	76.2 (32/42)	-30.7% (-46.5% to -14.8%)	<0.001	
LVEF					0.04
LVEF <60%	44.1 (26/59)	41.2 (7/17)	2.9% (-23.7% to 29.5%)	0.83	
LVEF ≥60%	44.1 (41/93)	74.4 (29/39)	-30.3% (-47.3% to -13.3%)	0.001	

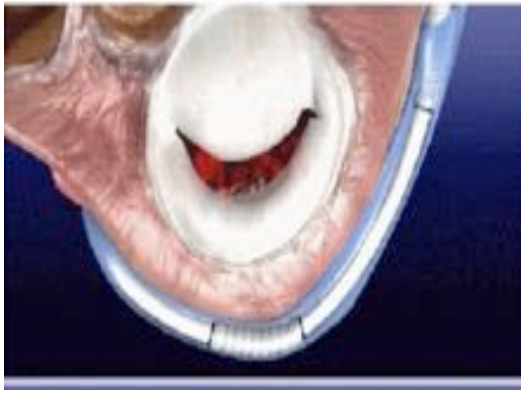


Reduction in LV Volumes at 1 and 5 Years

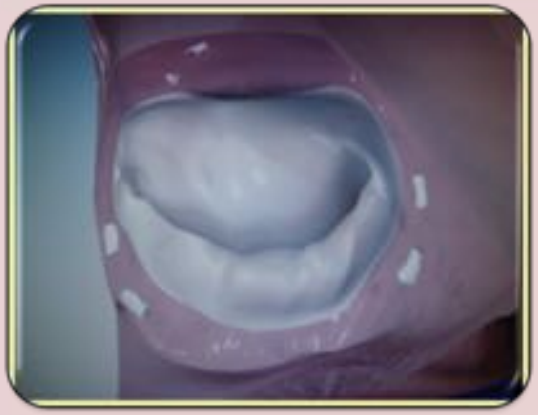


INDIRECT TRANS-CORONARY SINUS ANNULOPLASTY



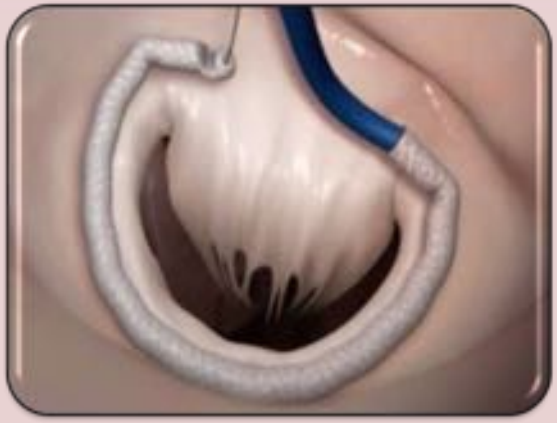


DIRECT ANNULOPLASTY SYSTEMS



Mitralign
Bident
Arterial access
Transannular cinching

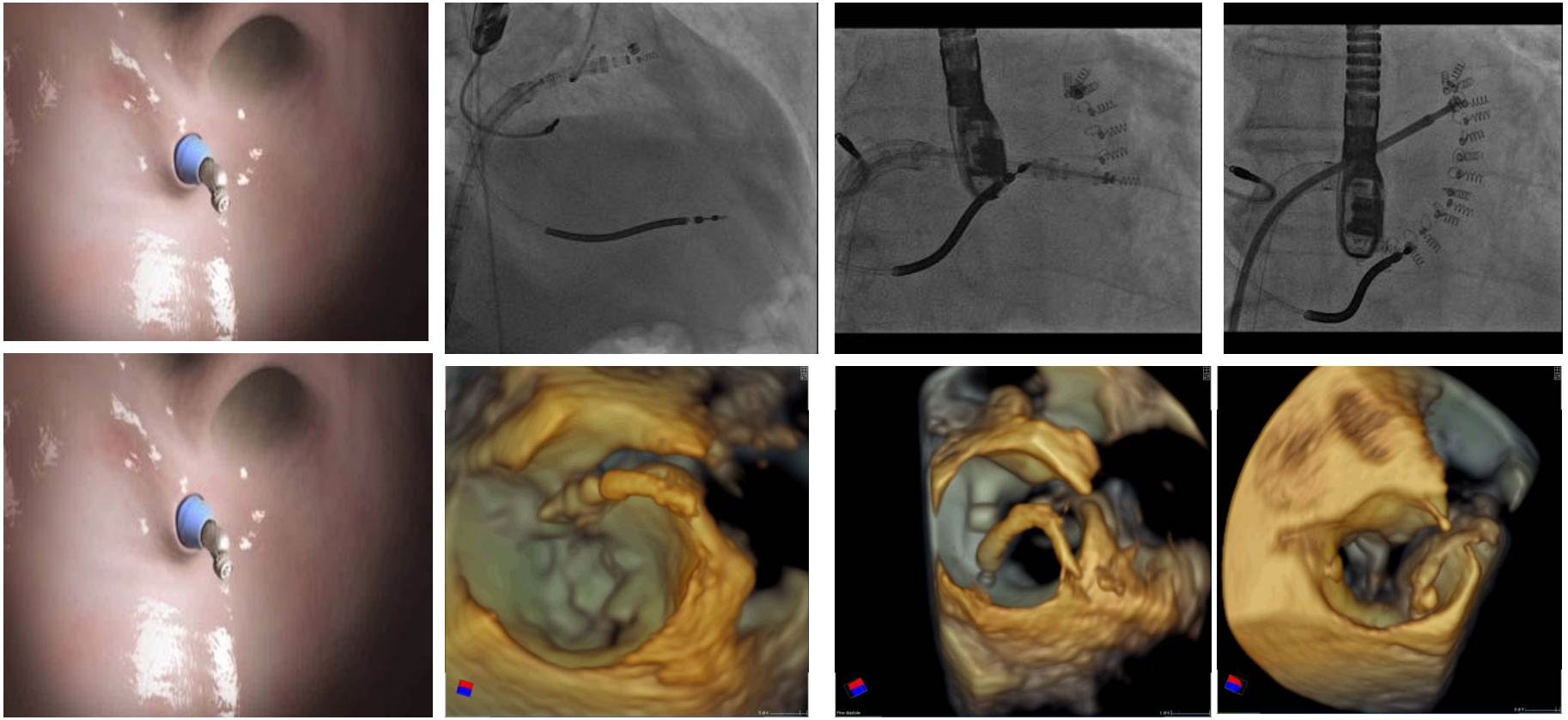
GDS
Accucinch
Arterial access
Subannular cinching



Valtech
Cardioband
Venous access
Annular fixation

PERCUTANEOUS MITRAL RING IMPLANTATION: First in-man Cardioband implantation

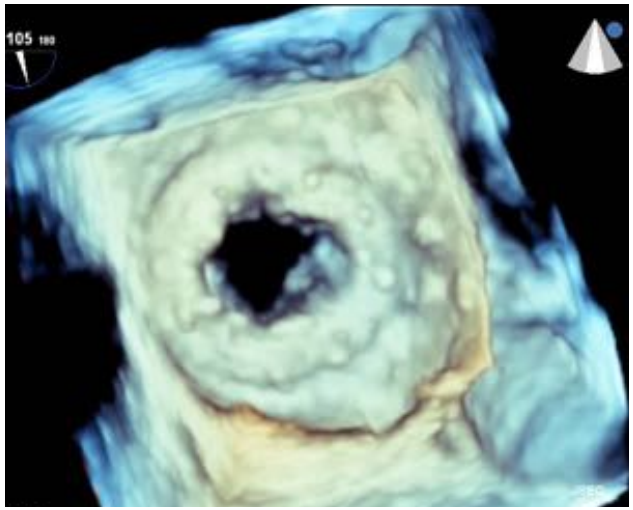
F. Maisano, G.La Canna, A. Latib et al. San Raffaele Hospital, JACC Intervention 2014

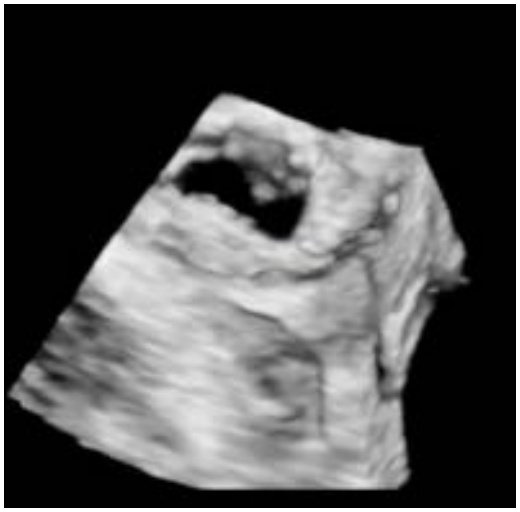


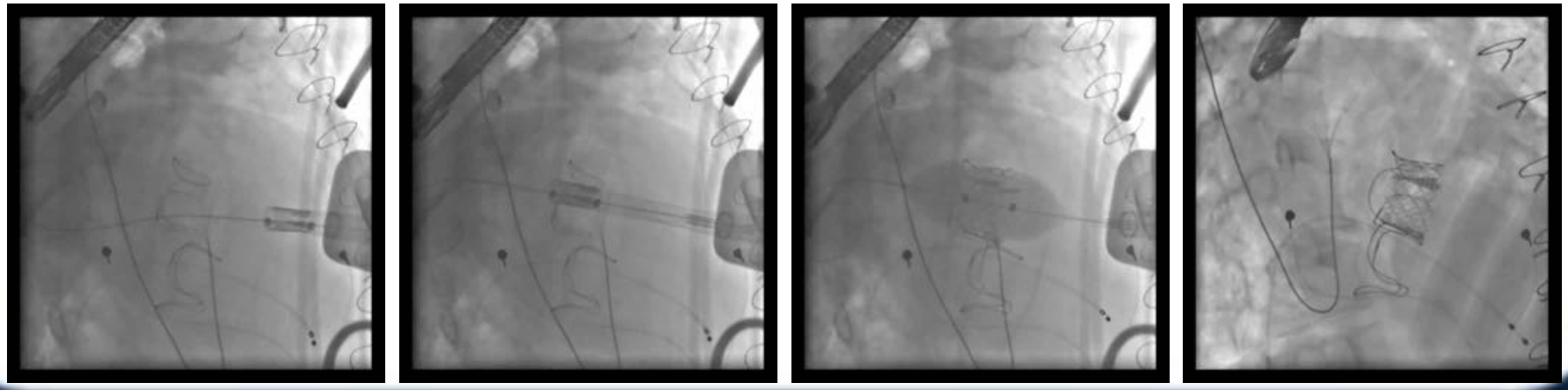
1° step
Cardioband implantation

2° step
Cardioband adjustement

Valve-in-valve (VIV) mitral implantation for SVD of mitral xenograft

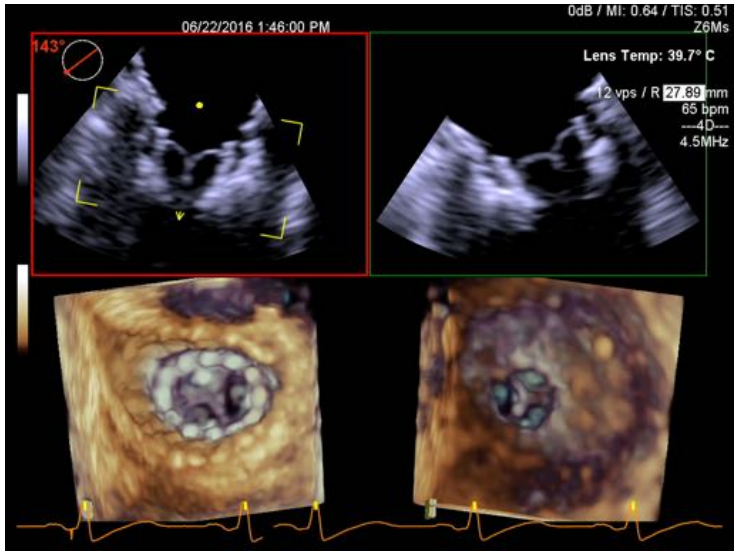


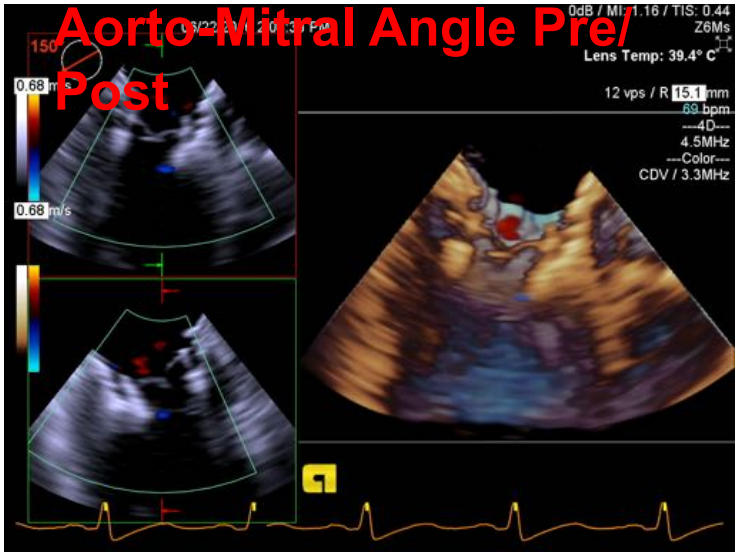


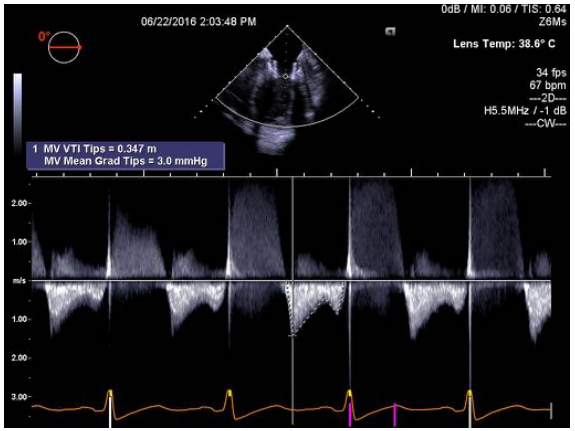


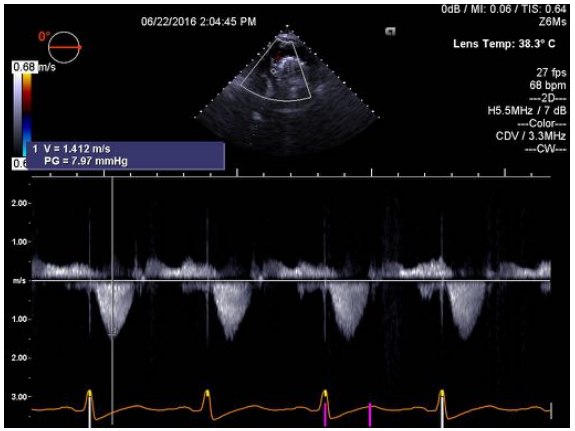
Y. Sharon

TMVR and LVOT Obstruction
Real-Time Volume Color Doppler









Anesthesia and monitoring

- General anesthesia
- Jugular vein access (large bore introducer)
- (Swan-ganz catheter)
- (Temporary PCMK)
- (Radial artery pressure monitoring)
- TEE probe
- Femoral artery access not mandatory (pigtail not mandatory)

Per-procedural Antibiotics and Anticoagulation

- **Antibiotic prophylaxis**

  Cefuroxime 3x 1,5g (1x pre, 2x post)

- **Anticoagulation/antiplatelet therapy**

  - ACT-guided heparinization: ACT> 250s after transseptal puncture
  - Consider Protamine for heparin-antagonization at end of procedure

Intraoperative management

- Most patients are very stable
  - Keep loading conditions stable (monitor wedge pressure and MAP)
- In case of instability
  - Amiodarone
  - Optimize CRT/consider pacing
  - Dopamine/dobutamine/adrenaline
  - IABP
  - Rule out pericardial effusion

Post-procedural Management

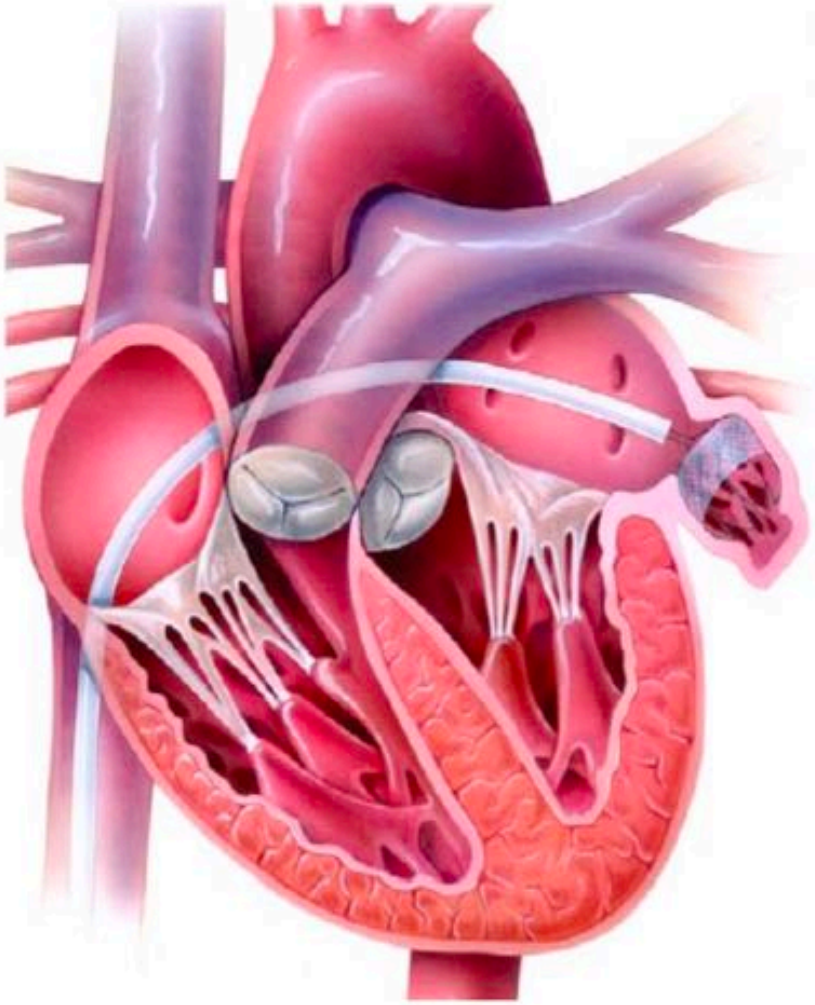
- **ICU/CCU monitoring (24-48h)**
  - Pt can be weaned from anesthesia in the lab or in the ICU
  - ICU stay is not mandatory, but advisable for at least 4 hrs after the procedure
  - Vital Signs
  - Rhythm and HD surveillance
  - Complications: access site bleeding, partial clip detachment or embolization, development of mitral stenosis, arrhythmia, pericardial effusion and tamponade, bleeding…
- **Cardiology Unit**
  - Clinical and echocardiographic parameters at discharge
  - Antithrombotic treatment:
    - if atrial fibrillation: anticoagulation (INR 2-3) lifelong + clopidogrel (75mg/d) for 4 weeks
    - if sinus rhythm: clopidogrel (75mg/d) for 3 months + aspirin (100mg/d) lifelong

Follow-up

- At 3, 6, 12, 18, … months:
  - Clinical assessment (NYHA, 6-MWT, Minnesota Questionnaire)
  - Lab: Pro-BNP
- Echocardiographic parameters:
  - MR grade, Clip in place
  - LVEF, LV-dimensions and volumes
  - MVA, mean gradient
  - RVSP
  - (LA dimension, LA volume (indexed), septal-lateral annular dimension
- Mitrabel Registry

Thank you for your attention!

Percutaneous Left Atrial Appendage Closure



Atrial Fibrillation and Stroke

- AF most common arrhythmia, 1% of the population, increasing with age
- Cardiac sources of emboli account for >25% of all ischemic strokes
- Strokes due to cardioembolism are in general severe and prone to early and long-term recurrence
- Nonvalvular AF remains the most common cause of cardioembolic stroke (50%)
- AF: 15% of all strokes and 30% of strokes in patients age >80 years
- Stroke is the number one cause of long-term disability
- Strokes associated with AF more severe:
  - 50% greater risk of disability or handicap
  - > 50% greater risk of death

Anticoagulation

Oral anticoagulation highly effective in preventing thromboembolism with AF

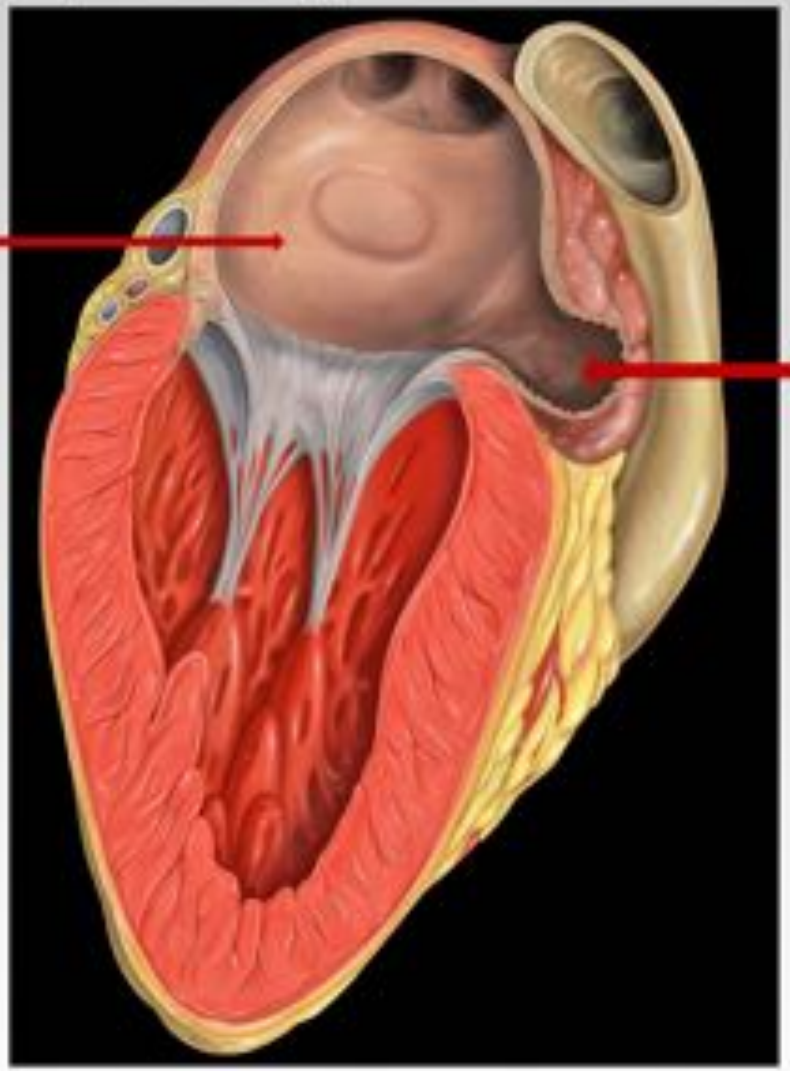
- 64% stroke reduction with warfarin
- 26% mortality reduction

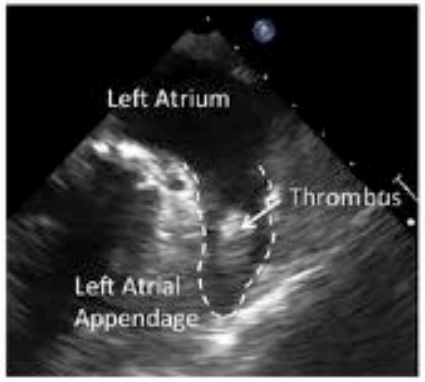
BUT…

1. Warfarin and NOAC have limitations
2. 20% to 50% of eligible patients do not receive OAC due to absolute contraindications or perceived risks of bleeding.

Left Atrial Appendage

Left atrium

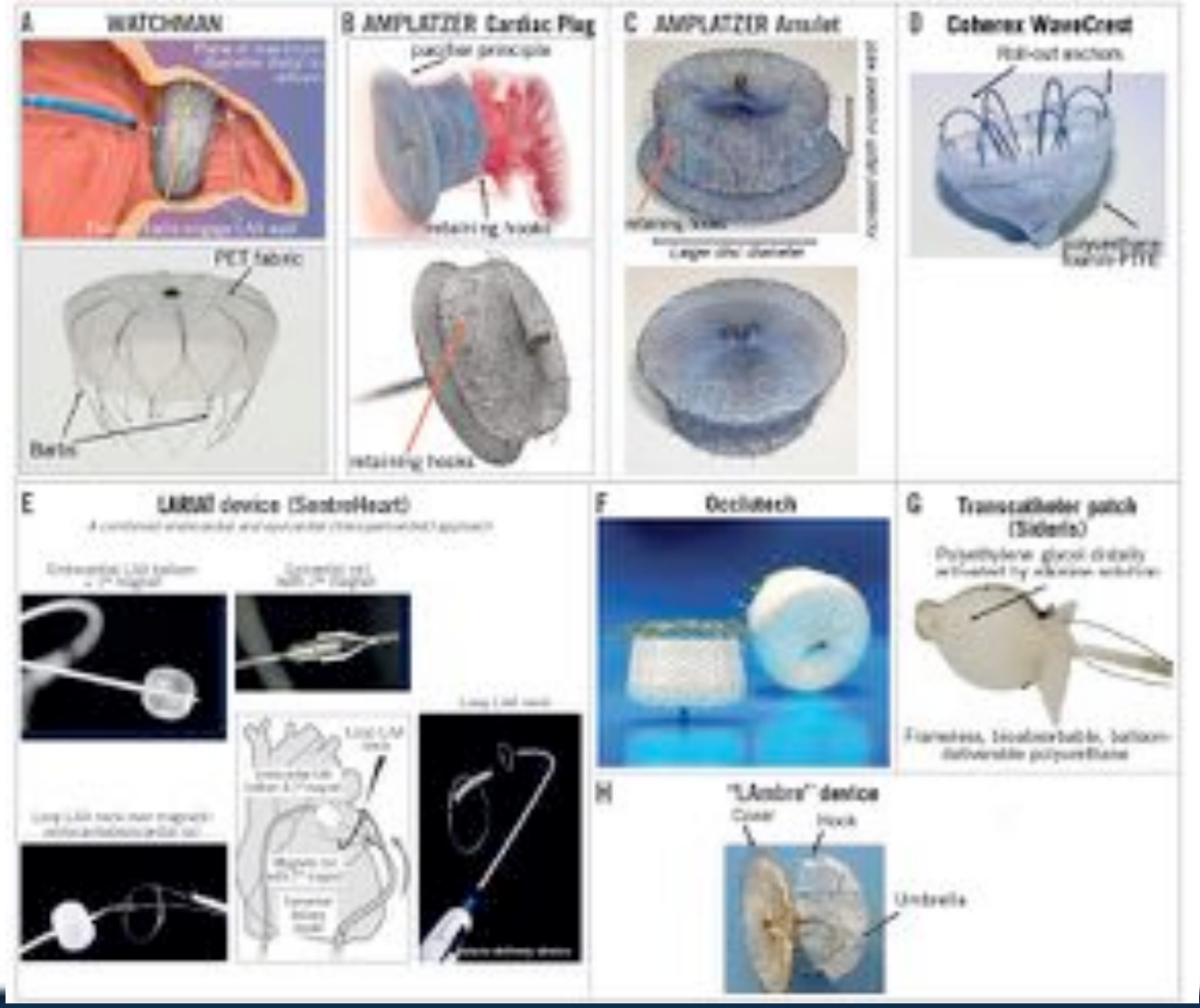




LAA: source of 90% of AF-related thrombi[a]

a. Blackshear JL, et al.[7]

DEVICES and TECHNIQUES



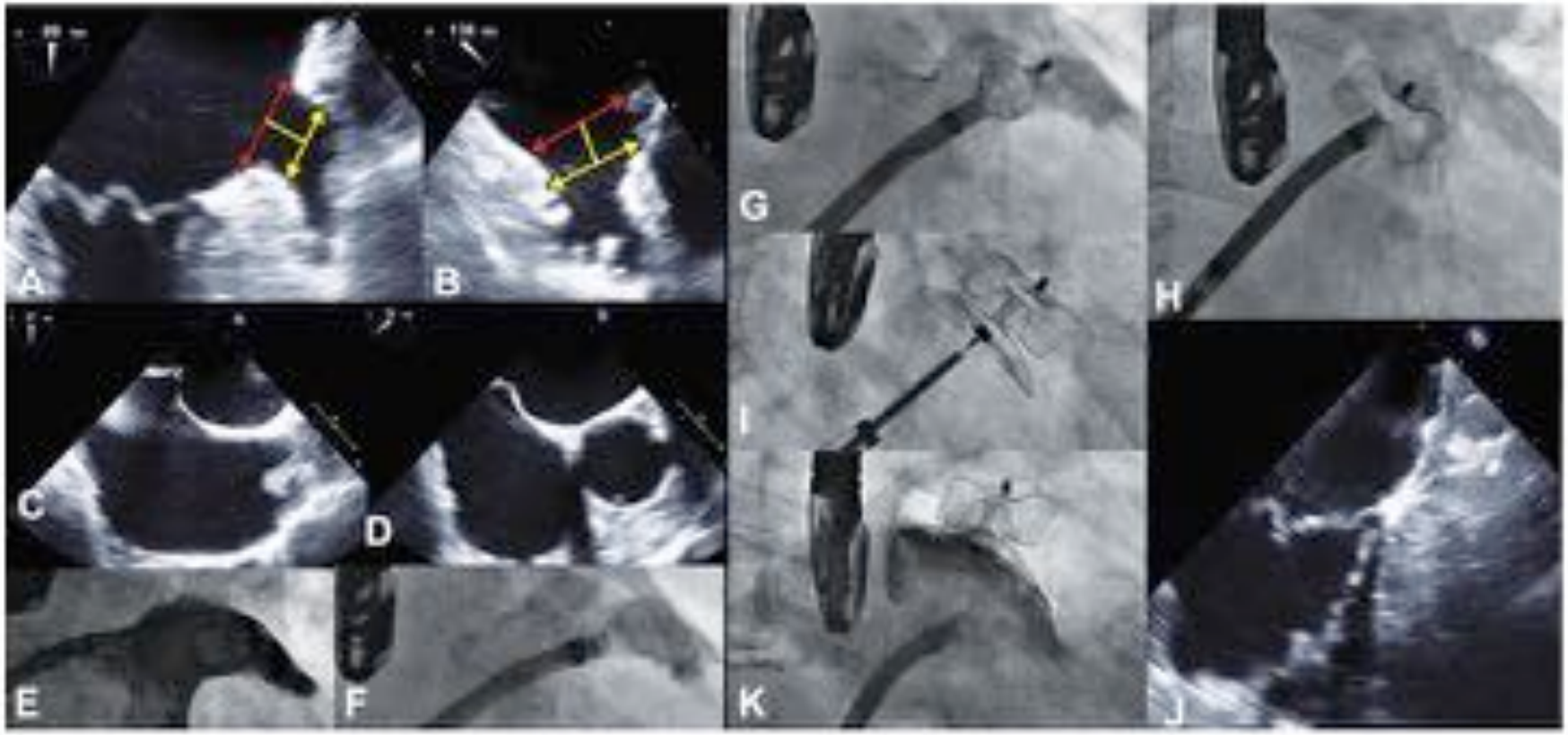


FIGURE 4 **ACP/Amulet Implantation**

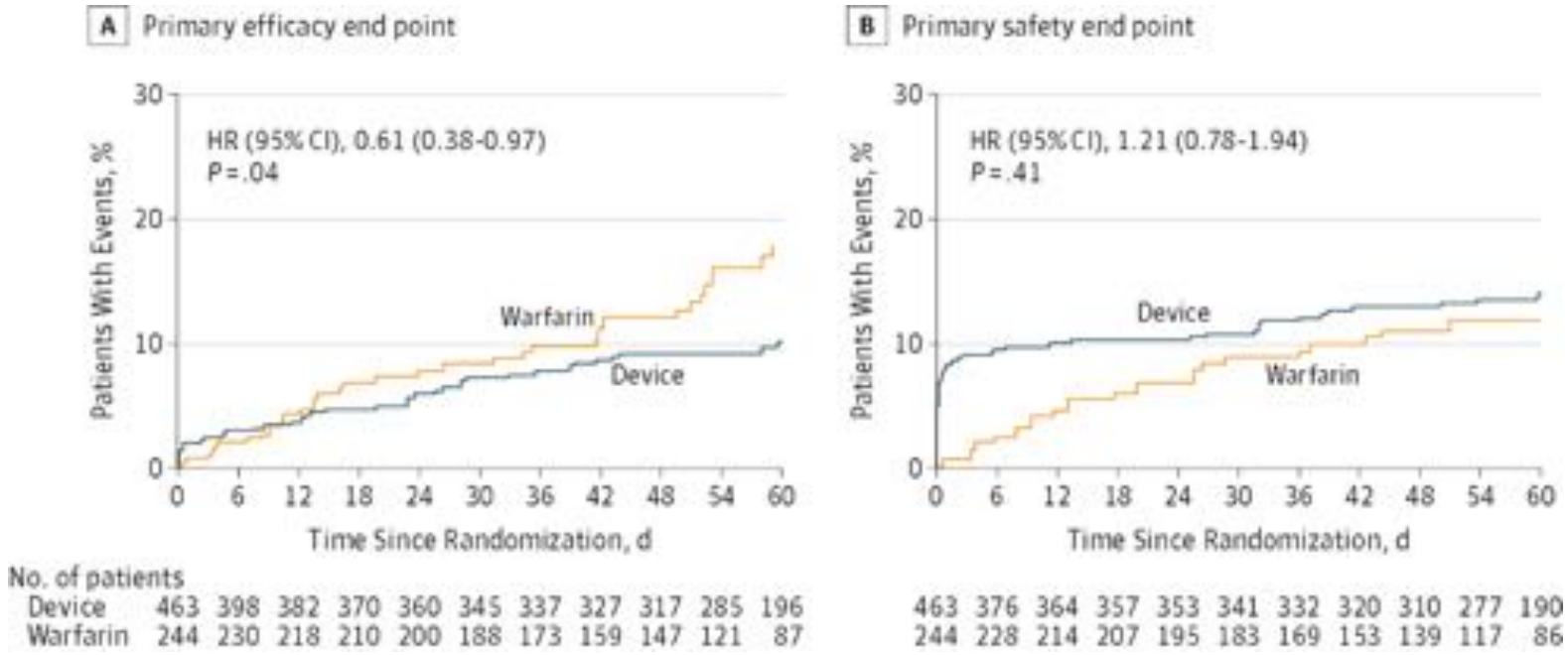
(A) Short- and **(B)** long-axis baseline TEE views showing measurements of the orifice **(red arrows)** and the landing zone **(yellow arrows)** at 10 mm **(yellow line)** within the orifice. Transseptal puncture in an inferior position on bicaval TEE view **(C)** and posterior position on short-axis TEE view **(D)**. **(E)** Cineangiogram with marker pigtail in the LAA, and same measurements taken as with TEE. **(F)** TorqueVue 45 × 45 sheath is advanced with distal tip aligned with the landing zone. **(G)** First step of ACP/Amulet deployment is unsheathing to a "bell" configuration. **(H)** The remainder of the lobe is unsheathed and the position is checked on cineangiogram and TEE. **(I)** The disk is then unsheathed. **(J)** Device position is confirmed on TEE with color Doppler to assess leak. **(K)** Device is released and final cineangiogram performed. Abbreviations as in Figures 2 and 3.

Original Investigation

Percutaneous Left Atrial Appendage Closure vs Warfarin for Atrial Fibrillation

A Randomized Clinical Trial

Vivek Y. Reddy, MD; Horst Sievert, MD; Jonathan Halperin, MD; Shephal K. Doshi, MD; Maurice Buchbinder, MD; Petr Neuzil, MD, PhD; Kenneth Huber, MD; Brian Whisenant, MD; Saibal Kar, MD; Vijay Swarup, MD; Nicole Gordon, BSEE; David Holmes, MD; for the PROTECT AF Steering Committee and Investigators



Implant success and safety of left atrial appendage closure with the WATCHMAN device: peri-procedural outcomes from the EWOLUTION registry

Lucas V.A. Boersma[1]*, Boris Schmidt[2], Timothy R. Betts[3], Horst Sievert[4], Corrado Tamburino[5], Emmanuel Teiger[6], Evgeny Pokushalov[7], Stephan Kische[8], Thomas Schmitz[9], Kenneth M. Stein[10] and Martin W. Bergmann[11], on behalf of the EWOLUTION investigators

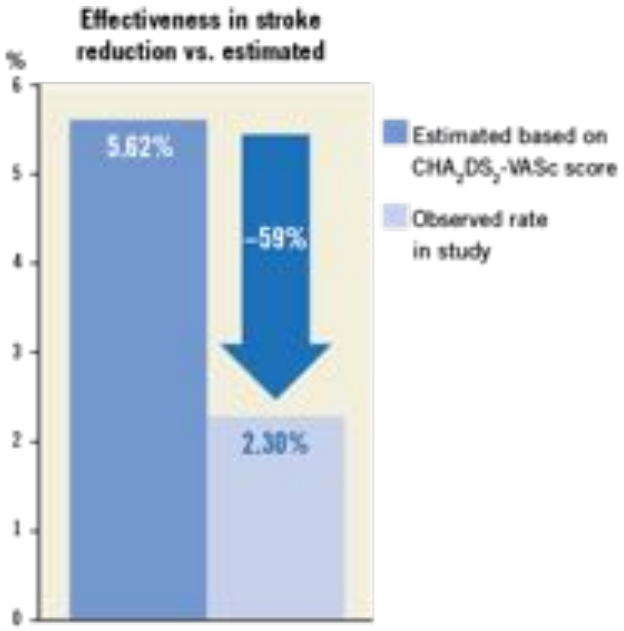
Aims Left atrial appendage closure is a non-pharmacological alternative for stroke prevention in high-risk patients with non-valvular atrial fibrillation. The objective of the multicentre EWOLUTION registry was to obtain clinical data on procedural success and complications, and long-term patient outcomes, including bleeding and incidence of stroke/transient ischaemic attack (TIA). Here, we report on the peri-procedural outcomes of up to 30 days.

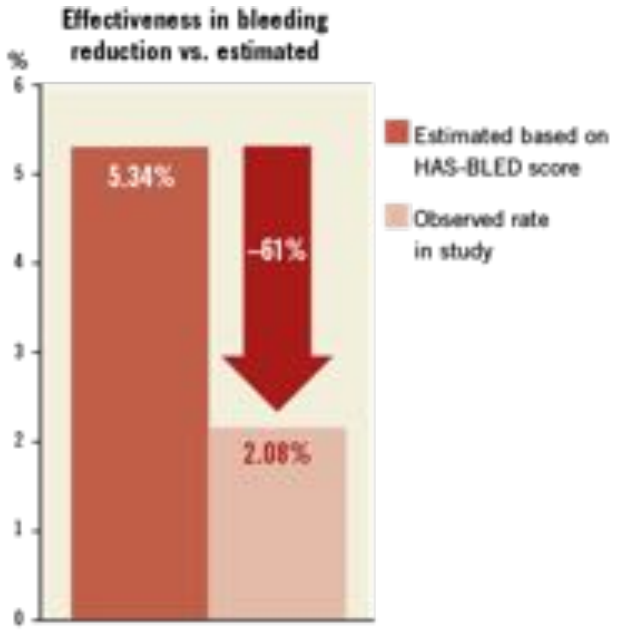
Methods and results Baseline/implant data are available for 1021 subjects. Subjects in the study were at high risk of stroke (average $CHADS_2$ score: 2.8 $\pm$ 1.3, CHA_2DS_2-VASc: 4.5 $\pm$ 1.6) and moderate-to-high risk of bleeding (average HAS-BLED score: 2.3 $\pm$ 1.2). Almost half of the subjects (45.4%) had a history of TIA, ischaemic stroke, or haemorrhagic stroke; 62% of patients were deemed unsuitable for novel oral anticoagulant by their physician. The device was successfully deployed in 98.5% of patients with no flow or minimal residual flow achieved in 99.3% of implanted patients. Twenty-eight subjects experienced 31 serious adverse events (SAEs) within 1 day of the procedure. The overall 30-day mortality rate was 0.7%. The most common SAE occurring within 30 days of the procedure was major bleeding requiring transfusion. Incidence of SAEs within 30 days was significantly lower for subjects deemed to be ineligible for oral anticoagulation therapy (OAT) compared with those eligible for OAT (6.5 vs. 10.2%, $P = 0.042$).

Conclusion Left atrial appendage closure with the WATCHMAN device has a high success rate in complete LAAC with low peri-procedural risk, even in a population with a higher risk of stroke and bleeding, and multiple co-morbidities. Improvement in implantation techniques has led to a reduction of peri-procedural complications previously limiting the net clinical benefit of the procedure.

- EWOLUTION Registry
  - Multicentre registry including 1021 high-risk AF patients implanted with the WATCHMAN device in 47 centres
  - Mean age: 73.4±9 years; Average CHA2DS2-VASc score: 4.5±1.6; Average HAS-BLED score: 2.3±1.2
  - 73% deemed unsuitable for oral anticoagulation therapy
  - Device successfully deployed in 98.5% of patients
  - 28 subjects experienced 31 serious adverse events (SAEs) within 1 day of the procedure.
  - Overall 30-day mortality rate: 0.7%
  - Most common SAE occurring within 30 days: major bleeding requiring transfusion
  - 1 year results showing good efficacy of the procedure with only 1.1% of ischemic stroke rate which translates to a RR reduction of 84% when compared to the estimated risk based on historical data

EuroIntervention





Total patients	Total patient-years	CHA_2DS_2-VASc score
1,001	1,349	4.43

Estimated stroke rate per CHA_2DS_2-VASc	Actual annual stroke rate (No. strokes+TIA)
5.62%	2.30% (31)

Total patients	Total patient-years	HAS-BLED score
1,001	1,349	3.12

Estimated bleeding rate per HAS-BLED	Actual annual bleeding rate (No. major bleeds)
5.34%	2.08% (28)

EuroIntervention 2015;10-online publish-ahead-of-print January 2015

Left atrial appendage occlusion for stroke prevention in atrial fibrillation: multicentre experience with the AMPLATZER Cardiac Plug

Amulet Observational Study

- Large prospective real-world registry which 1,088 patients implanted with the Amulet device
- Average age: 75 ±8.5 years; Average CHA2DS2-VASc score: 4.2±1.6; Average HAS-BLED score: 3.3±1.1
- 82.8% of patients were considered to have an absolute or relative contraindication to long-term anticoagulation and 72.4% had had a previous major bleeding
- Successful device implantation rate: 99.0%
- Periprocedural major events rate: 3.2%
- Adequate occlusion of the appendage in 98.2%

Indications

1. High risk of thrombo-embolic complications
   AND
   Contra-indications to OAC

2. AF-related stroke on OAC

Indications

1. **Contraindications to OAC**
   - History of IC bleeding
   - History of major GI bleeding
   - History of other major bleeding
   - Major intraocular bleeding
   - Other

2. **High bleeding risk**
   - High HAS-BLED score (HAS-BLED > 3)
   - Requirement of prolonged triple antithrombotic therapy
   - High risk of bleeding not well defined by bleeding risk score:
     - high risk of falls
     - patients with cancer
     - patients with chronic inflammatory bowel disease…
   - Severe renal failure (creatinine clearance <15-30 mL/min)

3. **Embolic event occurring despite optimal OAC**

4. **Pharmacological considerations**
   - Severe liver or renal dysfunction
   - High risk of drug interaction

5. **Other indications**
   - Noncompliance to treatment
   - Patient preferences

Guidelines

2012 focused update of the ESC Guidelines for the management of atrial fibrillation

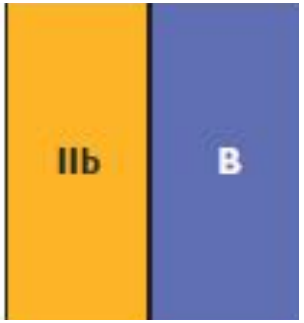
Recommendations for LAA closure/occlusion/excision

Recommendations	Class[a]	Level[b]	Ref[c]
Interventional, percutaneous LAA closure may be considered in patients with a high stroke risk and contraindications for long-term oral anticoagulation.	IIb	B	115, 118
Surgical excision of the LAA may be considered in patients undergoing open heart surgery.	IIb	C	

LAA = left atrial appendage.
[a]Class of recommendation.
[b]Level of evidence.
[c]References.

2014 ESC/EACTS Guidelines on myocardial revascularization

Percutaneous LAA closure and antiplatelet therapy may be considered in patients with atrial fibrillation undergoing PCI if a high stroke risk and contraindication for long-term combined antiplatelet + oral anticoagulation therapy is present.



Management post LAA occlusion

Antithrombotic treatment

Clopidogrel and ASA for 1-3 months and a single antiplatelet drug or nothing thereafter

Follow-up

Control TOE at 6-12 weeks

Prolonged (N)OAC

In case of a device-associated thrombus or large (≥5 mm) leak

PFO Closure

- Foramen ovale created by the overlap of the septum primum and septum secundum
- Foramen ovale may be patent in 25% of the population
- A Patent Foramen Ovale is a potential source for right-to-left intracardiac shunt and can result in **paradoxical emboli** (stroke or systemic embolization)
- Cryptogenic stroke (stroke with no identifiable cause) accounts for 40% of strokes in young adults. A PFO was present in 39% of the patients younger than 55 years with cryptogenic stroke compared to 29% in patients with an identifiable cause for the stroke.

Anatomic features suggesting high-risk PFO:

- large defects (> 5 mm)
- atrial septal aneurysm (ASA)
- persistent right-to-left shunt at rest
- 10 or more microbubbles appearing in the left atrium with a contrast TEE
- presence of a prominent eustachian valve

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Long-Term Outcomes of Patent Foramen Ovale Closure or Medical Therapy after Stroke

Jeffrey L. Saver, M.D., John D. Carroll, M.D., David E. Thaler, M.D., Ph.D., Richard W. Smalling, M.D., Ph.D., Lee A. MacDonald, M.D., David S. Marks, M.D., and David L. Tirschwell, M.D., for the RESPECT Investigators*

RESPECT trial

- Cryptogenic ischemic stroke in patients aged 18-60
- PFO closure vs. Medical group
- Long follow-up (median 5.9 years)
- 45% risk reduction in the PFO group (HR=0,55, p=0.046)
- 62% risk reduction for cryptogenic stroke

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Patent Foramen Ovale Closure or Antiplatelet Therapy for Cryptogenic Stroke

Lars Søndergaard, M.D., Scott E. Kasner, M.D., John F. Rhodes, M.D., Grethe Andersen, M.D., D.M.Sc., Helle K. Iversen, M.D., D.M.Sc., Jens E. Nielsen-Kudsk, M.D., D.M.Sc., Magnus Settergren, M.D., Ph.D., Christina Sjöstrand, M.D., Ph.D., Risto O. Roine, M.D., David Hildick-Smith, M.D., J. David Spence, M.D., and Lars Thomassen, M.D., for the Gore REDUCE Clinical Study Investigators*

REDUCE trial

- Cryptogenic stroke in patients aged 18-59
- PFO closure vs. Medical treatment (antiplatelet)
- 77% risk reduction for clinical ischemic stroke in PFO group (HR=0,23, p= 0.002)

The NEW ENGLAND JOURNAL of MEDICINE

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Patent Foramen Ovale Closure or Anticoagulation vs. Antiplatelets after Stroke

J.-L. Mas, G. Derumeaux, B. Guillon, E. Massardier, H. Hosseini, L. Mechtouff, C. Arquizan, Y. Béjot, F. Vuillier, O. Detante, C. Guidoux, S. Canaple, C. Vaduva, N. Dequatre-Ponchelle, I. Sibon, P. Garnier, A. Ferrier, S. Timsit, E. Robinet-Borgomano, D. Sablot, J.-C. Lacour, M. Zuber, P. Favrole, J.-F. Pinel, M. Apoil, P. Reiner, C. Lefebvre, P. Guérin, C. Piot, R. Rossi, J.-L. Dubois-Randé, J.-C. Eicher, N. Meneveau, J.-R. Lusson, B. Bertrand, J.-M. Schleich, F. Godart, J.-B. Thambo, L. Leborgne, P. Michel, L. Pierard, G. Turc, M. Barthelet, A. Charles-Nelson, C. Weimar, T. Moulin, J.-M. Juliard, and G. Chatellier, for the CLOSE Investigators*

CLOSE trial

- Stroke attributed to PFO with an associated atrial septal aneurysm or large interatrial shunt in patients 16 to 60 years of age
- PFO closure vs. antiplatelet therapy vs. oral anticoagulation
- 97% risk reduction in patients treated with PFO closure vs antiplatelet therapy

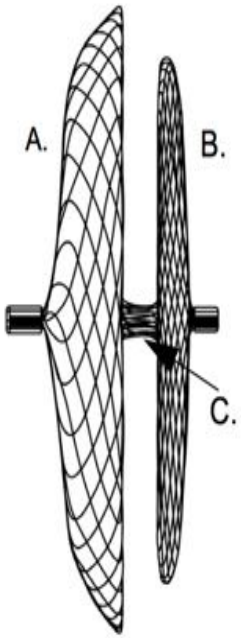
PFO closure Procedure and Management

Procedure

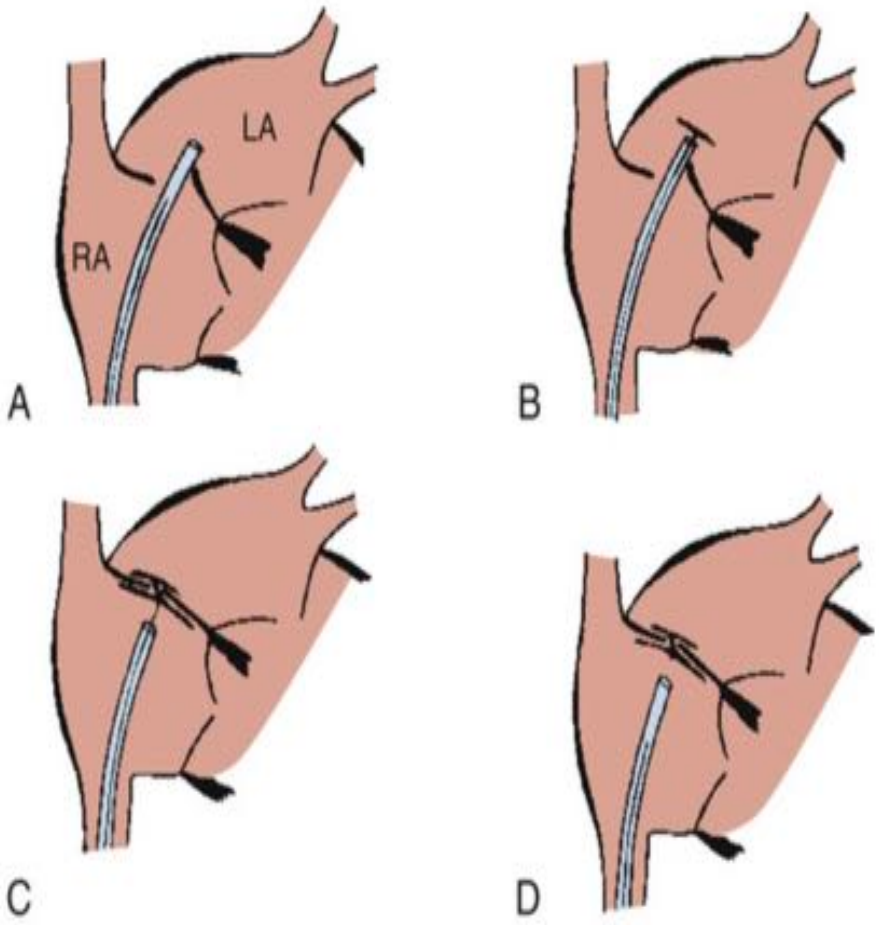
- One-day clinic
- TOE-guided
- Venous access (8-9 Fr)

Management

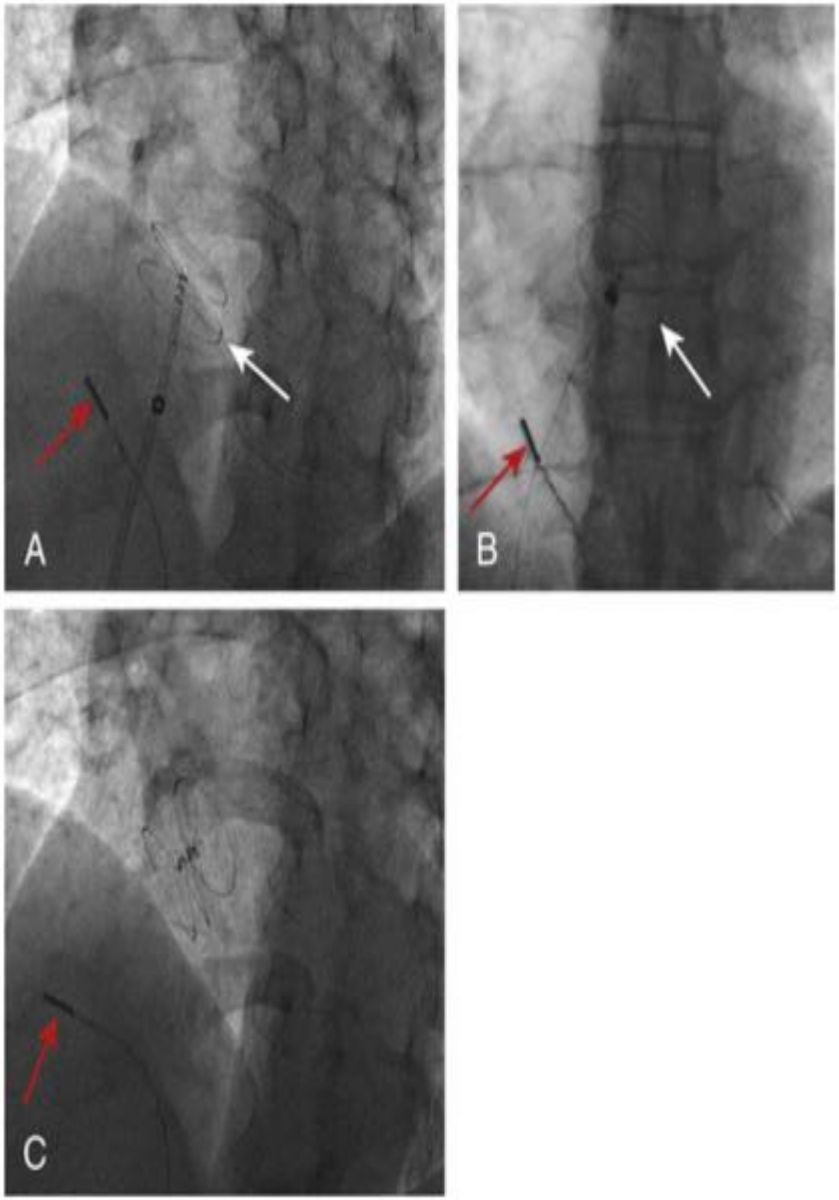
- Transoesophageal echocardiography 3 months after procedure
- Clopidogrel 3 months, ASA lifelong

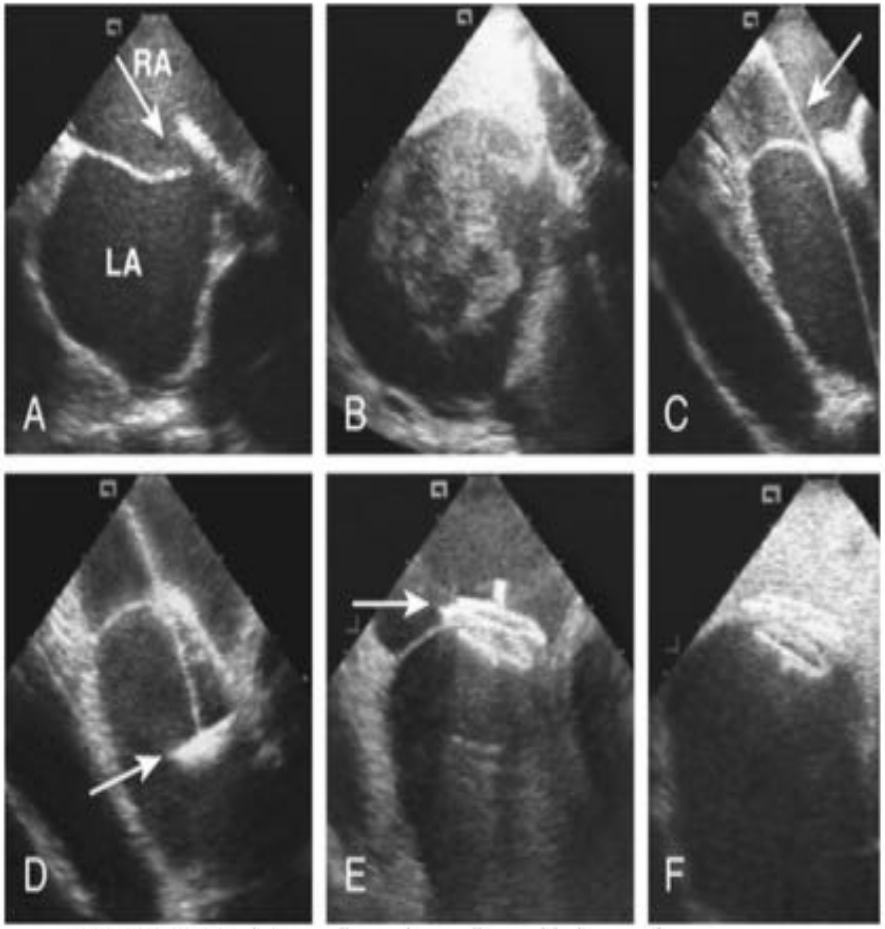


A. Right atrial disc
B. Left atrial disc
C. Waist



Kern, Morton J.; Lim, Michael J; Sorajja, Paul. The Interventional Cardiac Catheterization Handbook E-Book (p. 430). Elsevier Health Sciences. Kindle Edition.





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