MRI-Compatible Pacemaker, LA Appendage Occluder, Transcatheter Aortic Valve Implantation

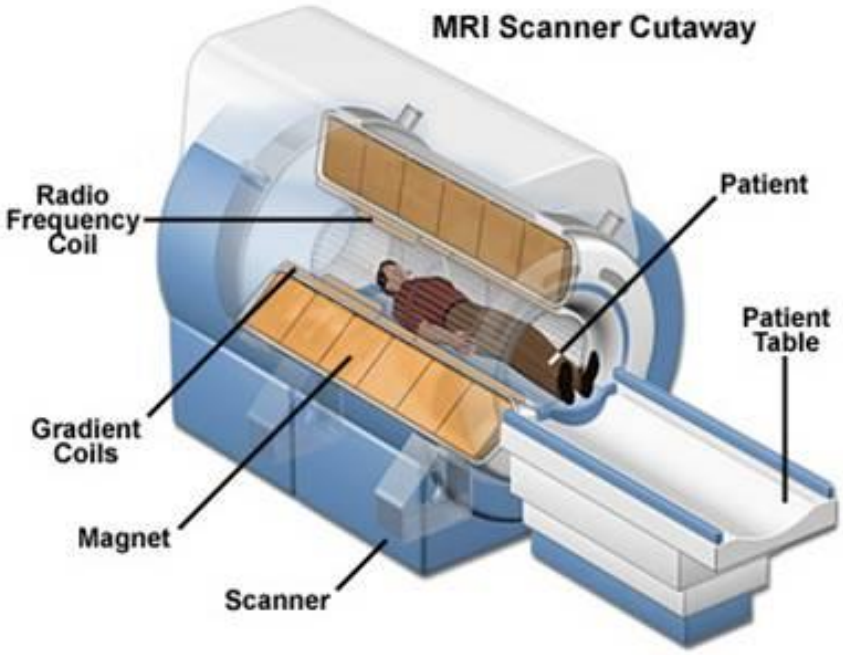
연세대학교 의과대학
세브란스병원 심장내과
엄 재 선

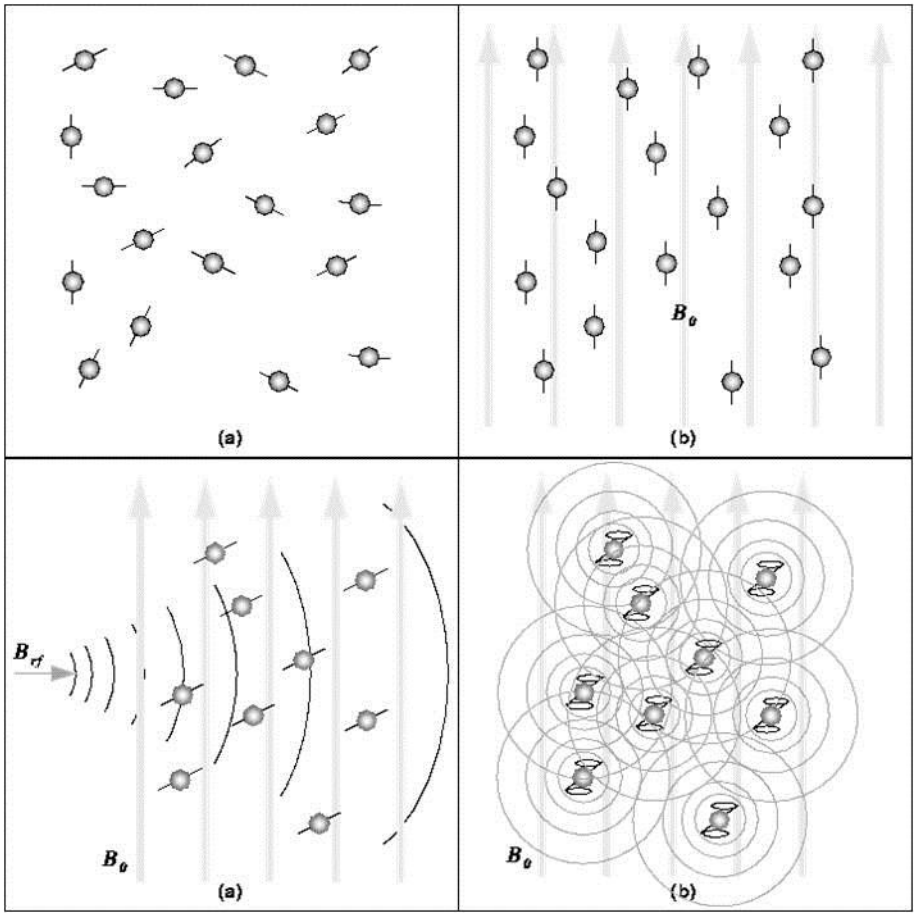
MRI-Compatible Pacemaker

Magnetic Resonance Imaging

- Gold standard for soft tissue imaging
- Neurologic disorders, musculoskeletal system, cancer, etc.
- No exposure to ionizing radiation
- Contrast material : Less likelihood of nephrotoxicity and allergic reaction

Principles of MRI





MRI-Related Pacemaker Problems

- Heating at the lead-tissue interface
- Force & torque on devices
- Alteration of programming
- Potential damage to the pacemaker circuitry
- Inhibition of pacing output
- Rapid atrial/ventricular pacing
- Induction of ventricular fibrillation

MRI-Related Pacemaker Problems

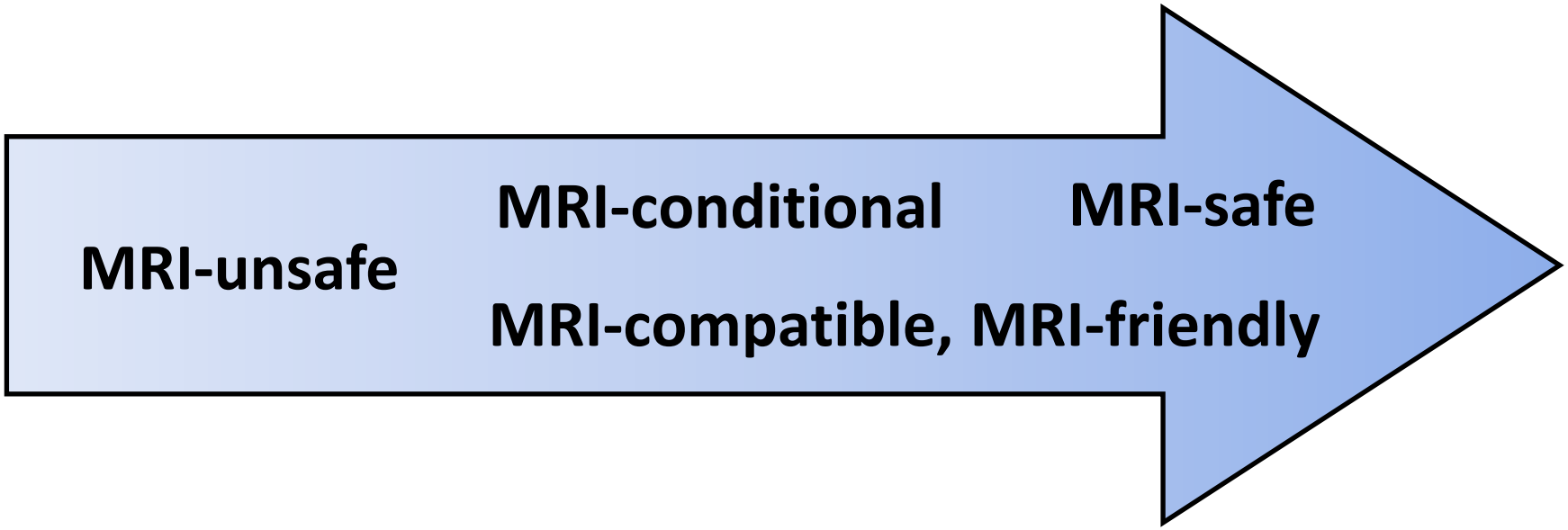
- Pacemaker : Relative contraindication to MRI
- 17% of patients with pacemaker should require an MRI within 8 years of implantation.
- Incidence of MRI-related pacemaker complications : Less than 10%
- MRI-related mortality in patients with pacemaker : 10 deaths in literature

2007 AHA Scientific Statement

- **Pacemaker : Relative contraindication to MRI**
- **Careful evaluation of risk-benefit ratio**
- **MRI of pacemaker-dependent patients should not be performed.**

AHA Scientific Statement, Circulation, 2007

Terminology



Available MRI-Compatible Pacemakers

	Advisa (Medtronic)	Accent (St Jude M)	Evia (Biotronik)
Scan range	Full body	Full body	Brain, lower limbs
MRI machine	1.5 T, cylindrical bore	1.5 T, cylindrical bore	1.5 T, cylindrical bore
SAR	≤ 2.0 W/kg	≤ 4.0 W/kg	≤ 2.0 W/kg
Patient positioning	Supine or dorsal	Supine or dorsal	Dorsal
Mode	DDDR	AAIR, VVIR, DDDR	AAIR, VVIR, DDDR
Lead fixation	Active	Active	Active & passive
Lead diameter	7 Fr	8 Fr	5.6 Fr, 6.6 Fr
Approval	FDA, CE	CE	CE

Randomized trial of pacemaker and lead system for safe scanning at 1.5 Tesla

J. Rod Gimbel, MD, FACC,[*] David Bello, MD,[†] Matthias Schmitt, MD PhD, MRCP,[‡] Béla Merkely, MD, PhD, DSc,[§] Juerg Schwitter, MD,[‖] David L. Hayes, MD, FHRS, CCDS,[¶] Torsten Sommer, MD, PhD,[#] Edward J. Schloss, MD, FACC,[**] Yanping Chang, MS,[††] Sarah Willey, MPH,[††] Emanuel Kanal, MD, FACR, FISMRM[‡‡] on behalf of the Advisa MRI System Study Investigators

*From the *Cardiology Associates of East Tennessee, Knoxville, Tennessee, [†]Mid Florida Cardiology, Orlando, Florida, [‡]University Hospital of South Manchester, Manchester, United Kingdom, [§]Heart Center Semmelweis University, Budapest, Hungary, [‖]Centre Hospitalier Universitaire Vaudois, Lausanne, Switzerland, [¶]Mayo Clinic, Rochester, Minnesota, [#]German Red Cross Hospital, Neuwied, Germany, **The Christ Hospital/The Lindner Center, Cincinnati, Ohio, [††]Medtronic Inc., Mounds View, Minnesota, and [‡‡]University of Pittsburgh Medical Center, Pittsburgh, Pennsylvania.*

BACKGROUND Magnetic resonance imaging (MRI) of pacemakers is a relative contraindication because of the risks to the patient from potentially hazardous interactions between the MRI and the pacemaker system. Chest scans (ie, cardiac magnetic resonance scans) are of particular importance and higher risk. The previously Food and Drug Administration-approved magnetic resonance conditional system includes positioning restrictions, limiting the powerful utility of MRI.

OBJECTIVE To confirm the safety and effectiveness of a pacemaker system designed for safe whole body MRI without MRI scan positioning restrictions.

METHODS Primary eligibility criteria included standard dual-chamber pacing indications. Patients (n = 263) were randomized in a 2:1 ratio to undergo 16 chest and head scans at 1.5 T between 9 and 12 weeks postimplant (n = 177) or to not undergo MRI (n =

RESULTS There were no MRI-related complications during or after MRI in subjects undergoing MRI (n = 148). Differences in pacing capture threshold values from pre-MRI to 1-month post-MRI were minimal and similar between the MRI and control groups.

CONCLUSIONS This randomized trial demonstrates that the Advisa MRI pulse generator and CapSureFix MRI 5086MRI lead system is safe and effective in the 1.5 T MRI environment without positioning restrictions for MRI scans or limitations of body parts scanned.

KEYWORDS Advisa MRI; CapSureFix MRI; Chest scan; EnRhythm MRI; Magnetic resonance imaging; Pacemaker; Revo MRI; Safety; SureScan; 5086MRI

Bhandiwad *et al. Journal of Cardiovascular Magnetic Resonance* 2013, **15**:18
http://jcmr-online.com/content/15/1/18

Journal of Cardiovascular Magnetic Resonance

CASE REPORT Open Access

Cardiovascular magnetic resonance with an MR compatible pacemaker

Anita R Bhandiwad[1*], Kristopher W Cummings[2], Michael Crowley[2] and Pamela K Woodard[2]

Abstract

Magnetic resonance imaging (MRI) within FDA guidelines for the MRI-conditional pacemaker precludes placing the heart at the center of the magnet's bore. This in effect appears to preclude cardiovascular MR. In this manuscript, we describe a protocol for cardiovascular MR of patients with a Revo pacemaker system while operating within FDA guidelines, and the first US case of cardiovascular MR in a patient with a Revo MRI-conditional pacing system despite position constraints.

Keywords: MRI-conditional pacemaker, Cardiovascular magnetic resonance, Revo pacer

The patient was referred for CMR 6 months after pacer implantation. The scan was performed on 1.5 T whole body scanner (TIM Symphony, Siemens Medical Systems, Malvern, NJ), slew rate 125 T/m/s. A cardiologist, radiologist and MRI physicist were present. Isocenter was placed inferior to T12, determined by the inferior rib (Figure 1). Minor modifications to the flip angle of the cine steady-state free precession (SSFP) sequences were made to maintain SAR < 2 W/kg. The table position was set to "FIXED" to prevent default movement. Prior to scanning, the device was interrogated: atrial lead impedance 568 ohms, ventricular lead impedance 472 ohms, atrial lead capture threshold 1 V at 0.4 ms, ventricular lead capture threshold 1 V at 0.4 ms, P-wave amplitude sensing 3.4 mV, R-wave amplitude sensing 10.3 mV. The device was switched to "SureScan On" and ODO mode. Following completion of imaging, device was set to "SureScan Off" and DDD mode, and interrogation showed no significant change in parameters: atrial lead impedance 544 ohms, ventricular lead impedance 472 ohms, atrial lead capture threshold 1 V at 0.4 ms, ventricular lead capture threshold 1 V at 0.4 ms, P-wave amplitude sensing 3.5 mV, R-wave amplitude sensing 9.9 mV. The patient was monitored throughout the study by telemetry, blood pressure, and voice communication. The patient had no complaints during scanning.

Journal of Cardiovascular Magnetic Resonance

RESEARCH Open Access

Monocenter feasibility study of the MRI compatibility of the Evia pacemaker in combination with Safio S pacemaker lead

Christian G Wollmann[1,3*], Erich Steiner[2], Paul Vock[1,3], Bonaventure Ndikung[4] and Harald Mayr[1,3]

Abstract

Background: The purpose of this study was to evaluate the feasibility of the magnetic resonance (MR) conditional pacemaker (PM) system (Evia SR-T and DR-T with Safio S leads) under MR conditions.

Methods: Patients with standard PM indications and Evia PM were eligible for enrollment in this single center prospective non-randomized pilot study. Patients underwent MR of the brain and lower lumbar spine at 1.5 Tesla. Atrial (RA) und ventricular (RV) lead parameters (sensing, pacing threshold [PTH], pacing impedance) were assessed immediately before (baseline follow-up [FU]) and immediately after MRI (1st FU), after 1 month (2nd FU) and 3 months (3rd FU). The effect of MR on serious adverse device effect (SADE) free-rate, on atrial and ventricular sensing (AS/VS; mV) and atrial (RA) and ventricular (RV) pacing thresholds (PTH; V/0.4 ms) were investigated between baseline and 2nd FU. Continuous variables are expressed as mean ± SD and were compared using paired Student's t-test. A $p < 0.05$ was considered significant.

Results: Thirty-one patients were enrolled. One patient had to be excluded because of an enrollment violation.

Special Design of MRI-PM

- The circuit protection normally applied to the power supply
- The leads, to minimize and attenuate RF energy discharge at the tip
- The firmware to provide MRI-conditional protection
- The change of reed-switch to a Hall sensor

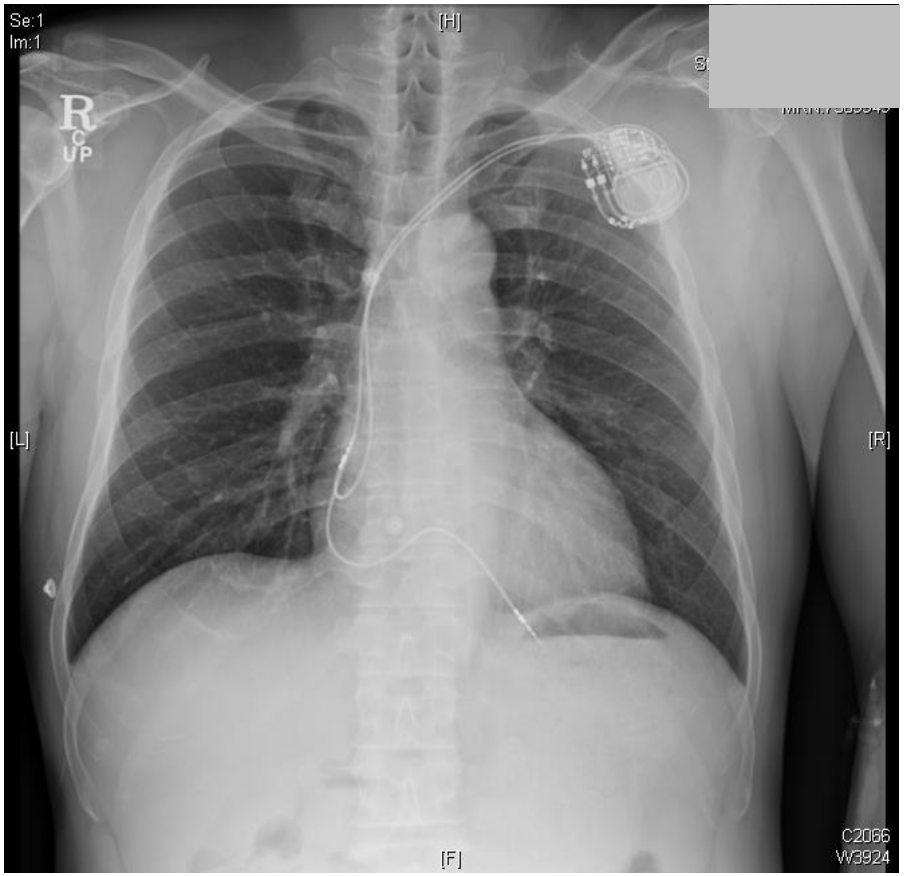
Cardiologist Checklist before MRI

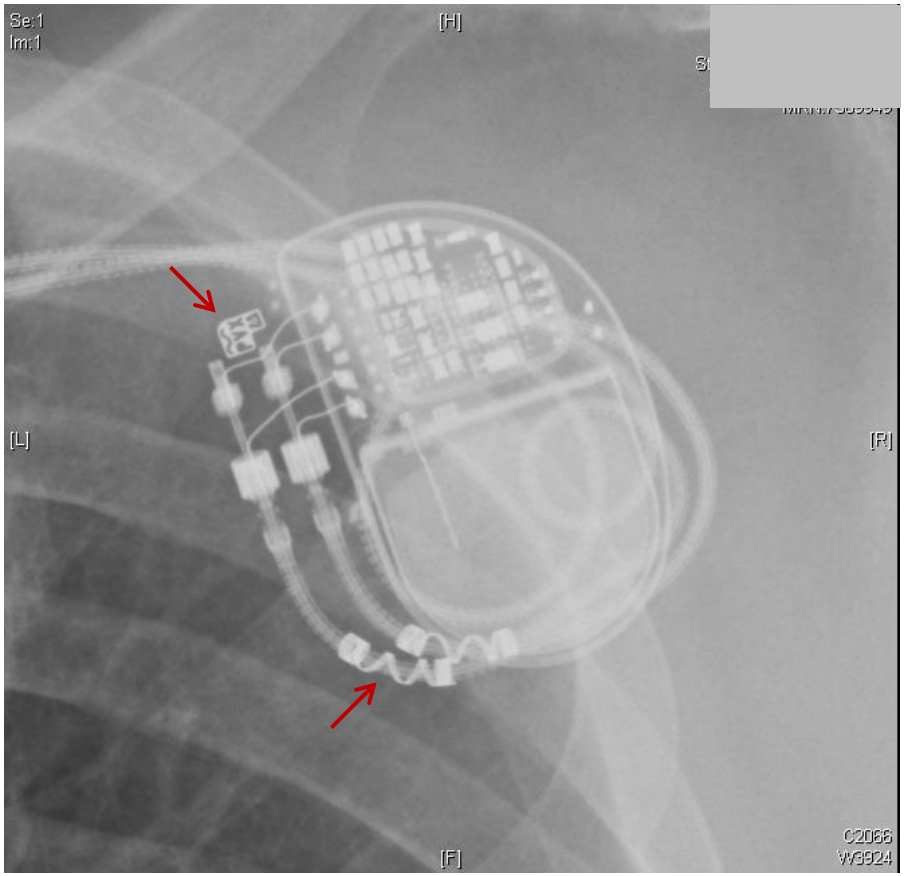
- Confirmation of MRI-compatible system
- Implanted for more than 6 weeks
- Pectoral region
- No additional active devices
- Lead impedance : 200 – 1500 ohms
- Capture thresholds ≤ 2.0V at 0.4 msec
- SureScan (or ProMRI) program ON before scan and OFF after scan

Radiologist Checklist before MRI

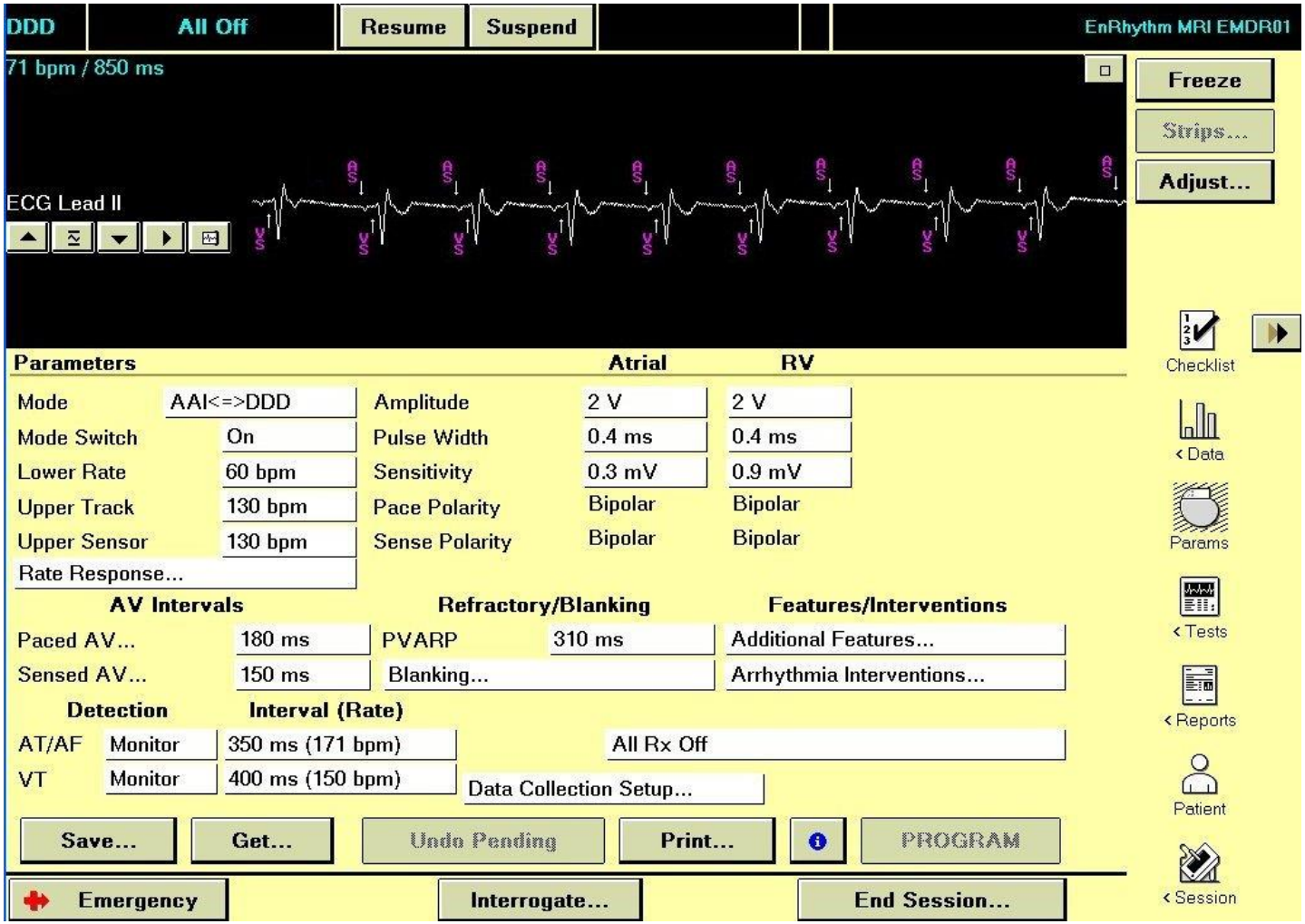
- Confirmation of MRI-compatible system
- 1.5 T closed bore MRI
- Whole body SAR ≤ 2 W/kg
- Consultation with cardiologists on SureScan (or ProMRI) program ON before scan & OFF after scan

Radiopaque Symbol - Advisa

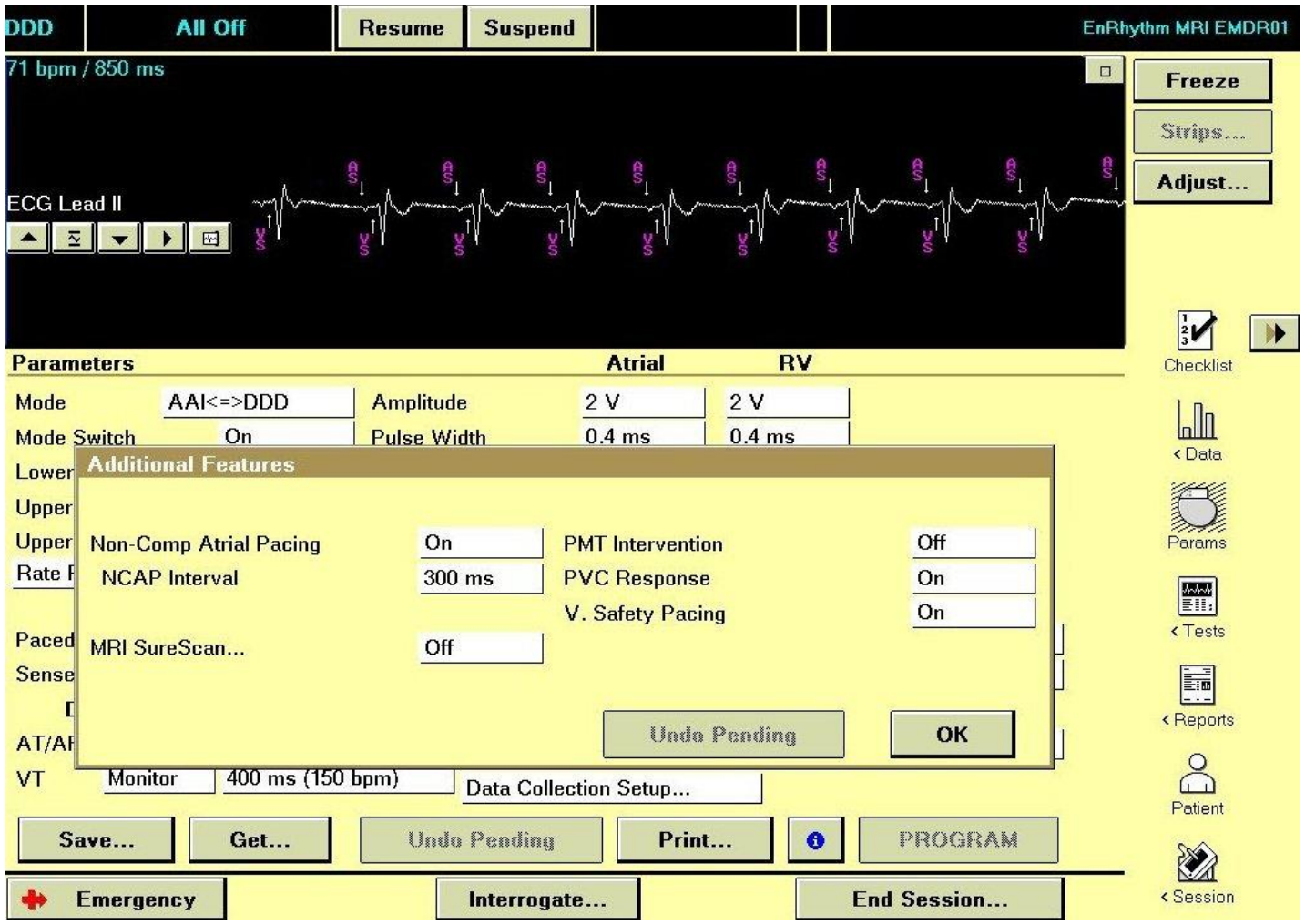




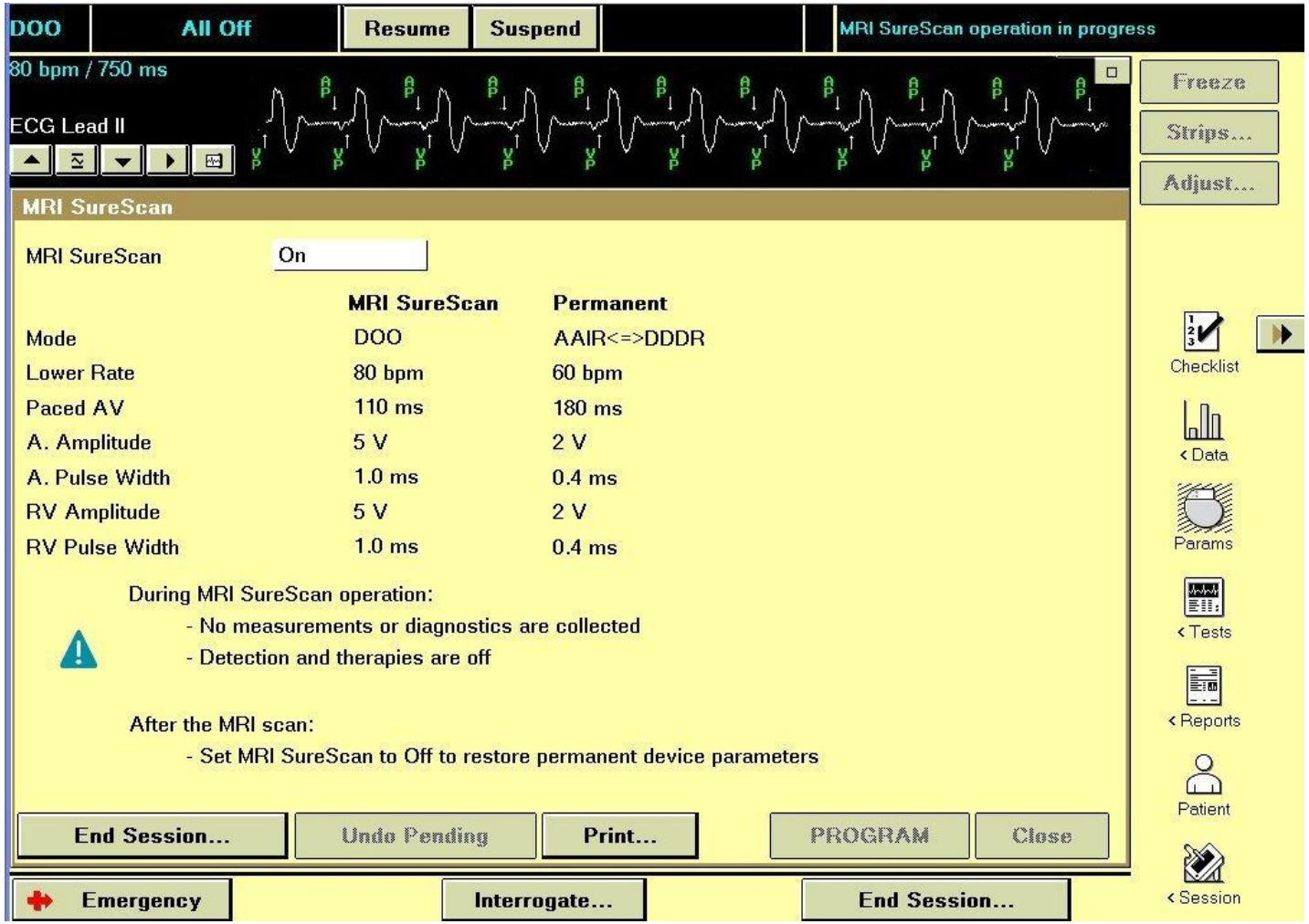
SureScan ON before MRI



SureScan ON before MRI



SureScan ON before MRI



Patient Monitoring during MRI

- Visual & verbal contact with the patient
- BP, ECG & pulse oximetry monitoring

Unresolved Questions

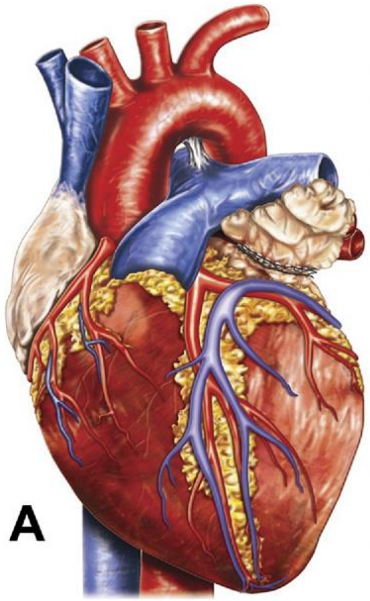
- Higher risk of lead failure?
- Higher risk of lead extraction?
- 3.0 T MRI?
- Whole body MRI? (especially, cardiac MRI)
- MRI-compatible ICD?

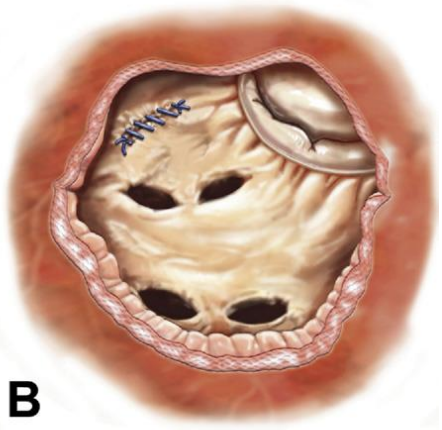
LA Appendage Occluder

Stroke in patients with AF

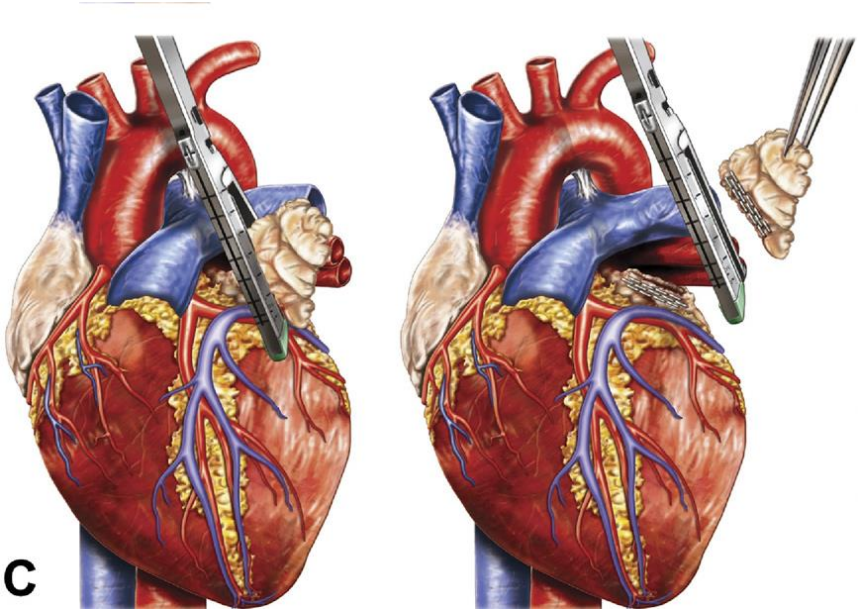
- 35% of patients with AF have stroke in their lifetime.
- LA appendage : 90% of thromboembolic source in non-rheumatic AF
- Warfarin: A cornerstone of stroke prevention
- However, warfarin is not always tolerable.
  - Narrow therapeutic range
  - Drug/food interaction
  - Requirement of INR monitoring

Surgical LAA Excision





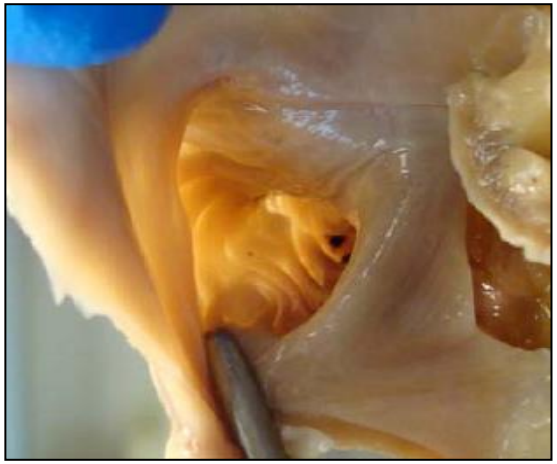
(C) Stapled excision.



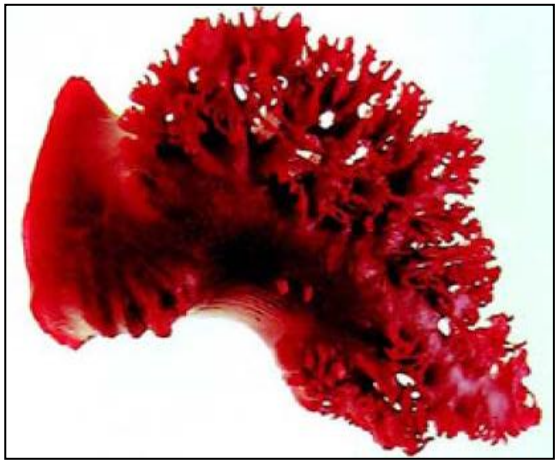
(A) Epicardial suture exclusion.

(B) Endocardial suture exclusion.

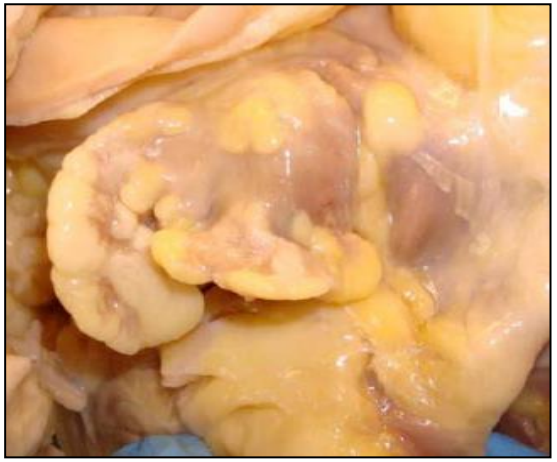
Anatomic Complexity of LAA



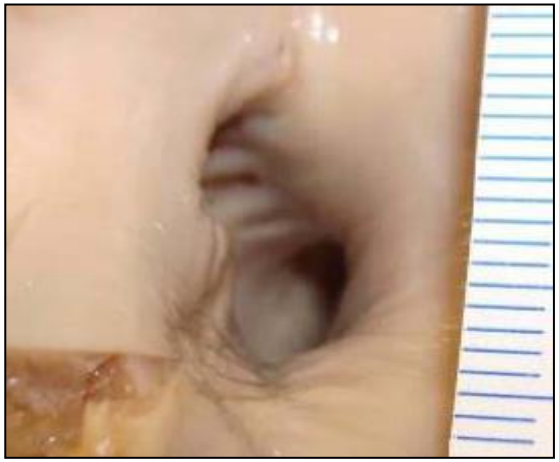
Thin wall



Angulated



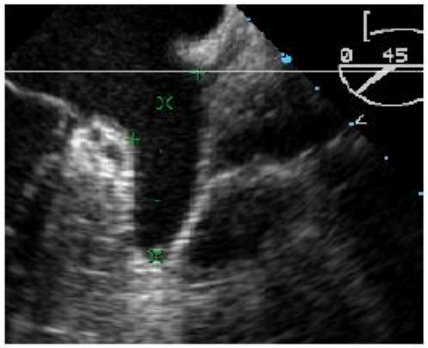
Multi-lobe

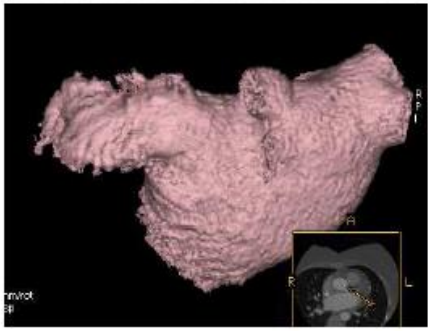


Oval ostium

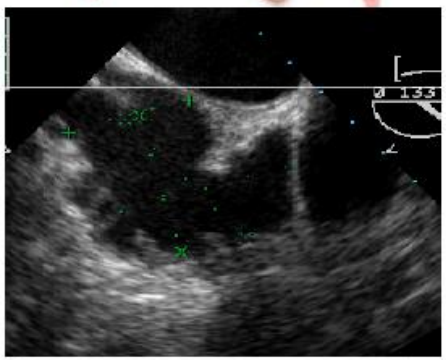
LAA Morphology

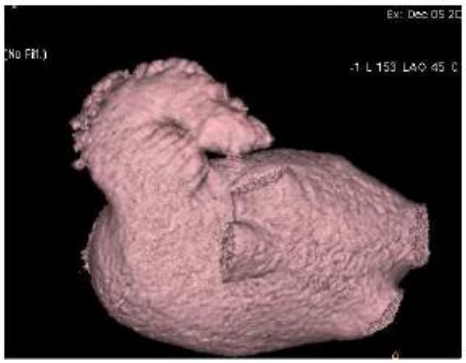
Wind sock.



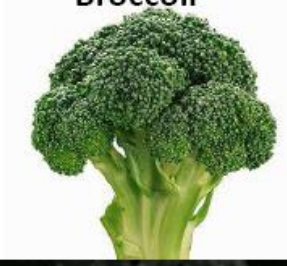


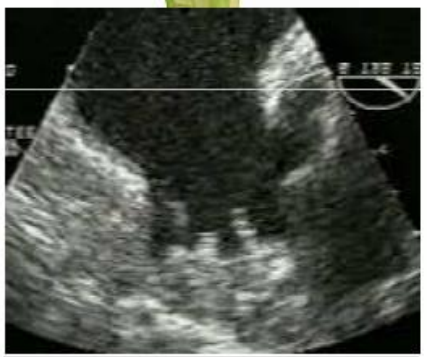
Chicken wing.

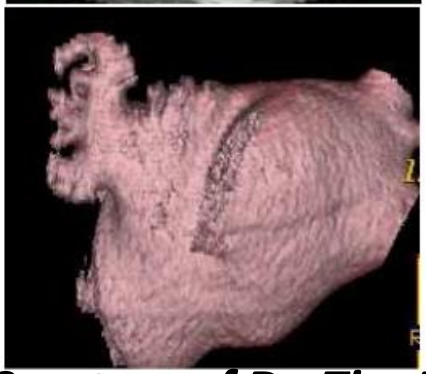




Broccoli







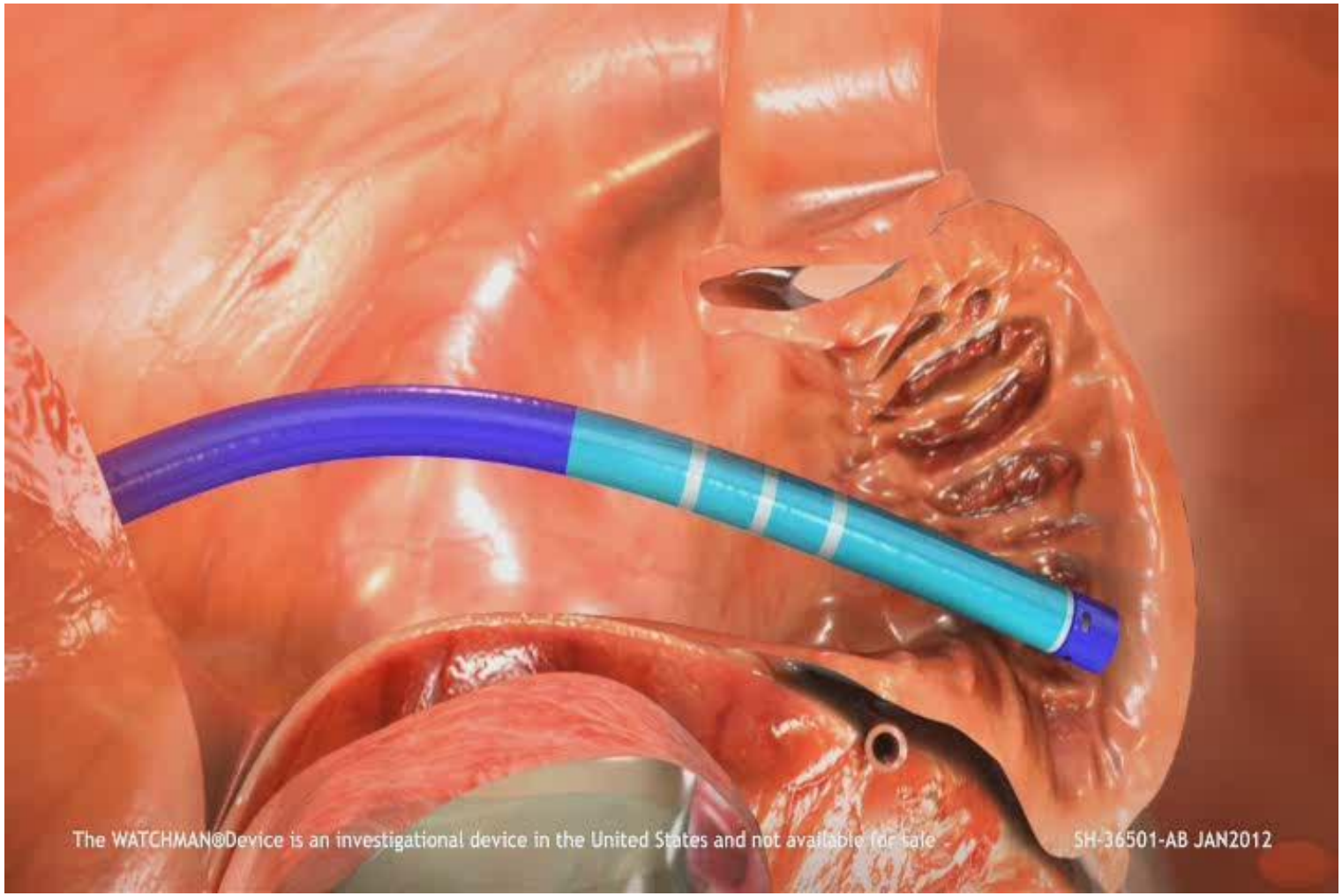
By Courtesy of Dr. Tim Betts

Transcatheter LAA Occlusion

Watchman (Boston Scientific)

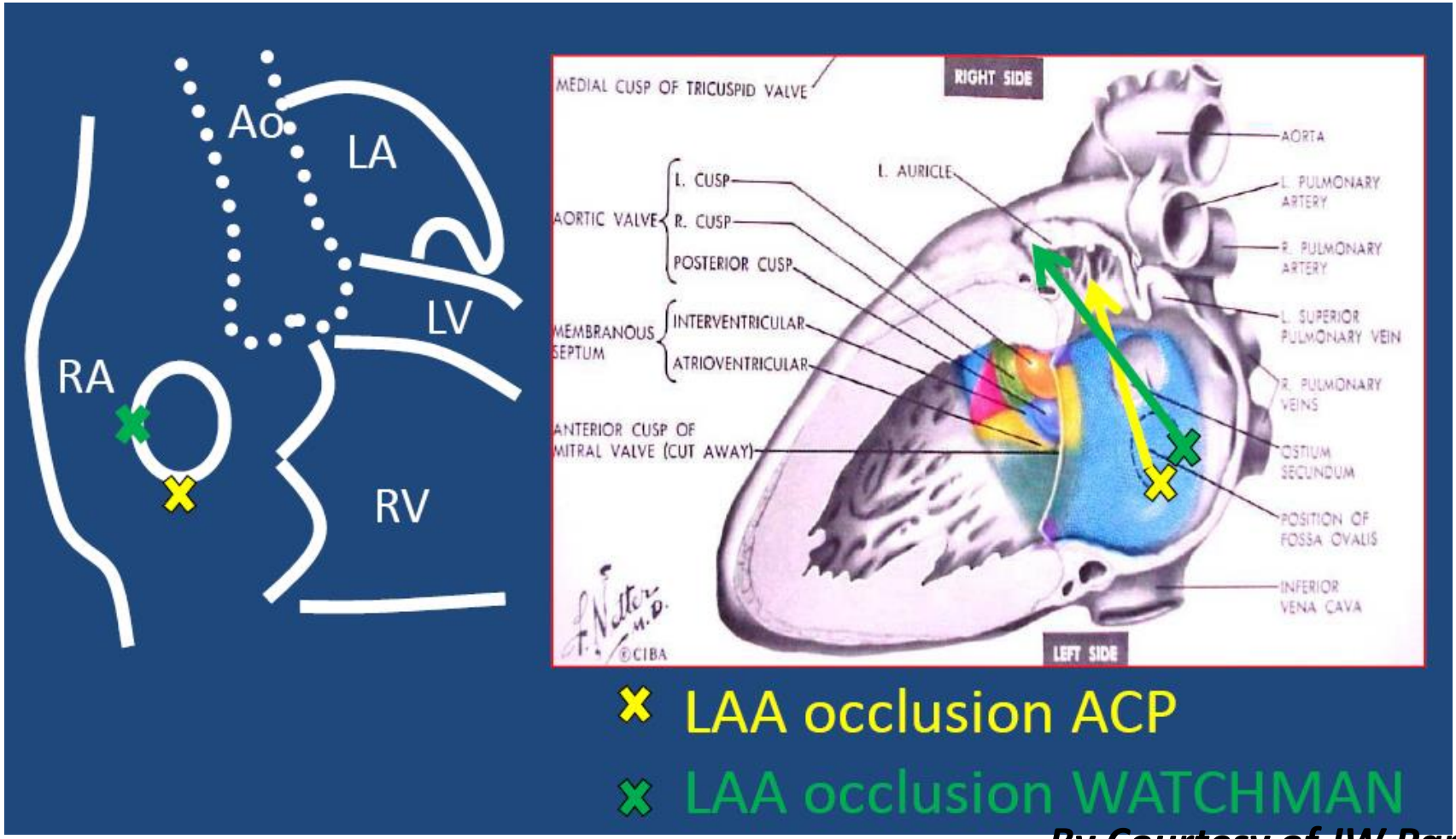
Amplatzer Cardiac Plug (SJM)

Watchman


The WATCHMAN®Device is an investigational device in the United States and not available for sale
SH-36501-AB JAN2012

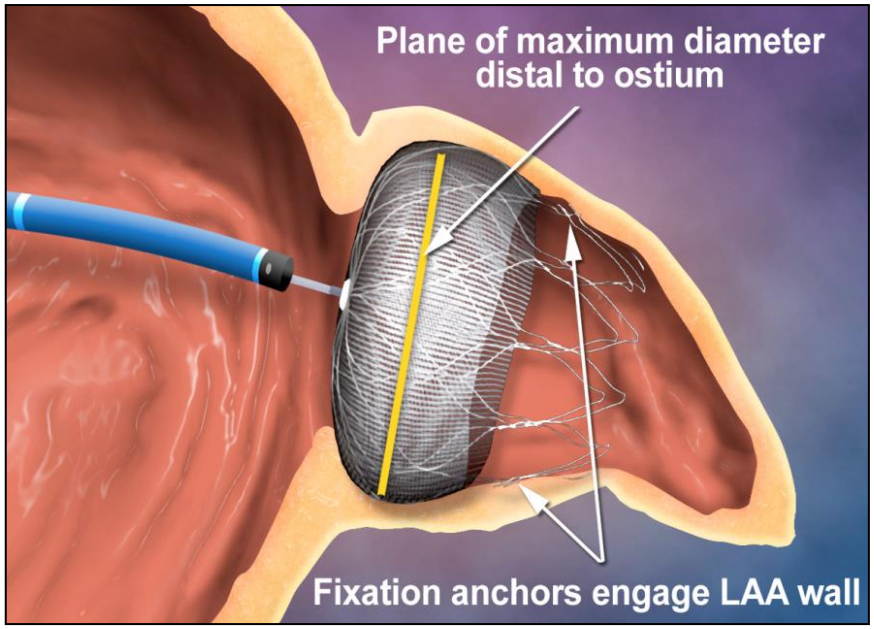
Amplatzer Cardiac Plug

Transseptal Puncture



By Courtesy of JW Park

Landing Zone & Sizing



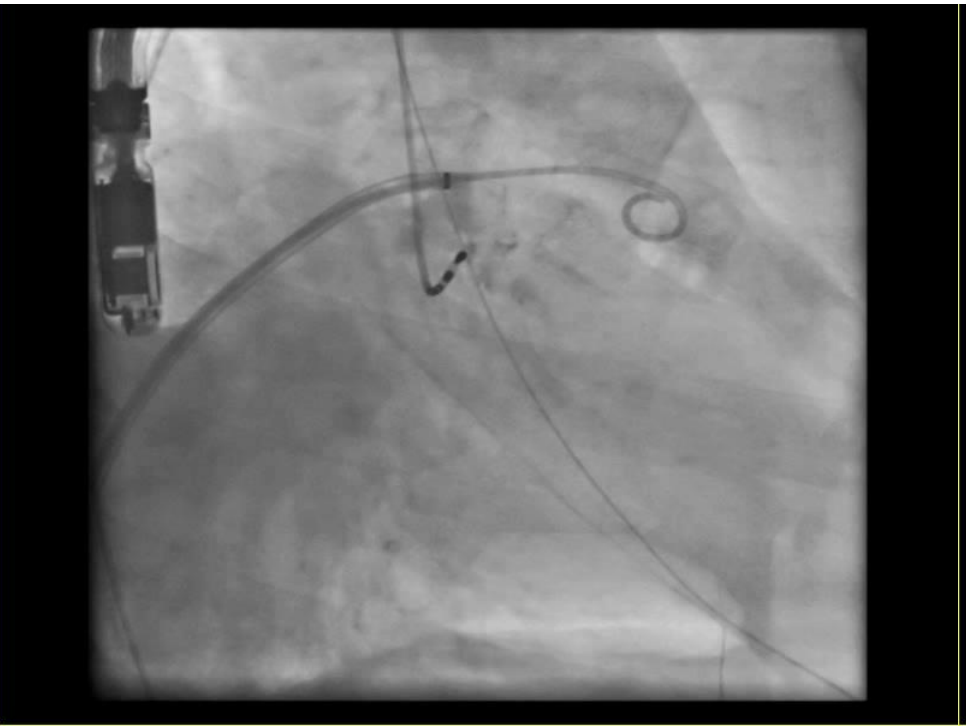
Maximum LAA Ostium (mm)	Device Size (mm) *(uncompressed diameter)*
17-19	21
20-22	24
23-25	27
26-28	30
29-31	33

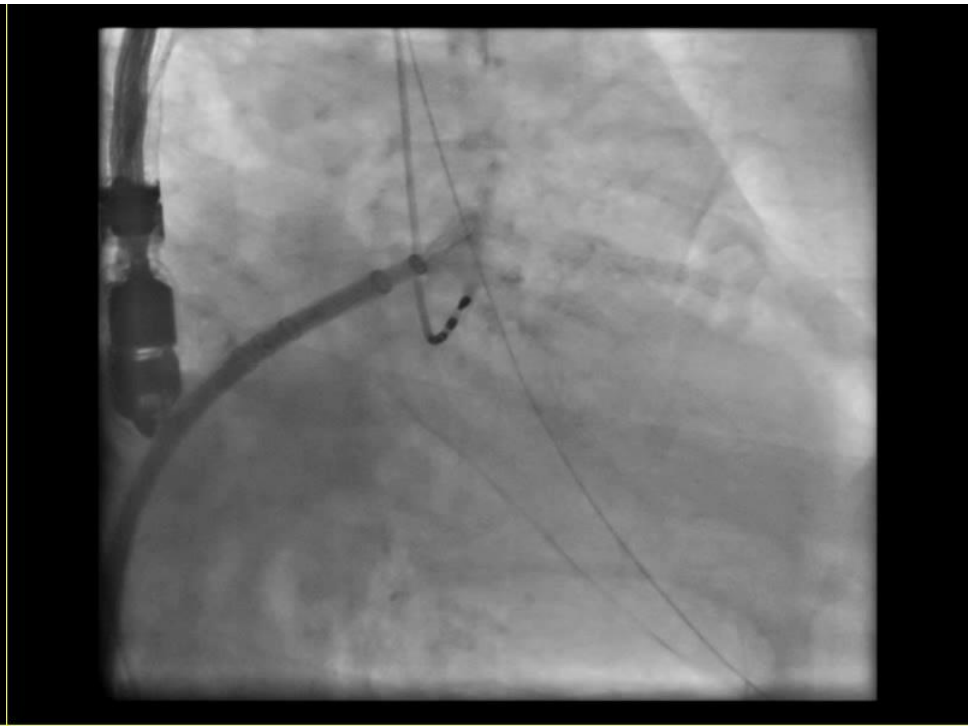
- **Measure LAA ostium in 4 TEE views:**

  At 0, 45, 90 & 135 degrees

- **8-20% oversizing**

Watchman Implantation

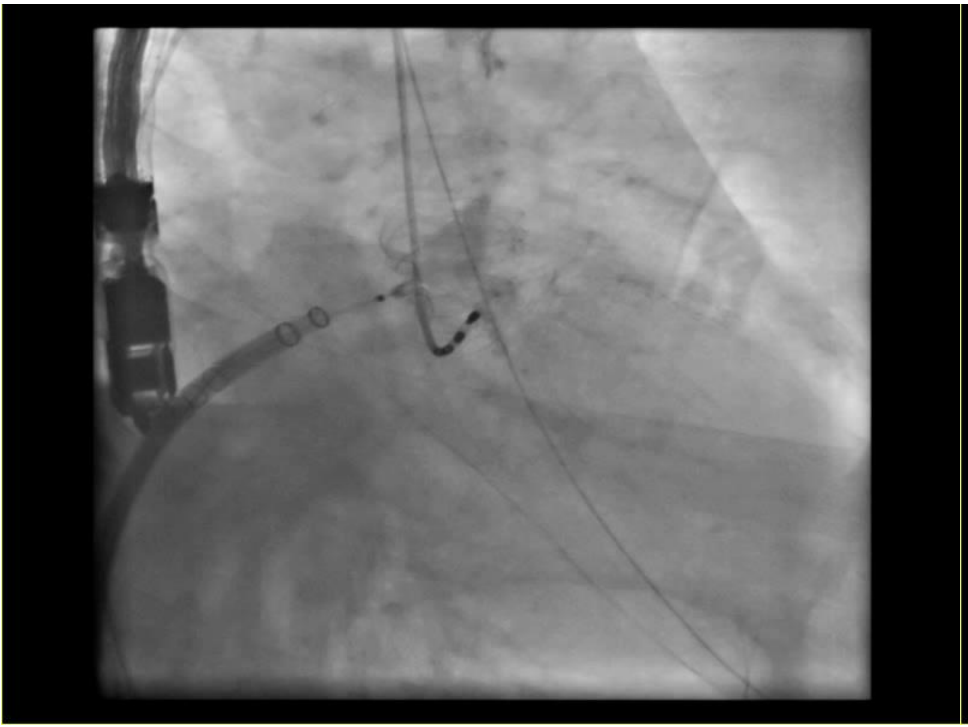


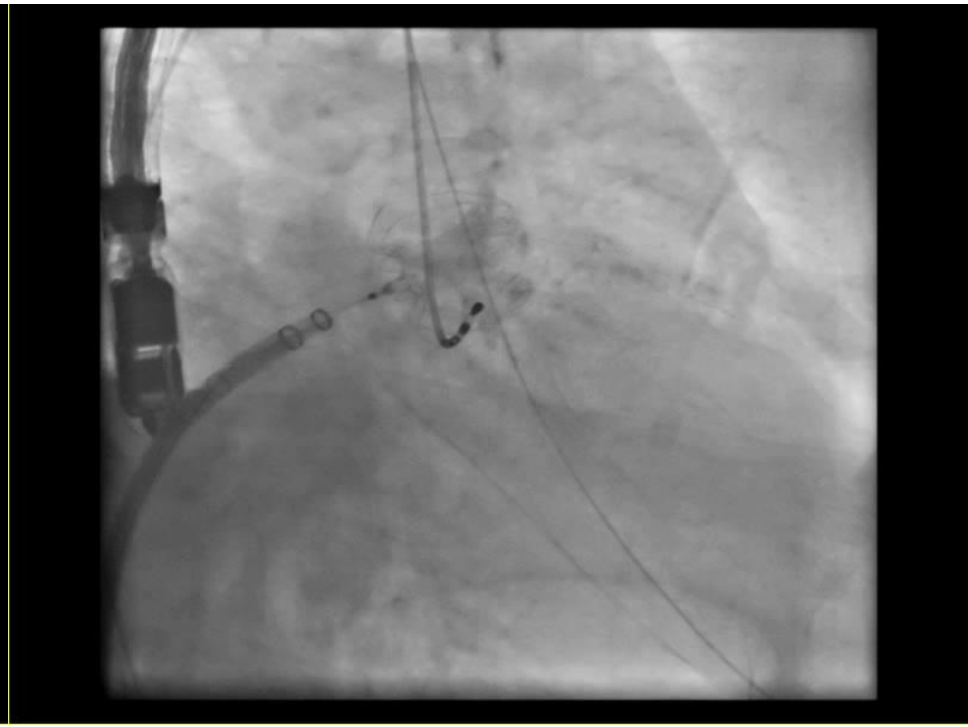


LAA angiogram

Deployment

Watchman Implantation

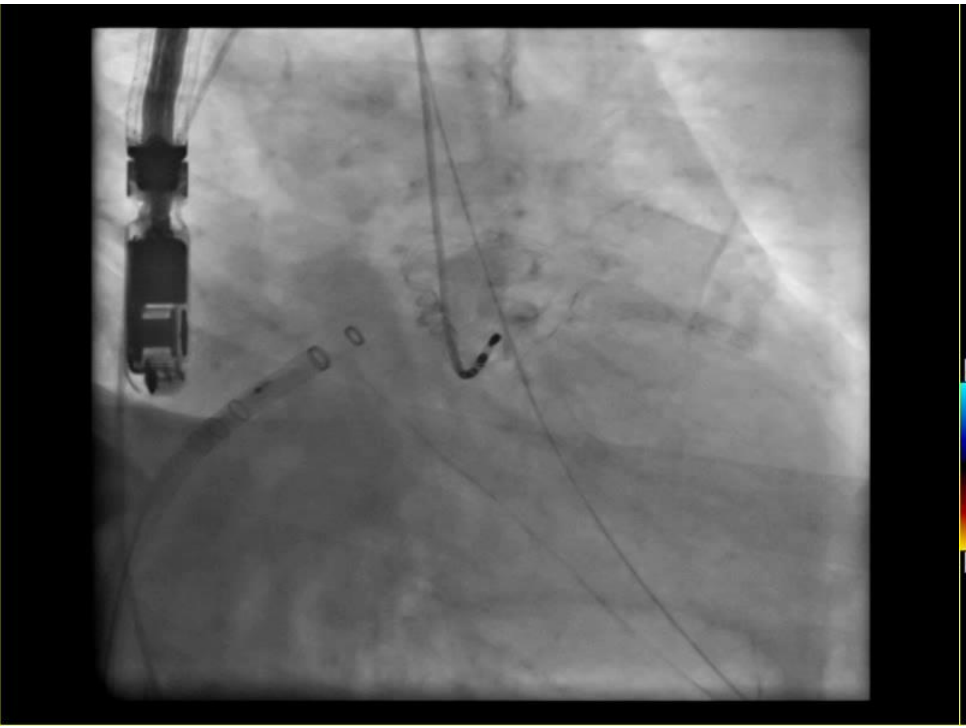


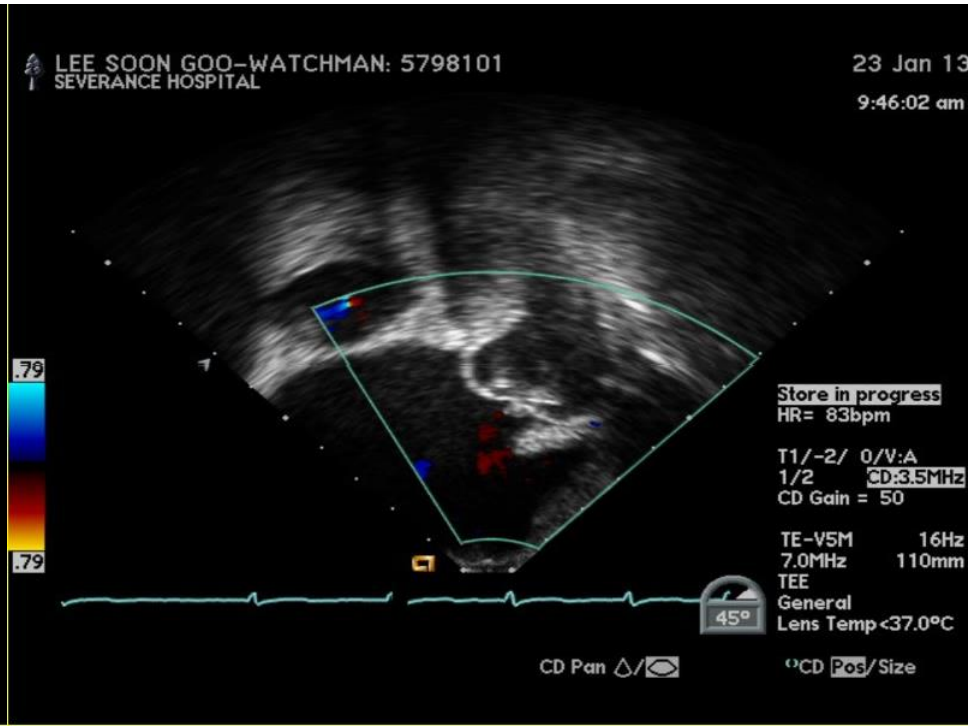


1st Confirmation of placement

2nd Confirmation of placement

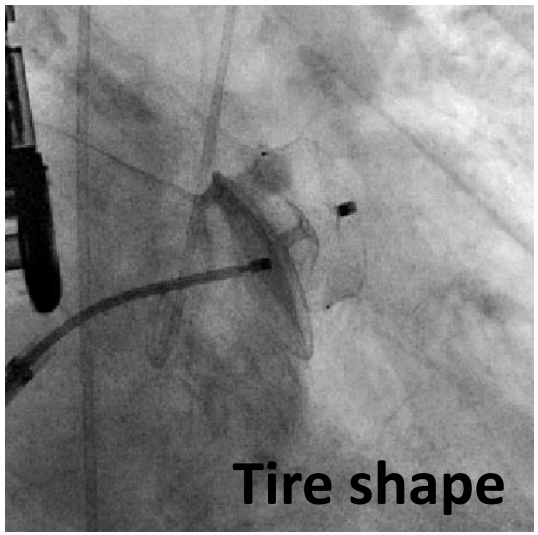
Watchman Implantation

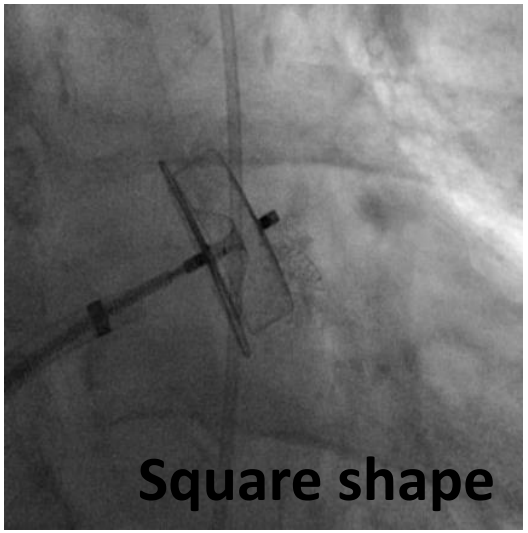


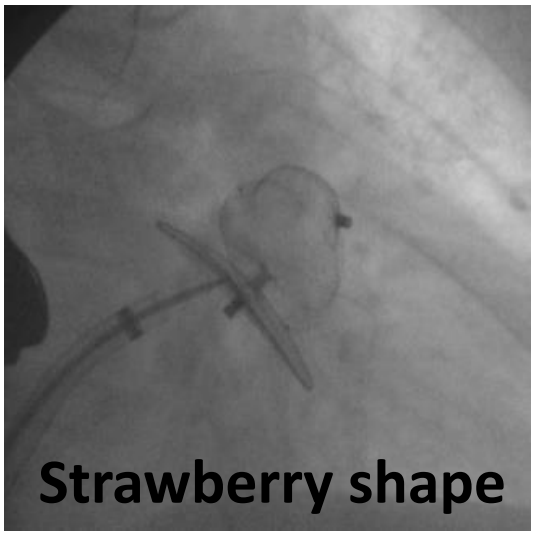


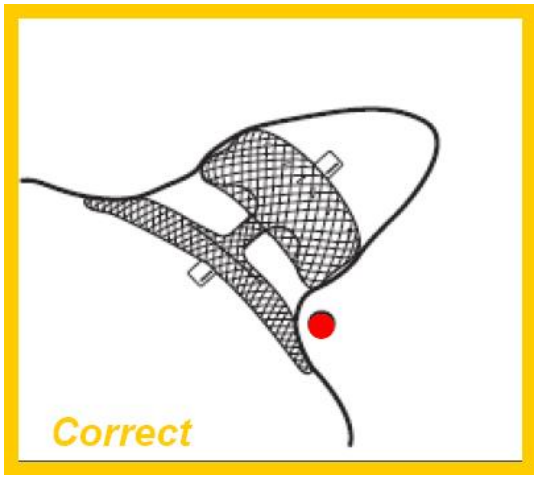
Detachment **Confirmation of sealing by TEE**

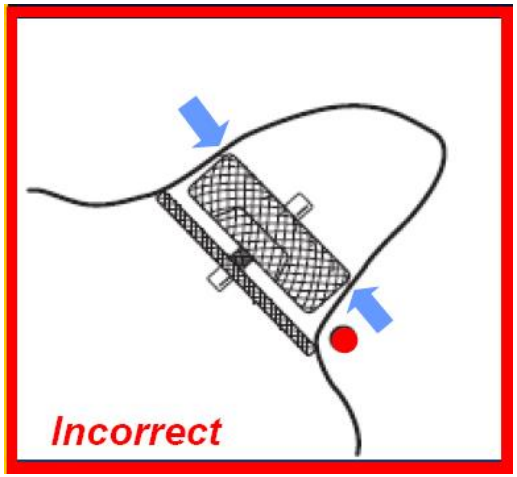
ACP Sizing


Tire shape


Square shape


Strawberry shape


Correct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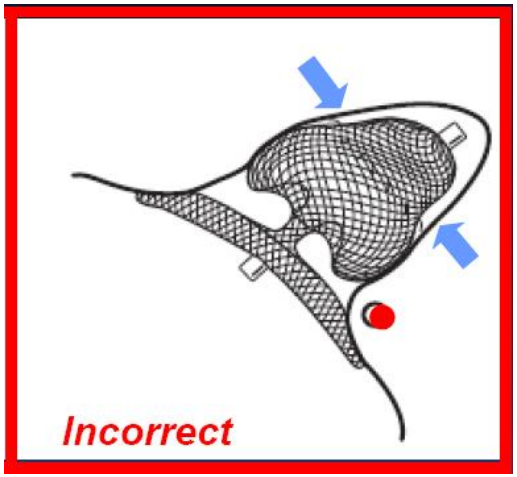

Incorrect

Anticoagulation

- During the procedure
  - Heparin to maintain 200-250 sec of ACT
  - Check ACT every 30 minutes
- After the procedure
  - Warfarin to maintain 2.0-3.0 of INR for at least 45 days

Complications of LAA Occlusion

- **Pericardial effusion : 5.0%**
- **Device-associated thrombus : 4.2%**
- **Stroke : 0.9%**
- **Bleeding : 0.8%**
- **Vascular complications : 0.8%**
- **Device embolization : 0.6%**

V Reddy, et al. Circulation, 2011

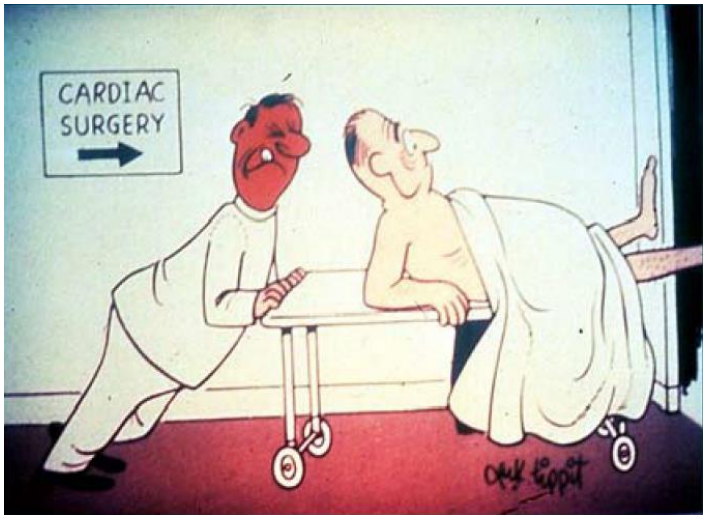
Transcatheter Aortic Valve Implantation

Aortic Stenosis

- AS is the most prevalent valve disease.
- Prevalence of AS and comorbidities increased with age.
- Mortality of symptomatic severe AS is 50-60% at 2 years.

Treatment of Severe AS

- **Surgical AVR : Gold standard**
- **However, 33% of patients > 75 years old are declined or have high risk for open heart surgery**



Aortic Valve for TAVI

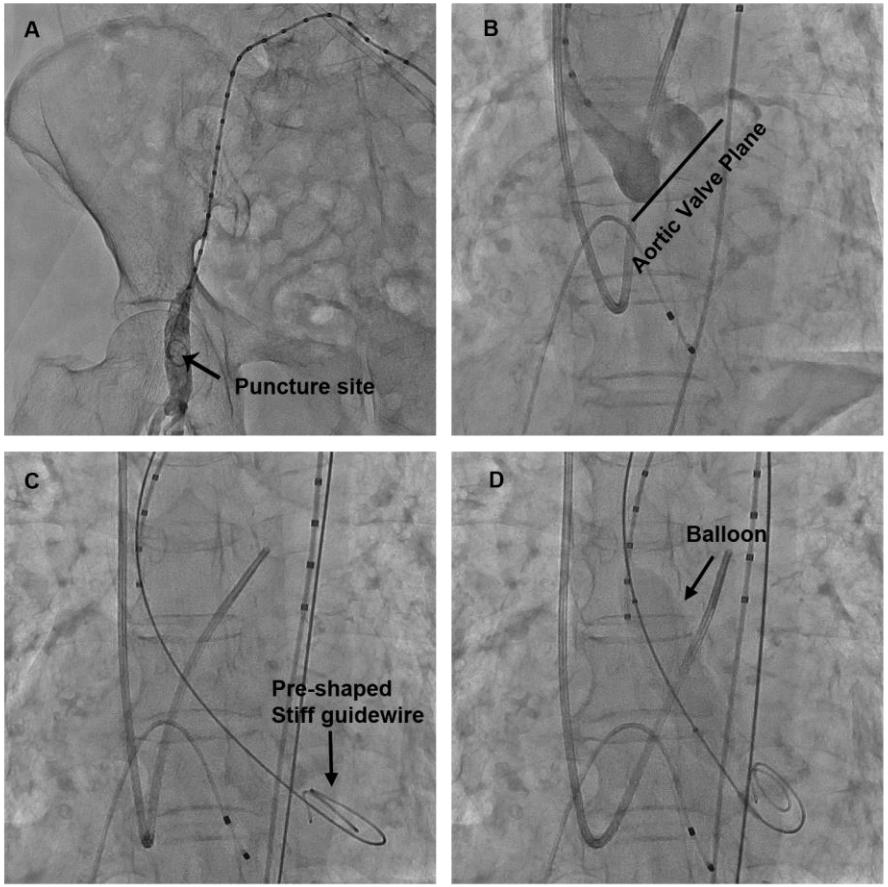
Edwards Sapien Valve:

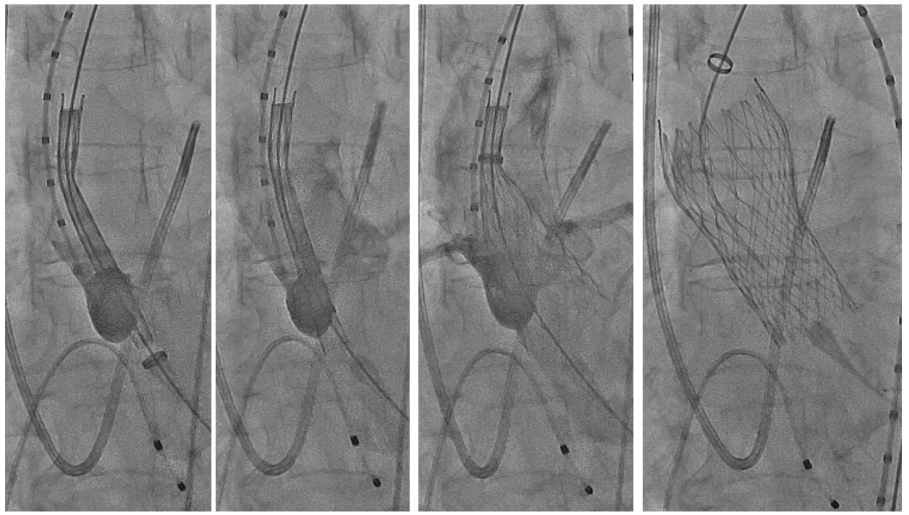
Balloon-expandable

Medtronic Core Valve :

Self-expandable

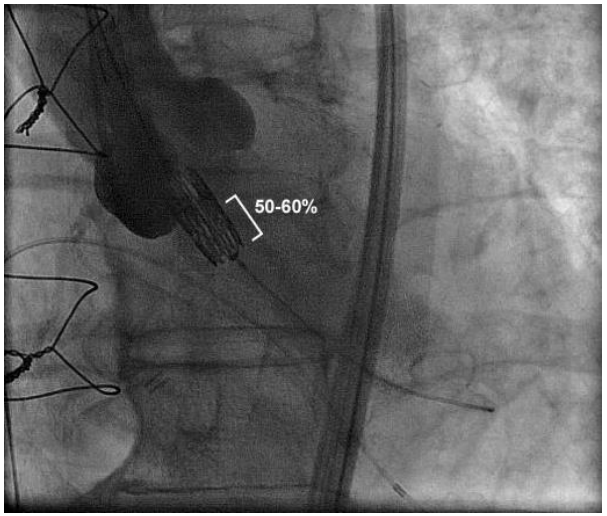
TAVI Procedure: Core Valve

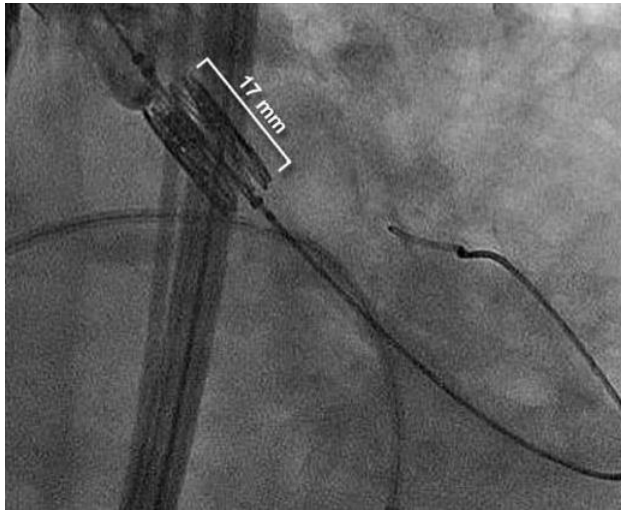


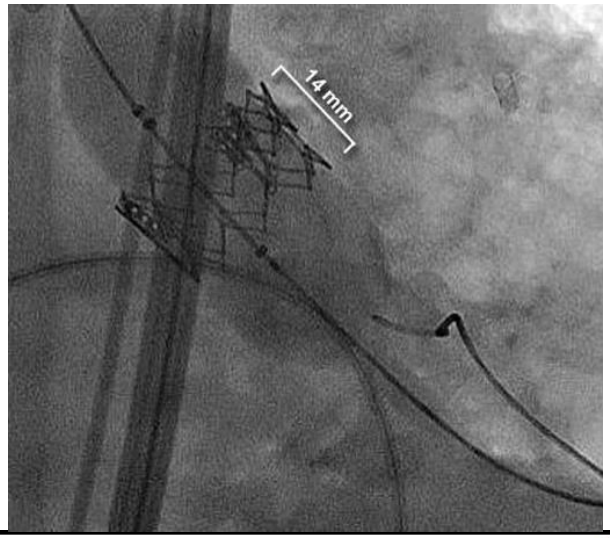


- **Core valve:**
  - Self-expandable
  - Stepwise deployment
  - Partially repositionalble

TAVI Procedure: Sapien Valve

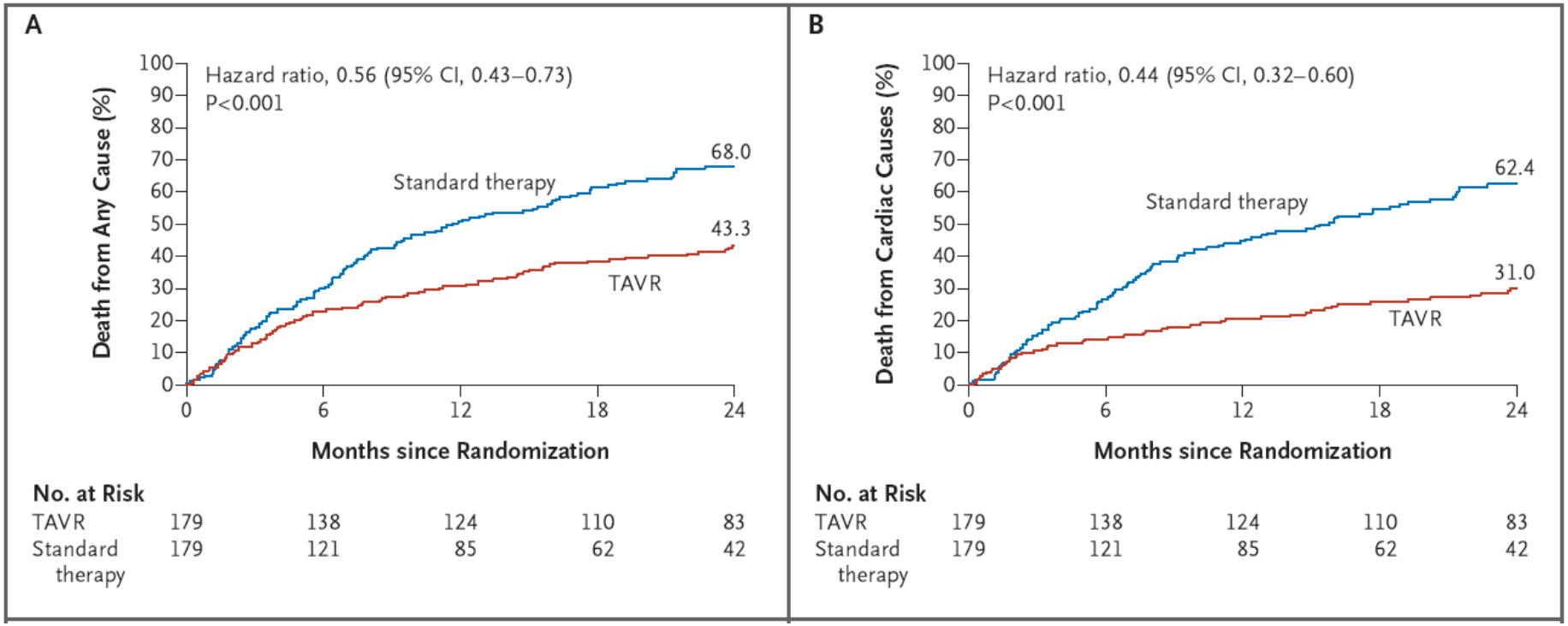




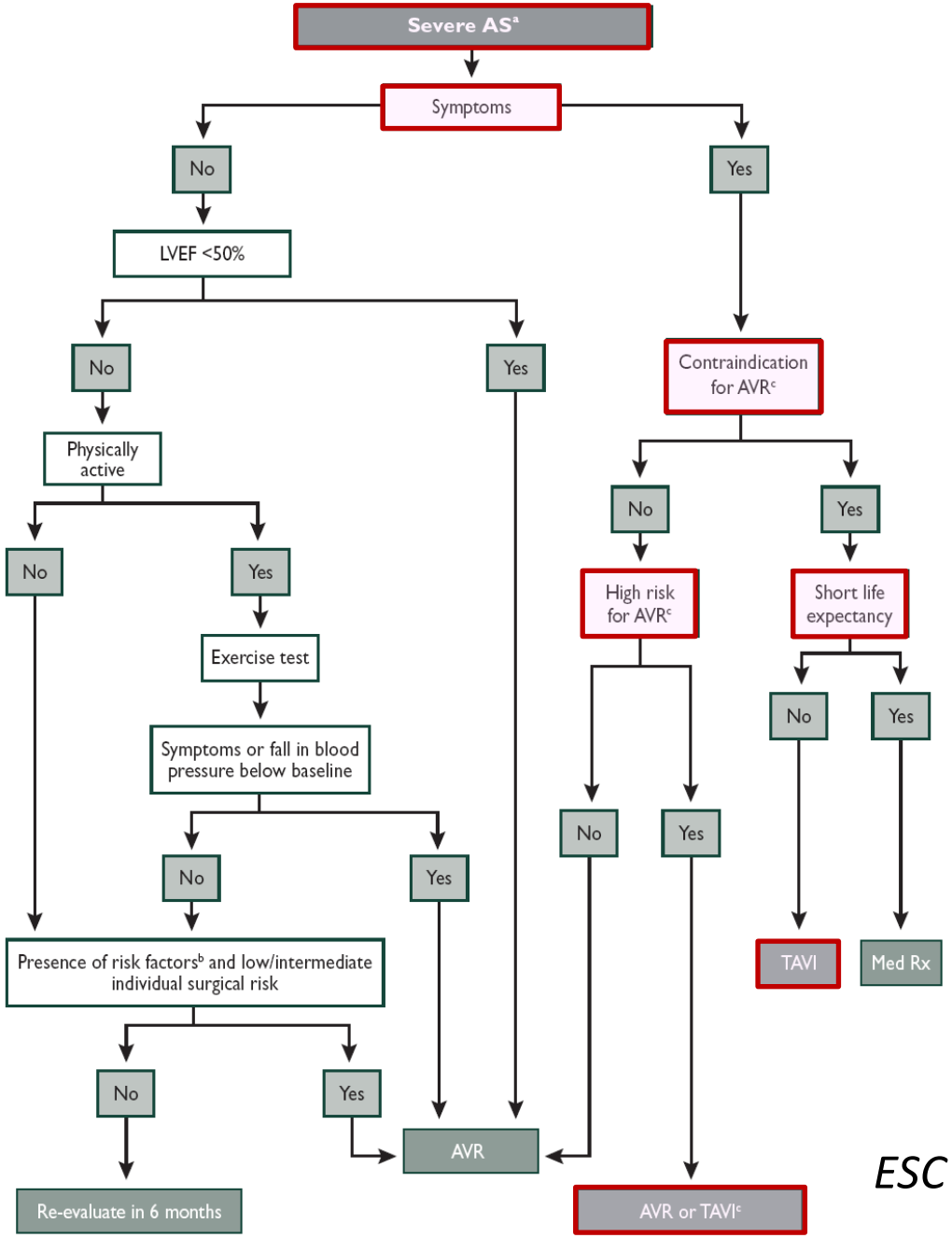


- **Edwards Sapien valve:**
  - Balloon-expandable
  - Transaortic & transapical

PARTNER Study



RR Makkar et al. New Engl J Med, 2012



ESC guidelines, 2012

Potential Complications of TAVI

- **Bleeding : 22.3%**
- **AV block : 13.9%**
- **Vascular complications : 11.9%**
- **Significant AR : 6.4%**
- **Major stroke : 3.2%**
- **Cardiac tamponade : 2.6%**
- **Valve embolization : 1.9%**
- **Coronary obstruction : 0.7%**

P Genereux et al. J Am Coll Cardiol, 2012

ESC Recommendations on TAVI

	Class	Level
TAVI should only be undertaken with a multidisciplinary "heart team" including cardiologists and cardiac surgeons and other specialists if necessary.	I	C
TAVI should only be performed in hospitals with cardiac surgery on-site.	I	C
TAVI is indicated in patients with severe symptomatic AS who are not suitable for AVR as assessed by a " heart team" and who are likely to gain improvement in their quality of life and to have a life expectancy of more than 1 year after consideration of their comorbidities.	I	B
TAVI should be considered in high risk patients with severe symptomatic AS who may still be suitable for surgery, but in whom TAVI is favoured by a "heart team" based on the individual risk profile and anatomic suitability.	IIa	B

ESC guidelines, 2012

경청해 주셔서 감사합니다.