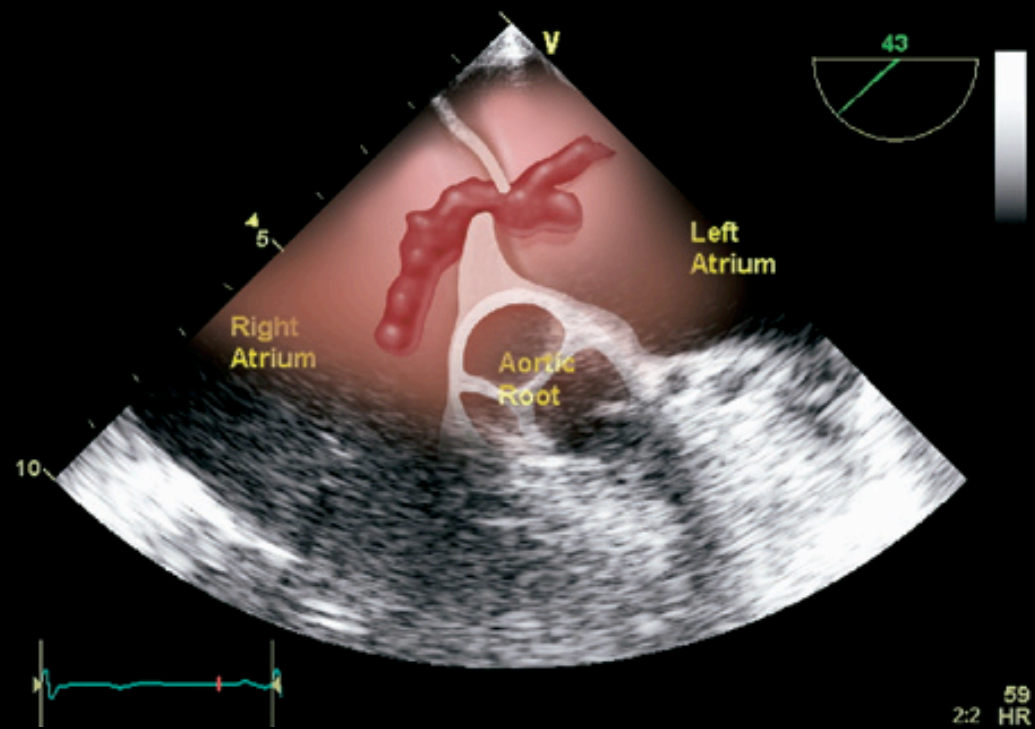
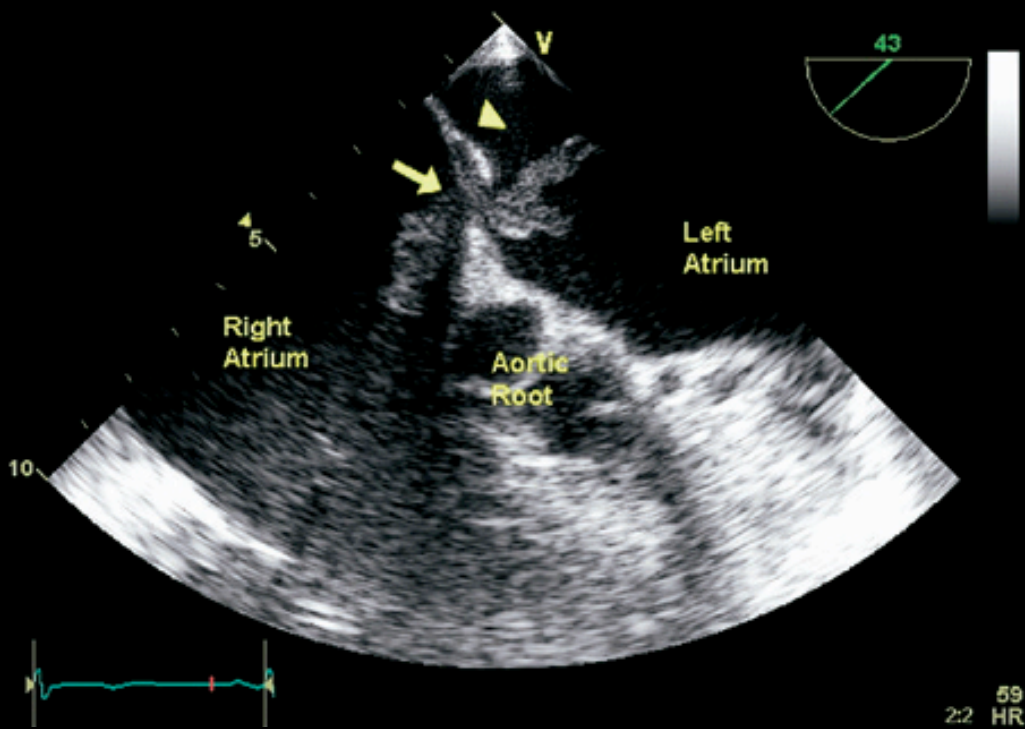


Clinical Results of Percutaneous PFO Closure



Swiss Cardiovascular Center Bern
University Hospital
Bern, Switzerland

Thrombus in Transit Through PFO

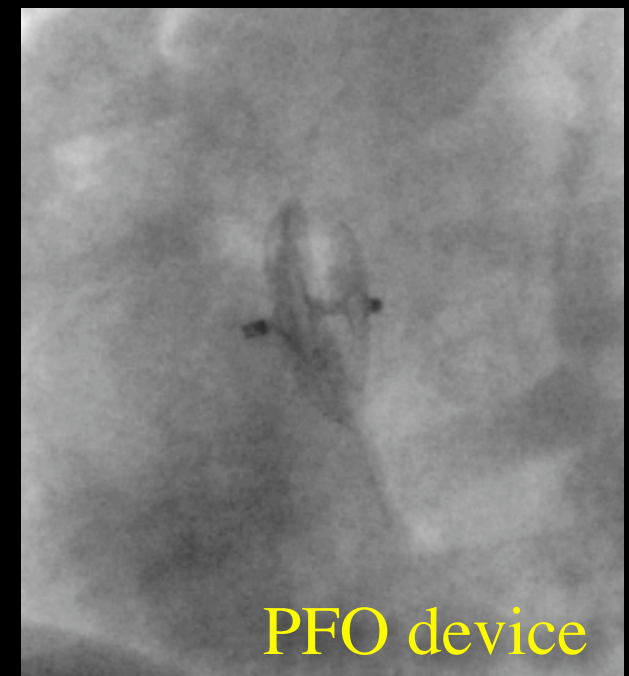
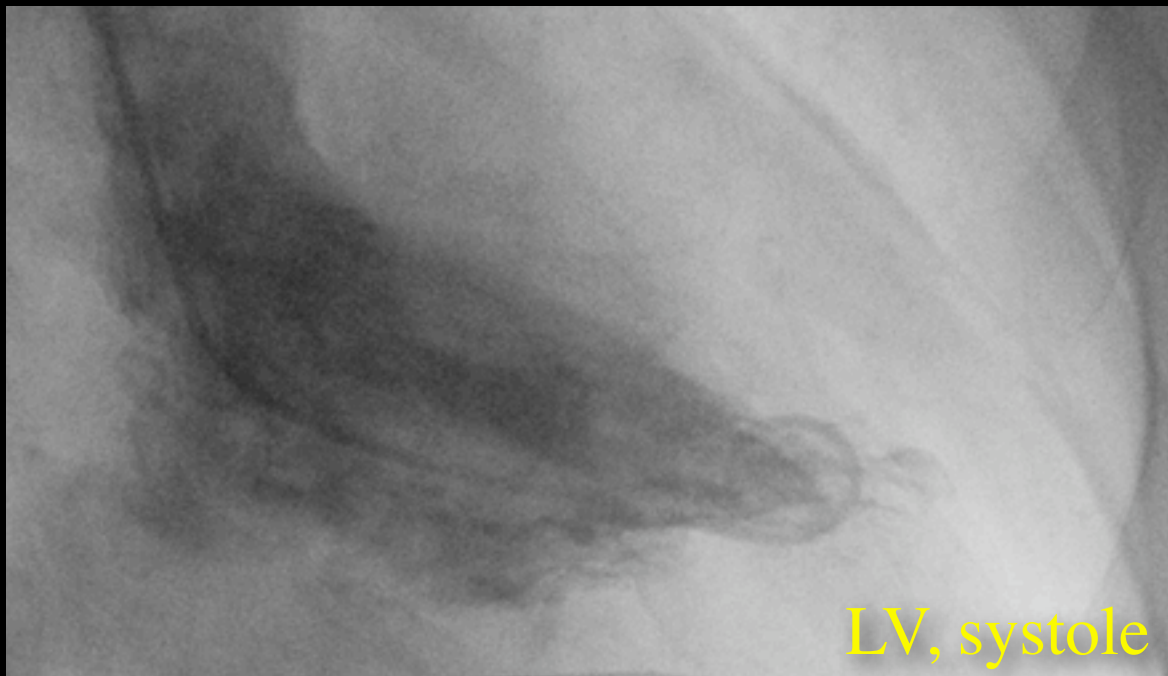
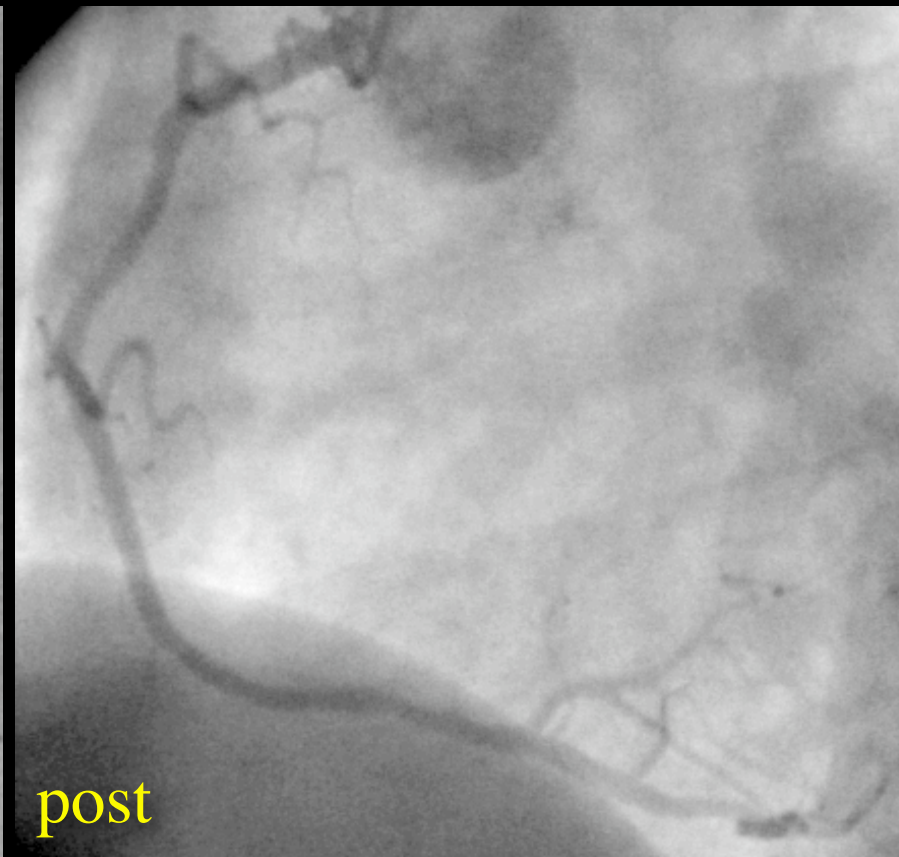
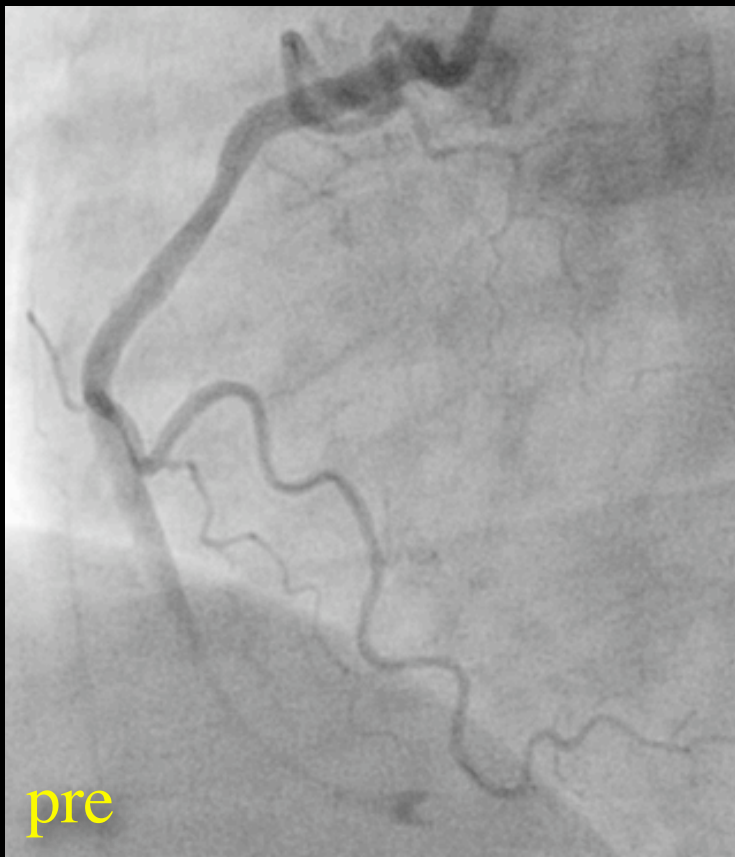


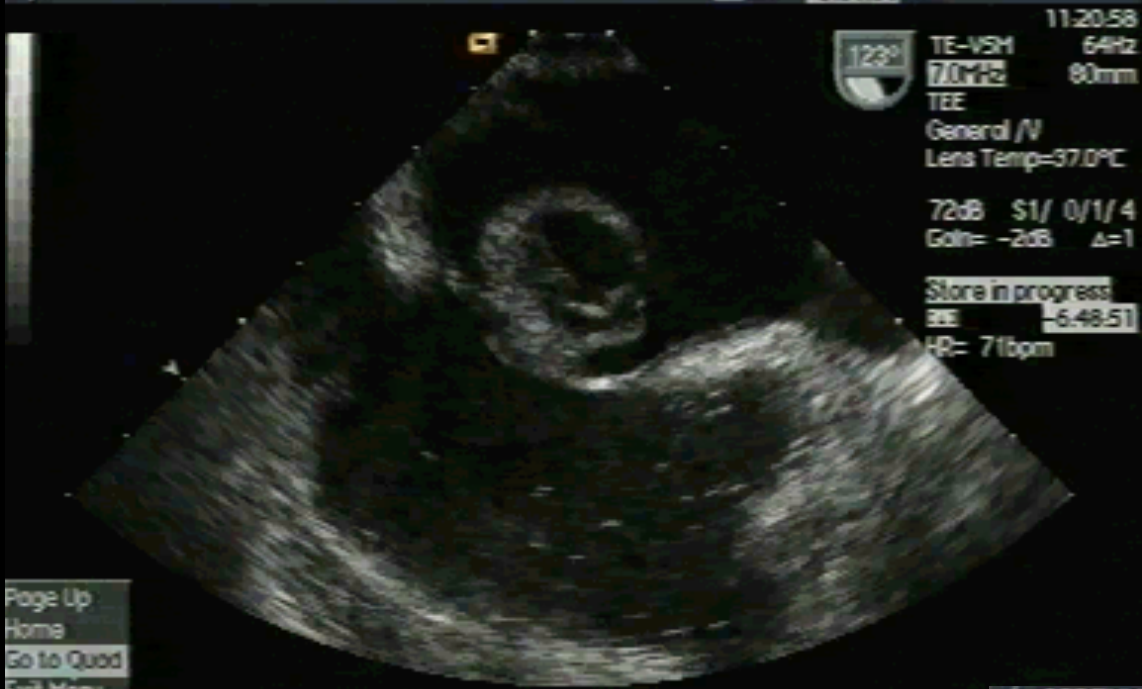
History of Interventional Cardiology

<i>1953 Rubio-Alvarez</i>	<i>Pulmonary wire valvuloplasty</i>	
<i>1966 Rashkind</i>	<i>Atrial septostomy</i>	
<i>1966 Porstmann</i>	<i>PDA closure</i>	
<i>1974 King/Mills</i>	<i>ASD closure</i>	
<i>1975 Gianturco</i>	<i>Coil occlusion of shunt</i>	
<i>1977 Grüntzig</i>	<i>PTCA (coronary angioplasty)</i>	
<i>1979 Semb</i>	<i>Pulmonary balloon valvuloplasty (newborns)</i>	
<i>1981 Singer</i>	<i>Re-coarctation angioplasty</i>	
<i>1982 Kan</i>	<i>Pulmonary balloon valvuloplasty</i>	
<i>1982 Gallagher</i>	<i>His bundle ablation</i>	
<i>1983 Lababidi</i>	<i>Aortic balloon valvuloplasty</i>	
<i>1984 Inoue</i>	<i>Mitral balloon valvuloplasty</i>	
<i>1984 Fisher</i>	<i>Ablation of WPW pathway</i>	
<i>1986 Puel</i>	<i>Coronary stent implantation</i>	
<i>1987 Simpson</i>	<i>Coronary atherectomy (debulking)</i>	
<i>1990 Palacios</i>	<i>Pericardial balloon fenestration</i>	<i>1992 Bridges PFO closure</i>
<i>1994 Sigwart</i>	<i>Transluminal ablation of septal hypertrophy</i>	
<i>1996 Condado</i>	<i>Brachytherapy against coronary restenosis</i>	
<i>1997 Oesterle</i>	<i>PTMR (percutaneous transmyocardial laser revascularization)</i>	
<i>1998 Waxman</i>	<i>Transatrial pericardial access</i>	
<i>2000 Bonhoeffer</i>	<i>Percutaneous pulmonary valve replacement</i>	
<i>2001 Sievert</i>	<i>Obliteration of left atrial appendage in atrial fibrillation</i>	
<i>2002 Cribier</i>	<i>Percutaneous aortic valve replacement</i>	
<i>2003 Feldman</i>	<i>Percutaneous mitral valve repair</i>	

PFO

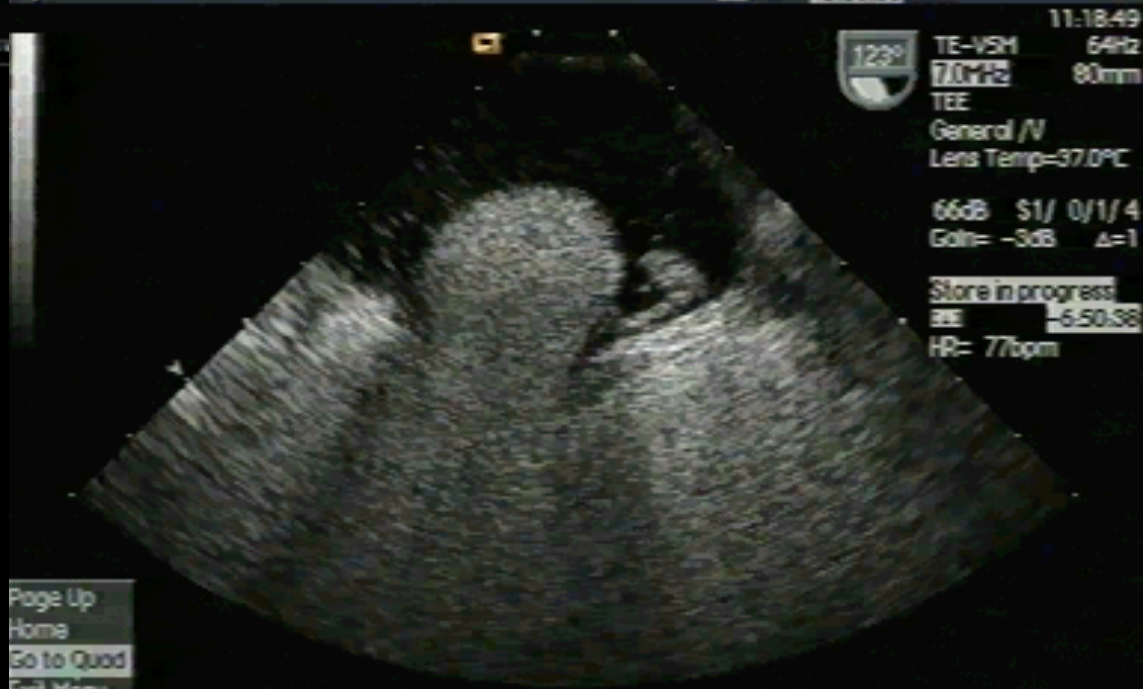
- 34-year-old man
- Paradoxical coronary embolism
- Inferior ST \uparrow
- \pm normal coronary arteries except for distal RCA occlusion
- Recanalization RCA (no stent!)
- Amplatzer 25 mm PFO Occluder





Page Up
Home
Go to Quad
Exit Menu
End
Page Down

18/F/100%
1 Beat 71



Page Up
Home
Go to Quad
Exit Menu
End
Page Down

16/F/100%
1 Beat 75

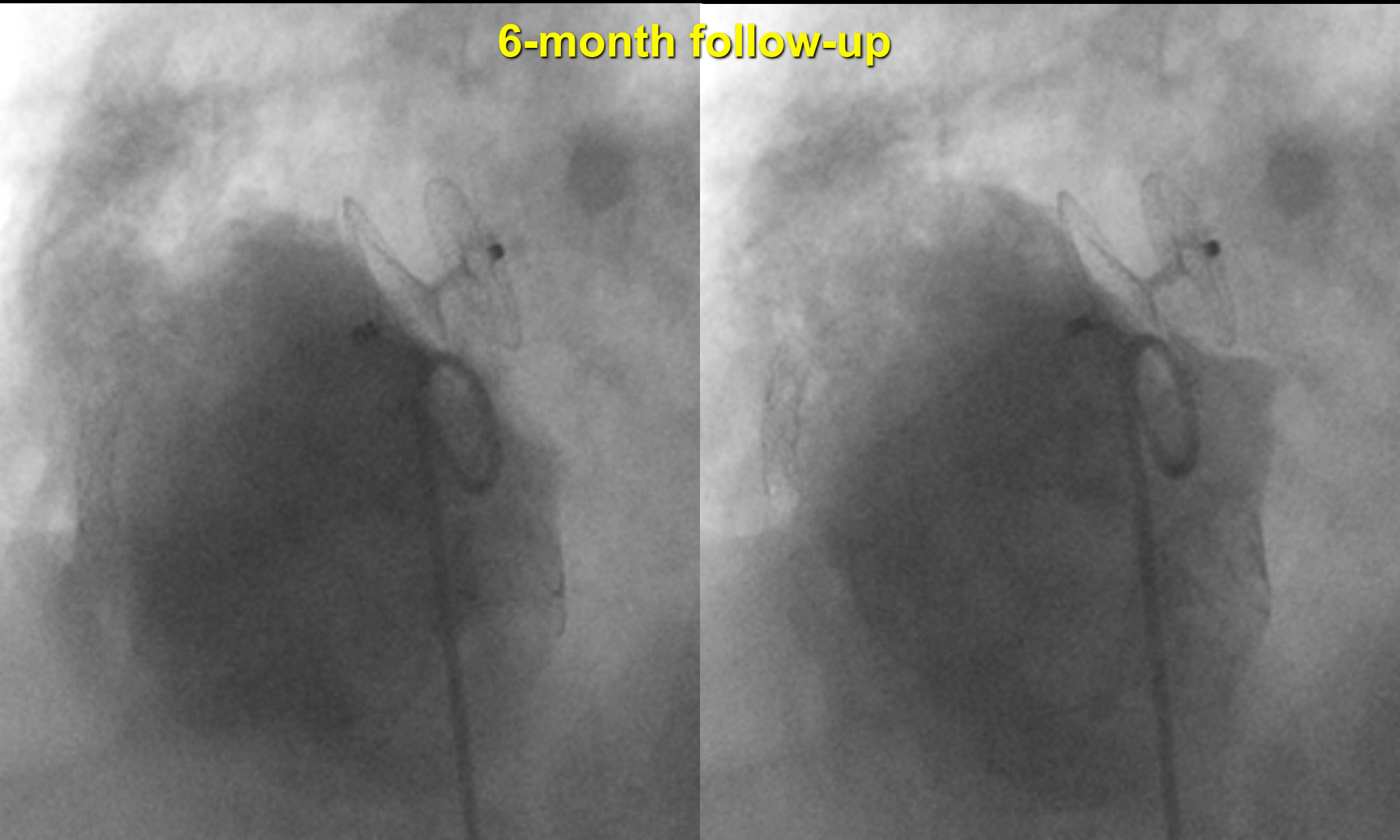
ASA and PFO

PFO

Tunnel and Atrial Septal Aneurysm (ASA)

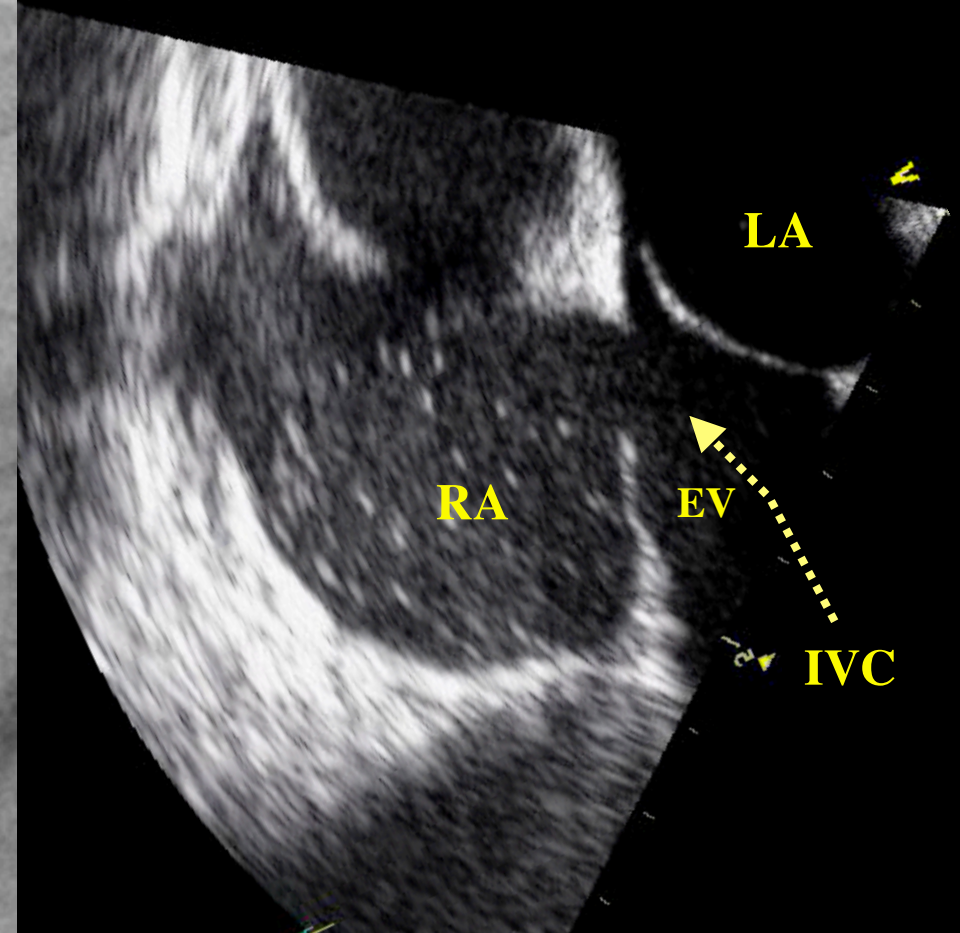
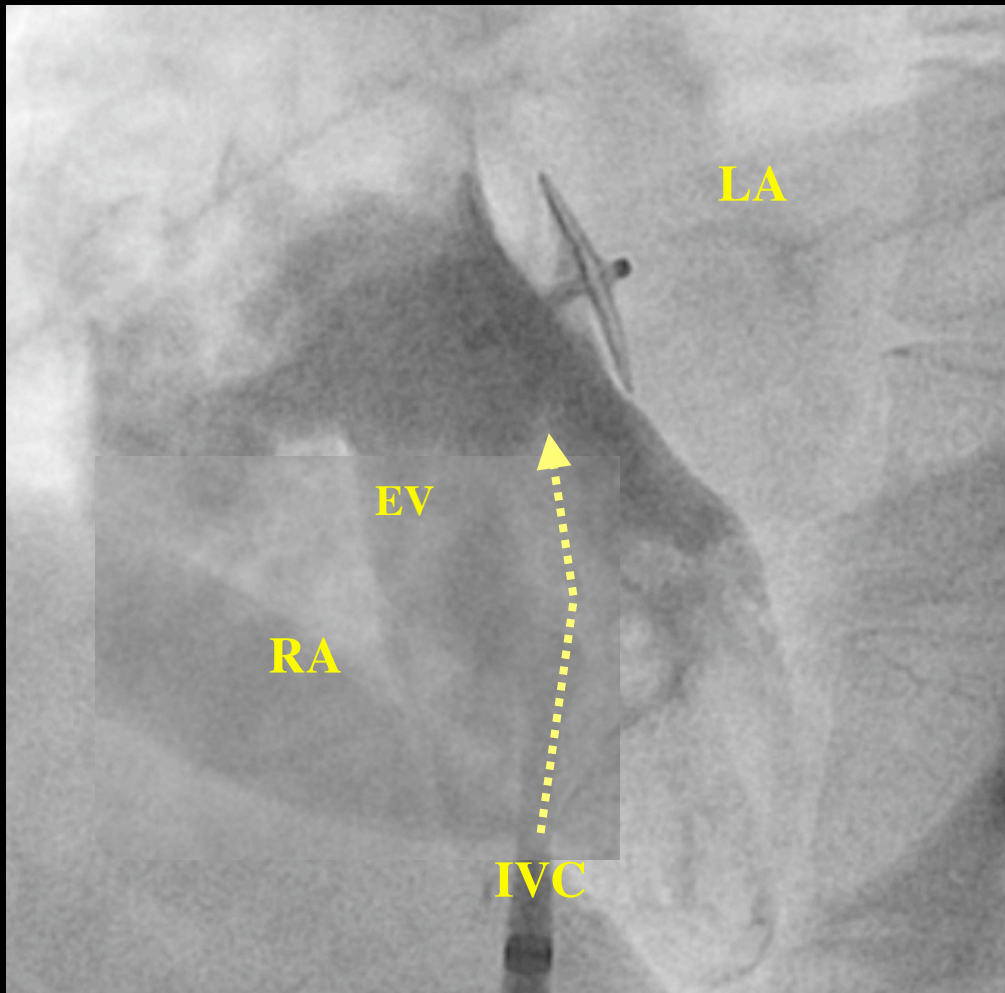
Man, 70 years, 25 mm PFO occluder

6-month follow-up



Eustachian Valve (EV) and PFO

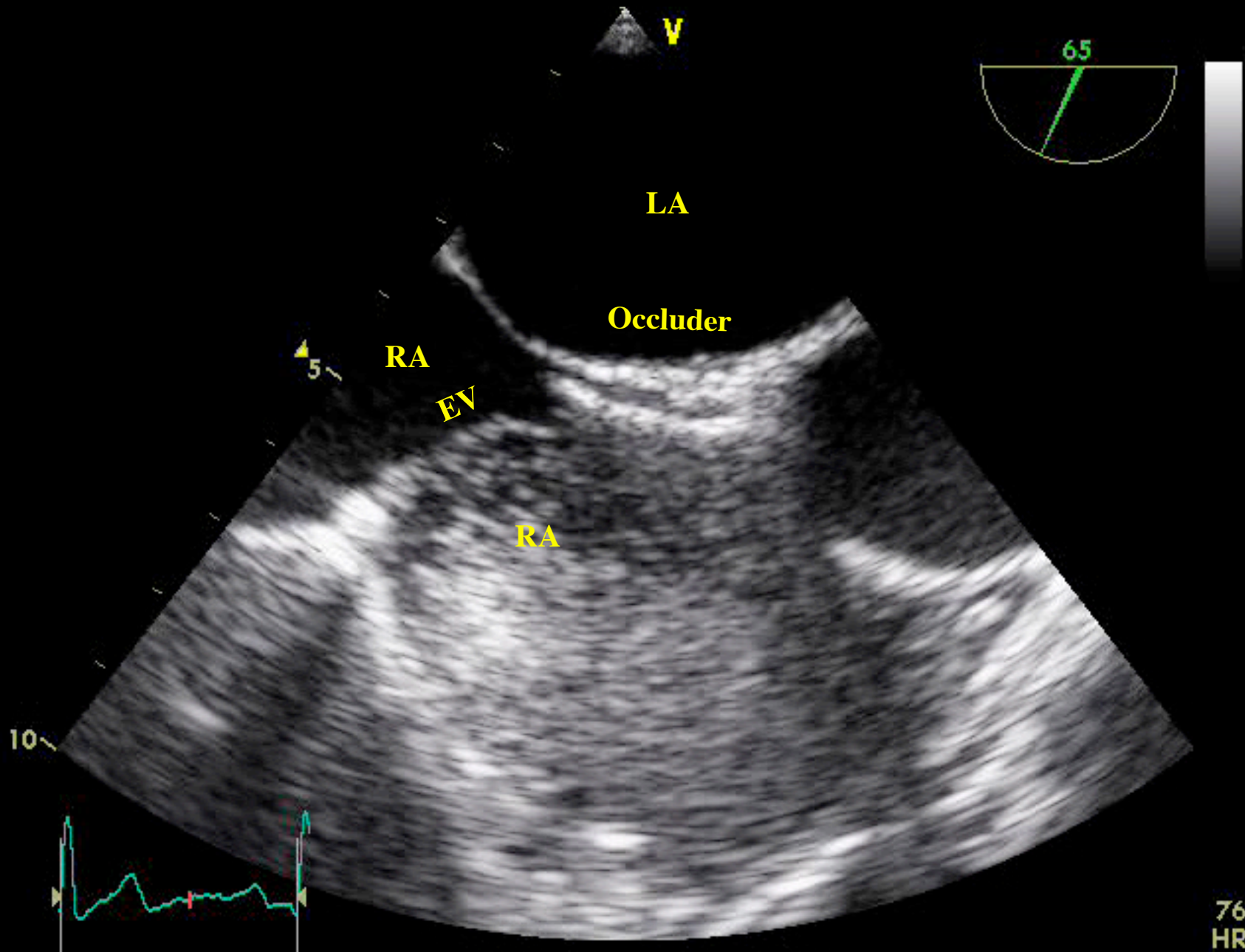
Woman 46 y, TIA and severe migraine



Eustachian Valve and PFO with LR Shunt (= Small ASD)

Woman 46 y, TIA and severe migraine

6-month FU, perfect TEE result, no more migraine



Indications

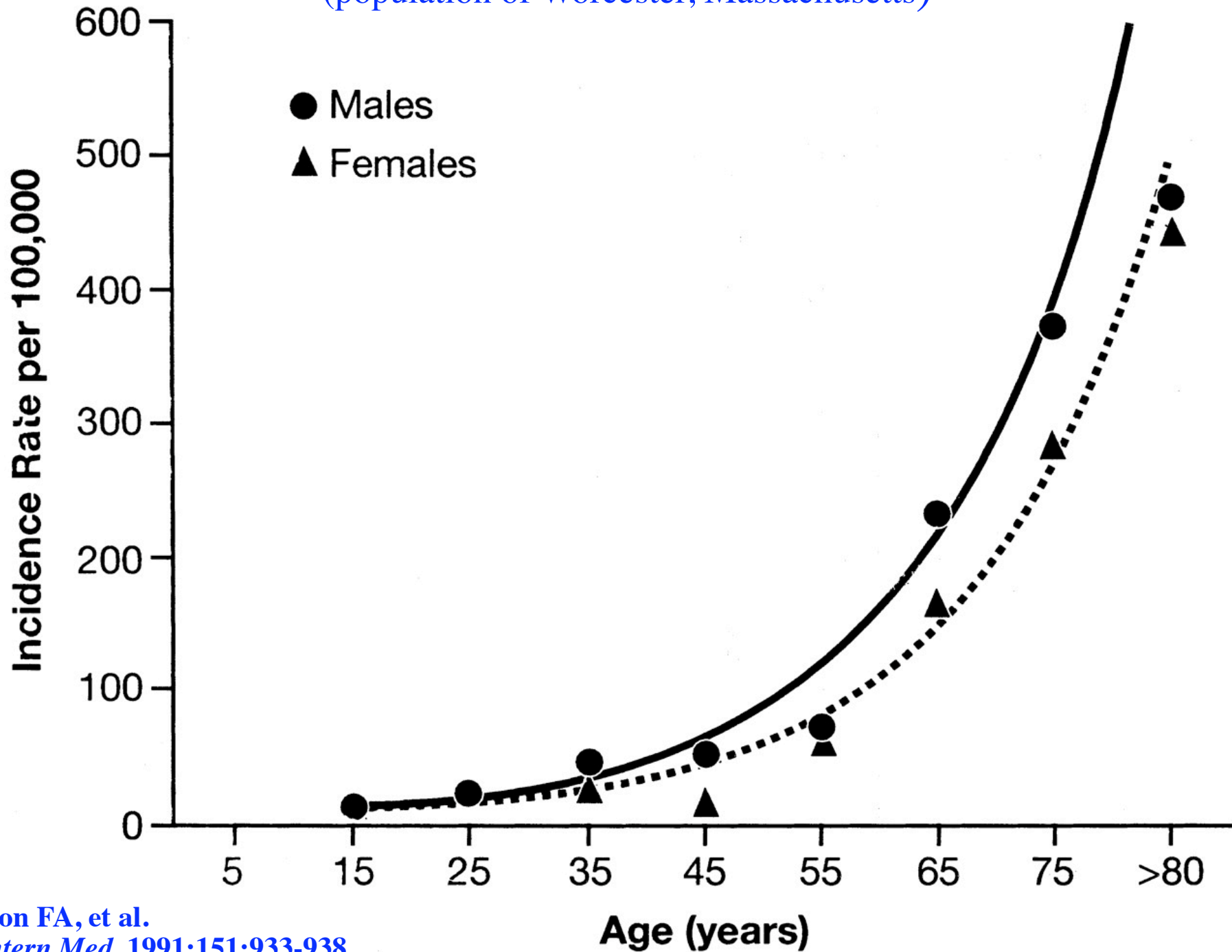
- **PFO** (right to left shunt by echocardiography [bubble transit])
 - TTE (period after Valsalva)
 - TEE (period after Valsalva)
- History of unequivocal systemic embolism(s)
- Non-paradoxical source of embolism excluded
 - ultrasound of
 - cerebral arteries
 - heart (TEE)
 - aorta
 - 24 hour ECG
 - hypercoagulability

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Annual Incidence of Venous Thrombotic Events

(population of Worcester, Massachusetts)



Indications

- **PFO** (right to left shunt by echocardiography [bubble transit])
 - TTE (period after Valsalva)
 - TEE (period after Valsalva)
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Indications

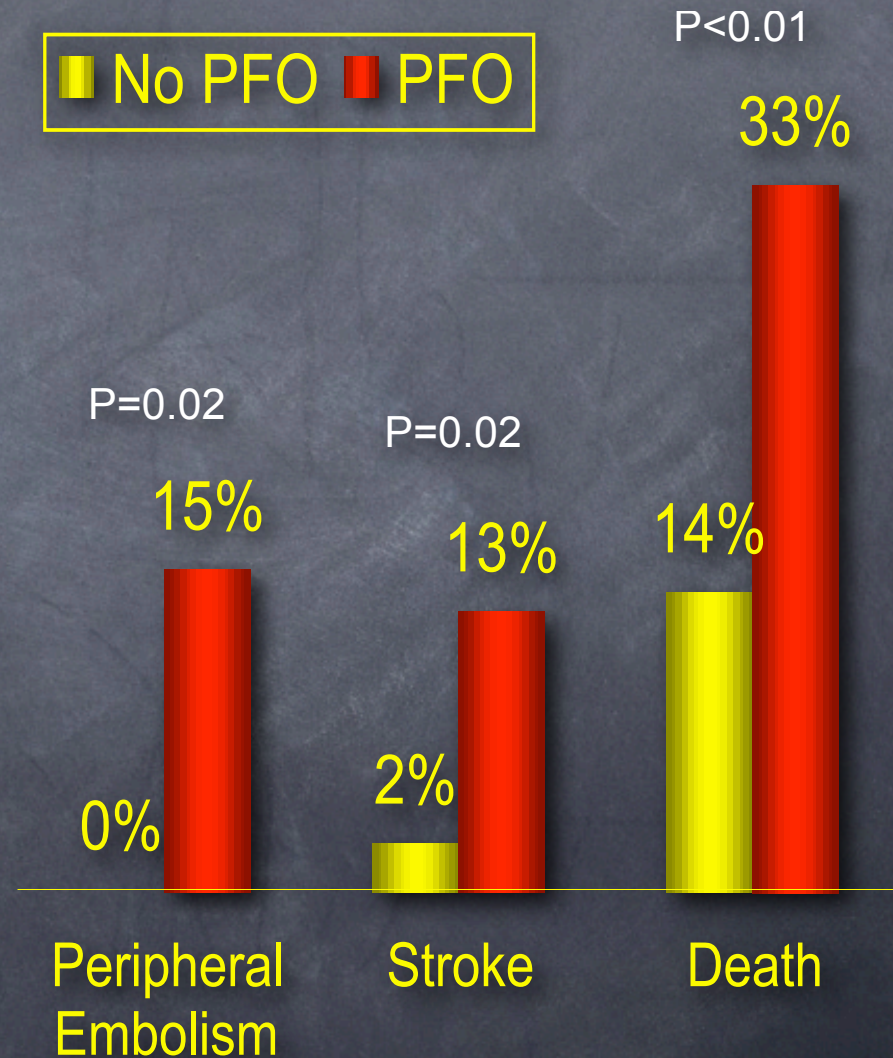
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 - cerebral arteries
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 - aorta
 - 24 hour ECG
 - hypercoagulability

PFO as Predictor of Adverse Outcome in Patients With Major Pulmonary Embolism

Konstantinides S et al. *Circulation* 1998;97:1946

- 139 patients with major pulmonary embolism undergoing TEE
 - 35% with PFO
- Clinical endpoints
 - death
 - cerebral embolism
 - arterial thrombo-embolism
 - major bleeding

- PFO independent predictor of mortality
- Suggested mechanism: paradoxical embolism



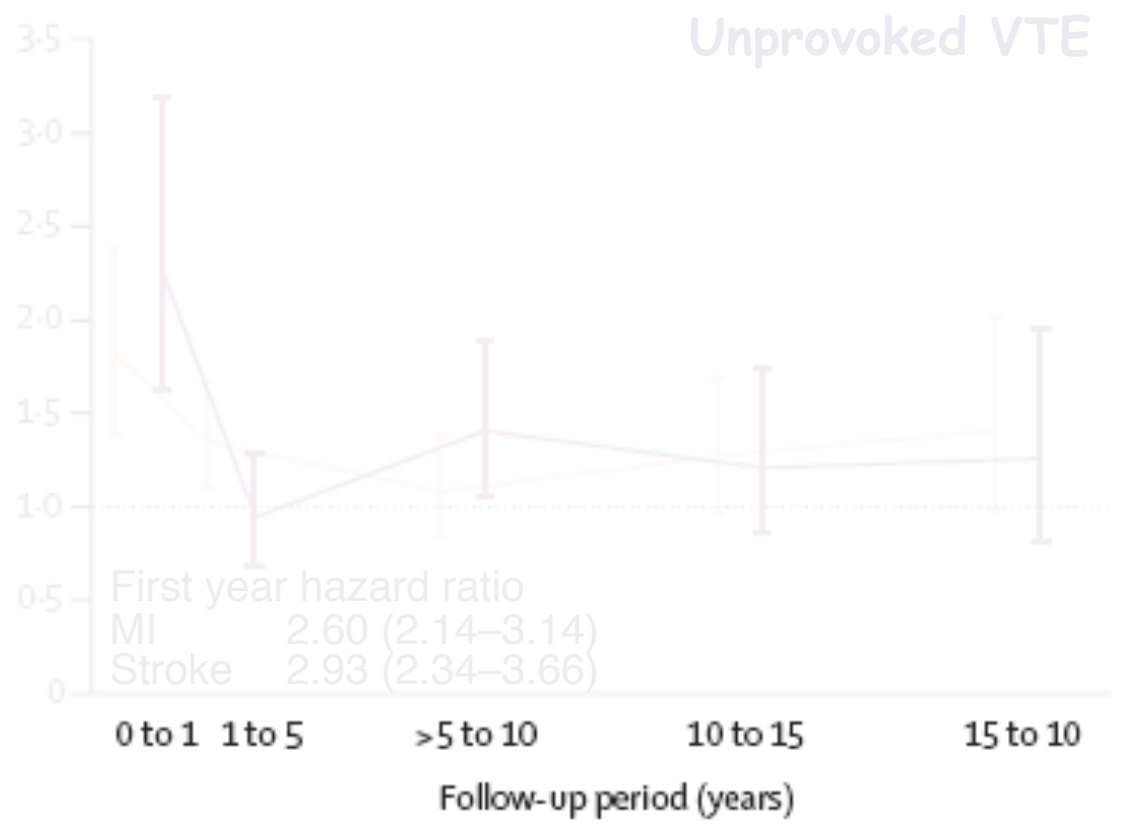
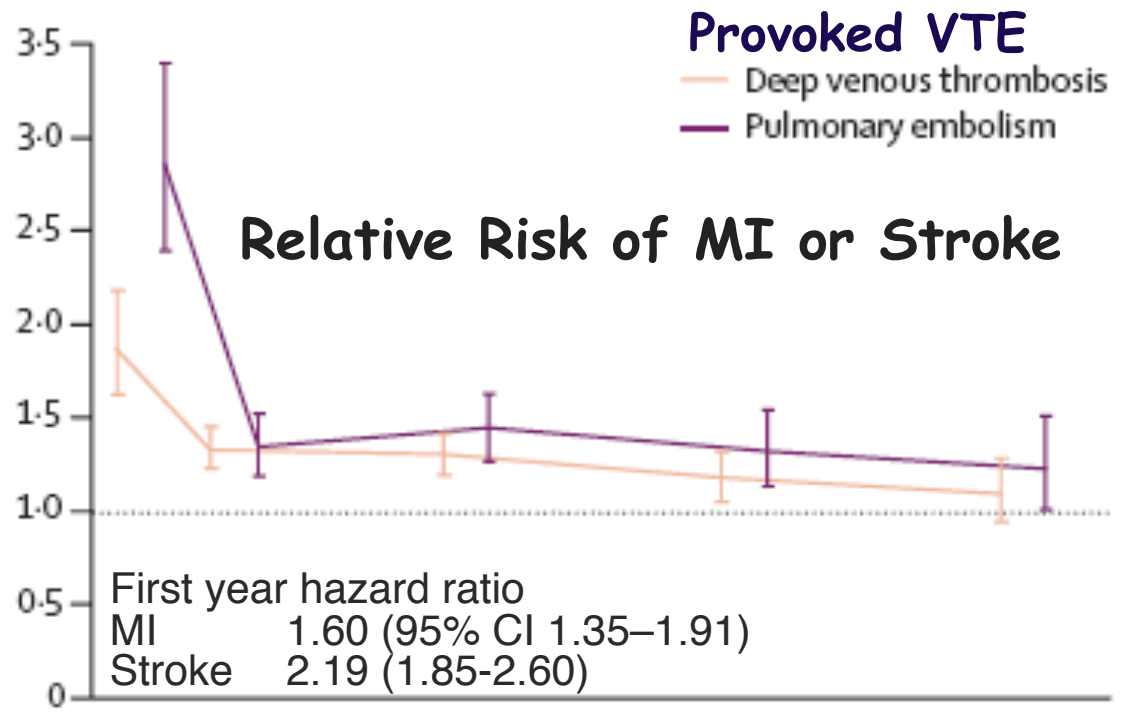
Venous Thromboembolism (VTE) and Stroke/MI

- 20-year population-based cohort study
- Danish medical databases
- No known cardiovascular disease
- 25 199 patients with deep venous thrombosis
- 16 925 patients with pulmonary embolism
- 163 566 population controls

No consideration of PFO !!

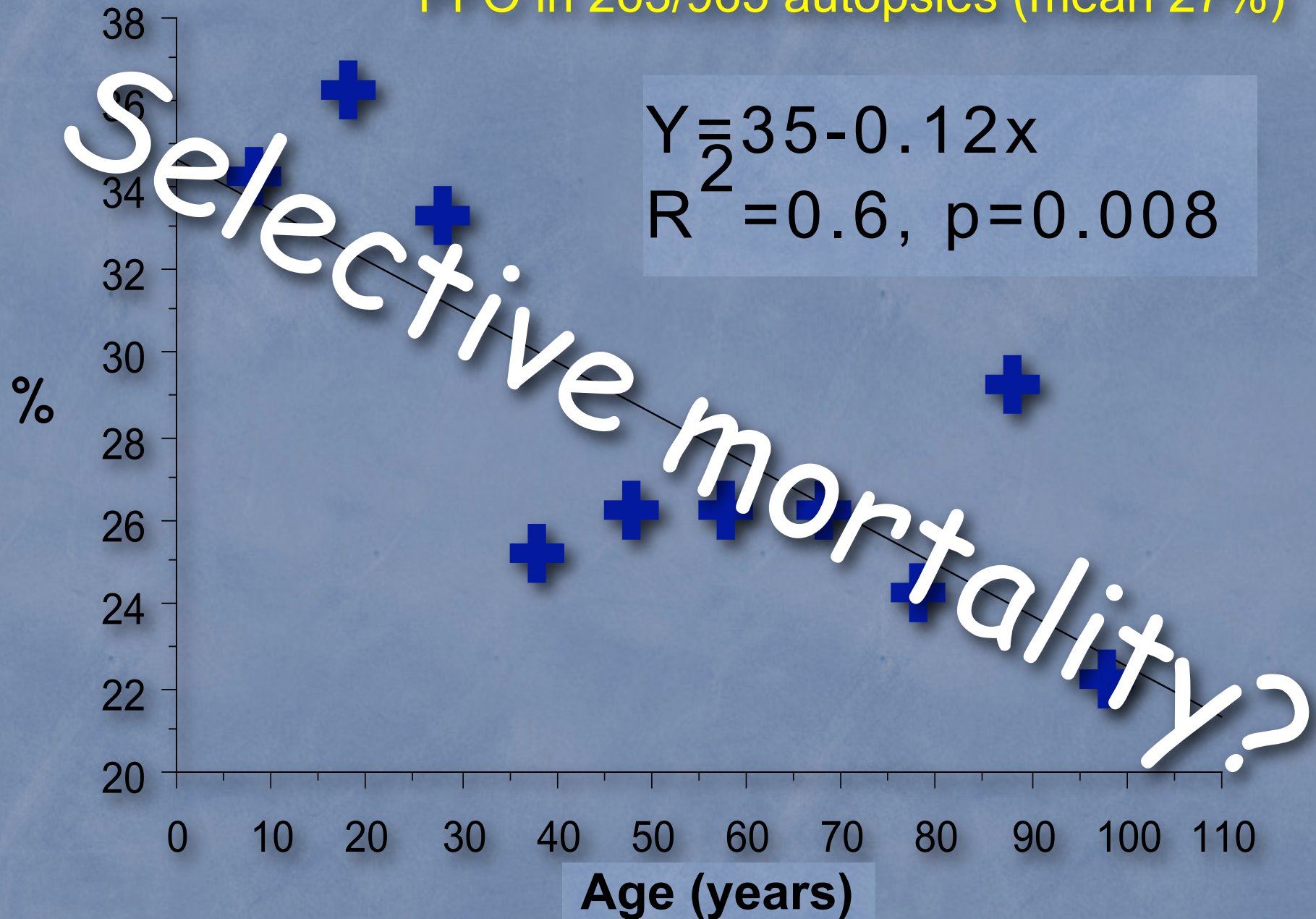
Paper
 Sørensen HT, Lancet 2007; 370: 1773-9
 (Denmark, Italy, US)

Editorial
 O Lowe GD, Lancet 2007; 370: 1743-4
 (Glasgow)



Prevalence of PFO According to Age

PFO in 263/965 autopsies (mean 27%)



Nurse, 39 Years, Mother of 2 Teenage-Boys **permanently aphasic** after stroke



MIST Serious Adverse Events

implant group

tamponade

pericardial effusion

retroperitoneal bleed

atrial fibrillation

chest pain

sham group

incision site bleed

anemia

nose bleed

brainstem stroke

MIST Serious Adverse Events

implant group

tamponade

pericardial effusion

retroperitoneal bleed

atrial fibrillation

chest pain

sham group

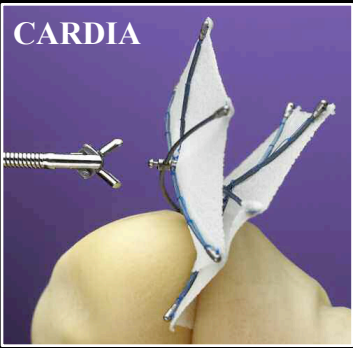
incision site bleed

anemia

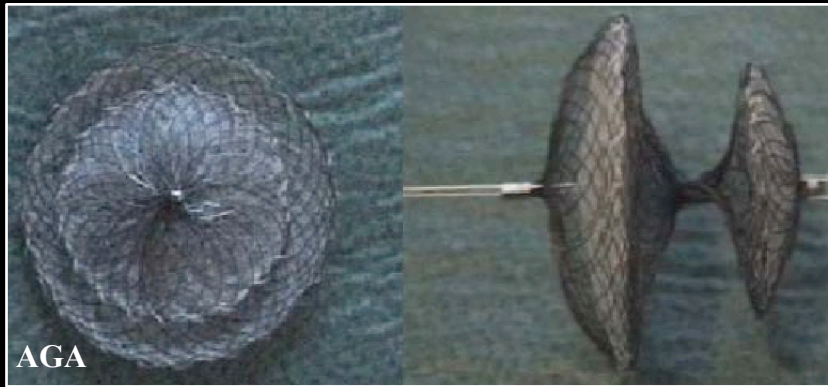
nose bleed

brainstem stroke

INTRASEPT



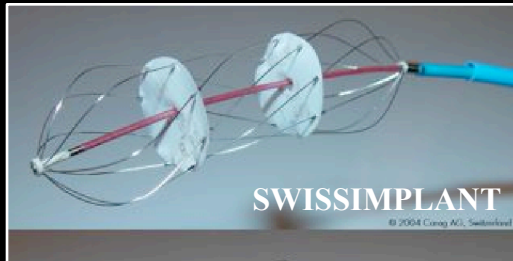
Amplatzer PFO Occluder



Figulla PFO Occluder



Solysafe



CardioSEAL



STARFlex



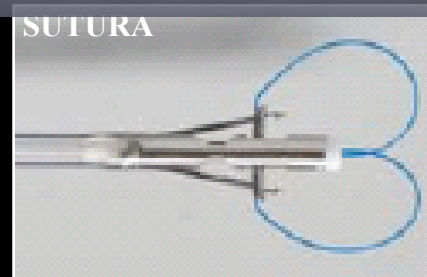
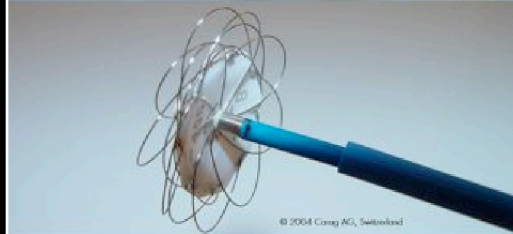
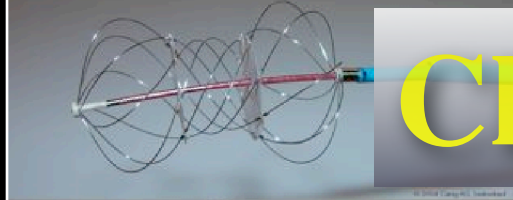
BioSTAR



Helix Septal Occluder

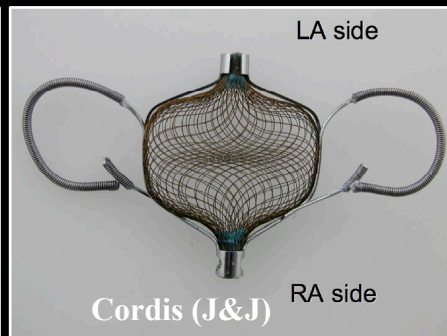


Clinically Used Devices

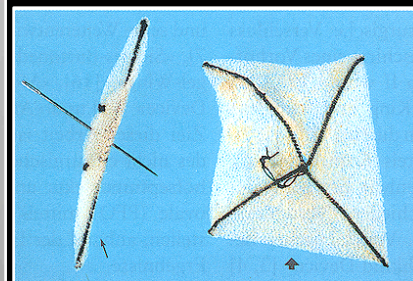


PFx

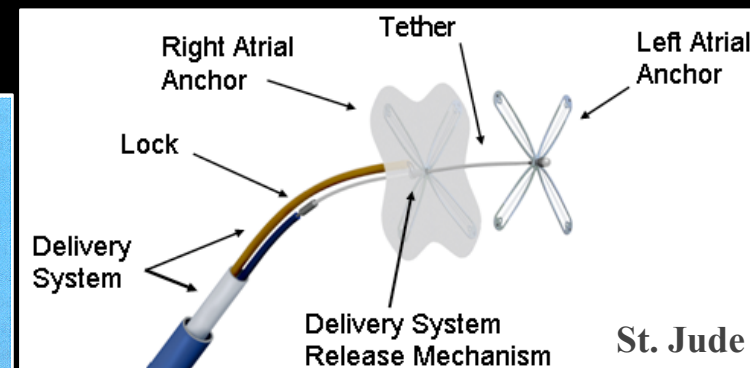
SeptRx



Buttoned Device



Premere

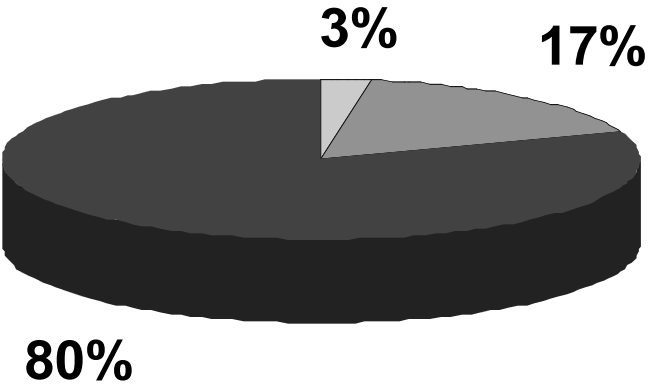


Amplatzer PFO Occlusion

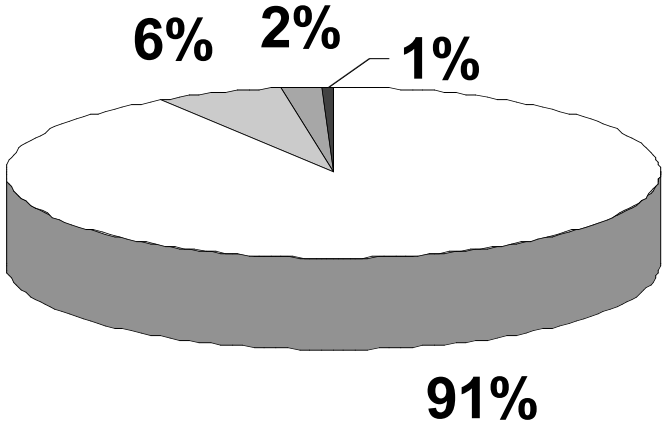
TEE

620 patients

Before

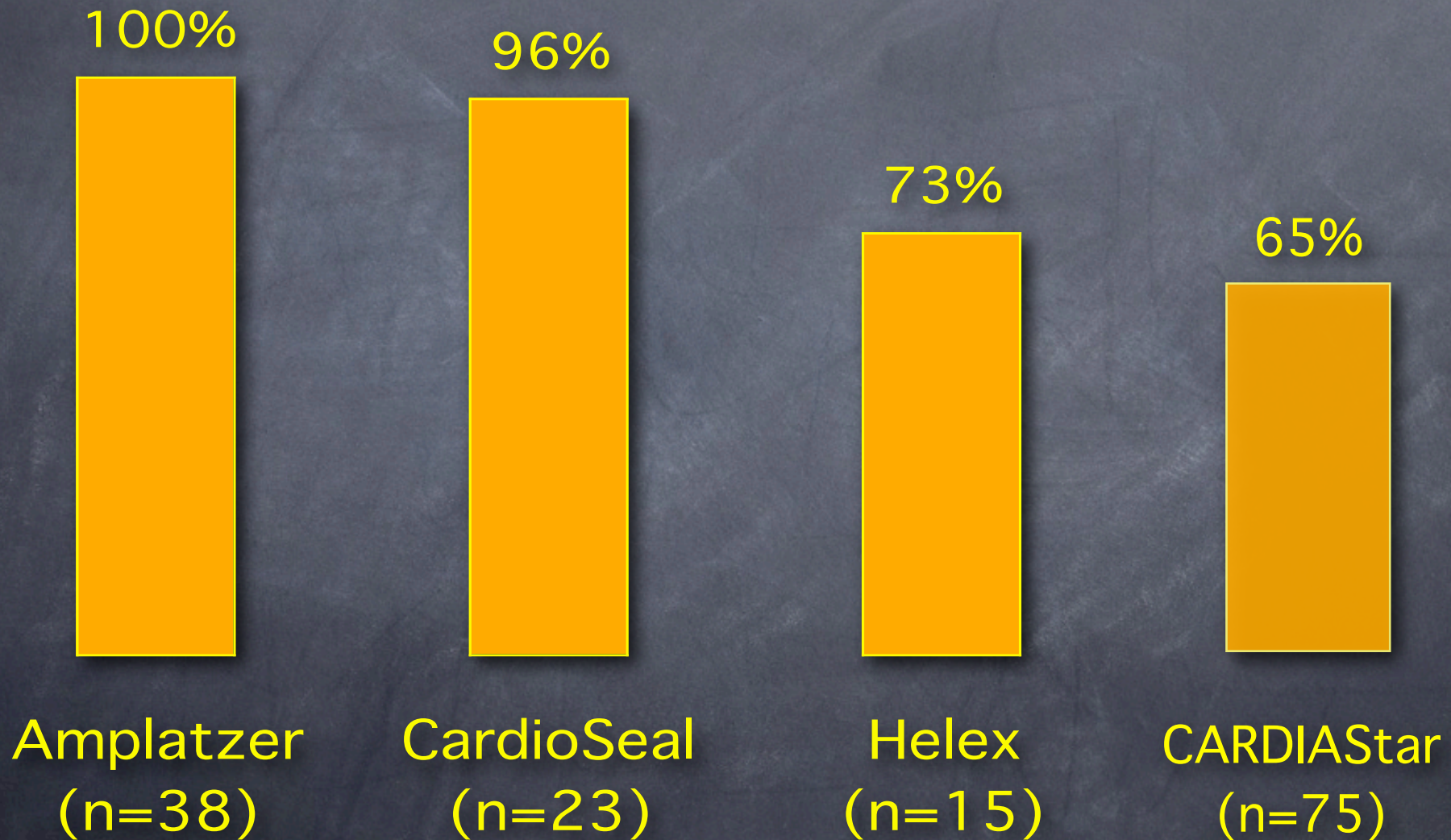


At 6 Months



- Grade 0
- Grade 1
- Grade 2
- Grade 3

PFO Closure Rates at 6 Months (TEE with contrast and Valsalva)



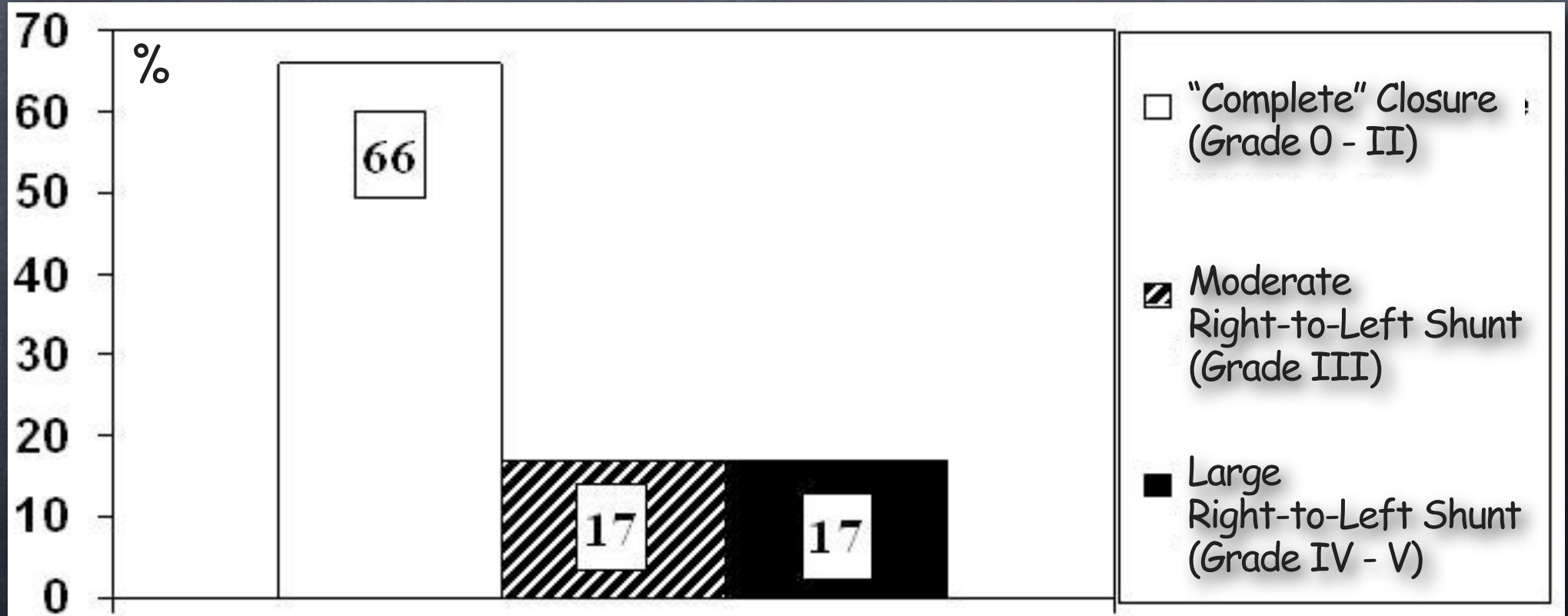
Bauriedel et al., Circulation 110: III-441, 2004

Nusser et al.
JACC 48: 322, 2006

PFO Closure Rates at 12 Months (Power M-Mode Transcranial Doppler and Valsalva)

237 patients

- 85% CardioSeal
- 15% Amplatzer



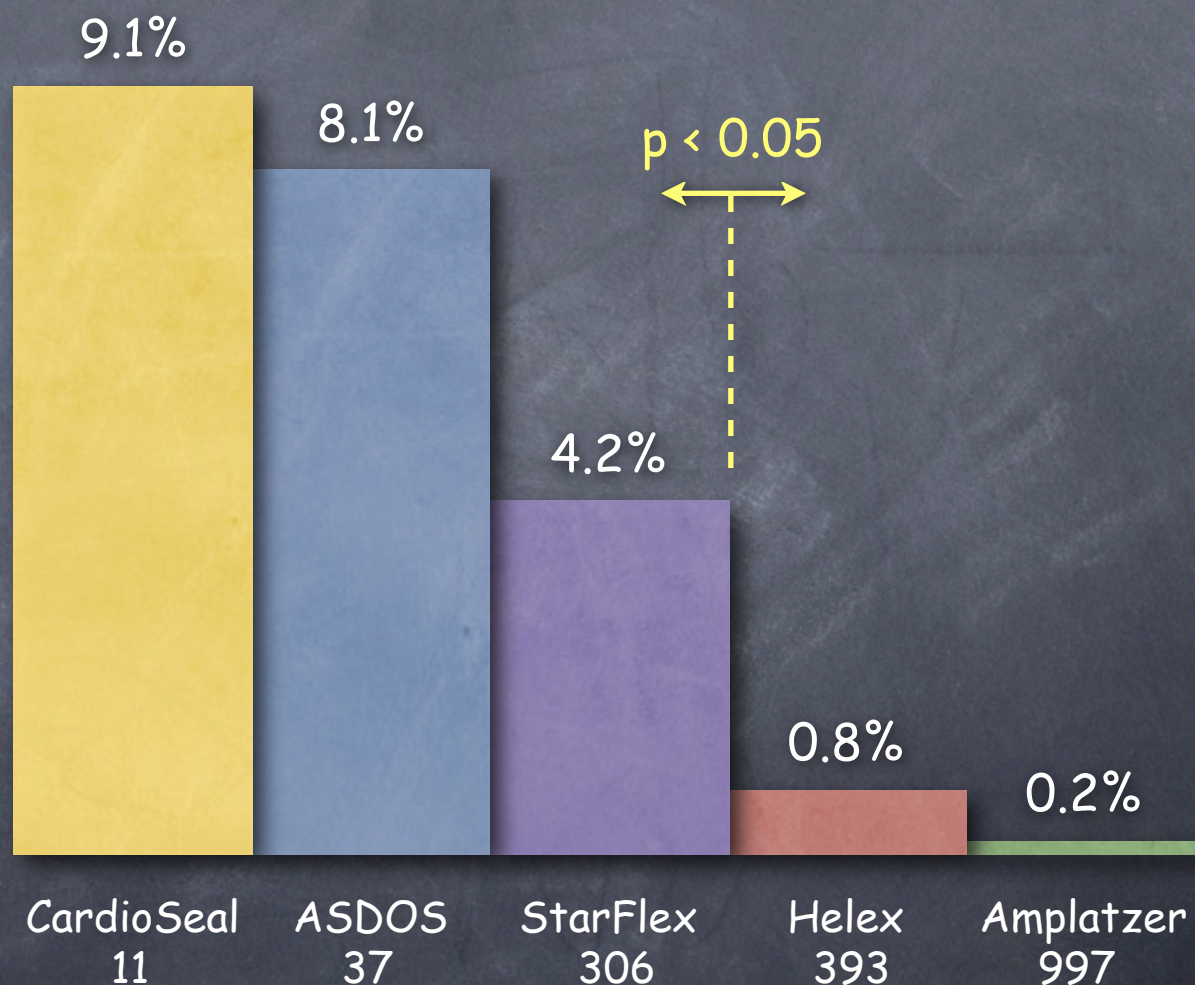
Risk of Thrombosis with Various Devices

- 1229 PFO
- 679 ASD
- 997 Amplatzer
- 393 Helex
- 306 StarFlex
- 37 ASDOS
- 11 CardioSeal
- 172 other

• Thrombus seen in 22 patients (1.2%)

- PFO 1.2%
- ASD 1.0%
- Left side 13
- Right side 7
- Both sides 2

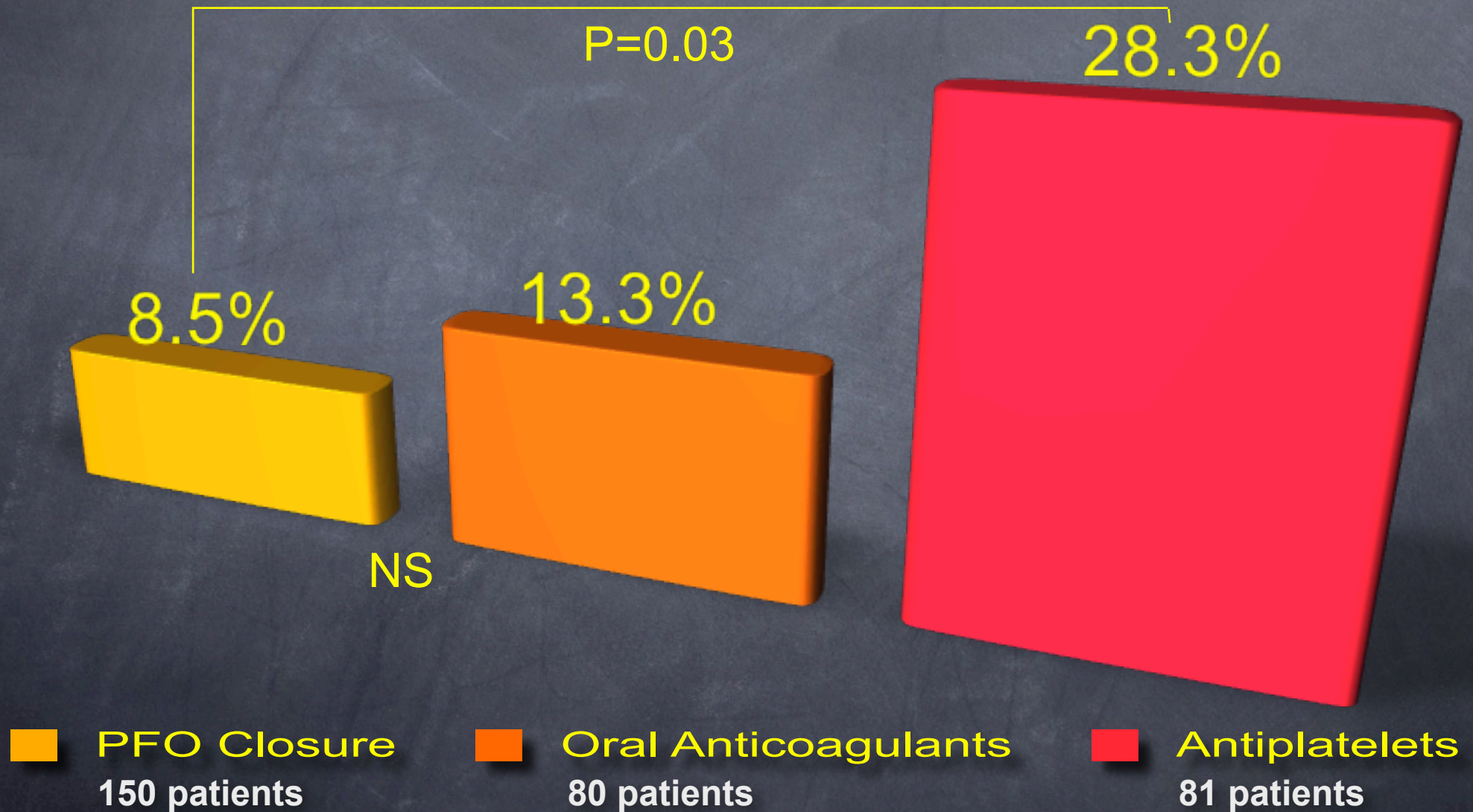
- 1908 patients, TEE at least at 1 month and 6 months
- Clinically: 2 strokes and 1 TIA in patients with thrombus (14%)
- Surgical removal: 3 patients (14% [or 0.2% of all])



Baranowski A, Sievert H, Frankfurt, Circulation 114:II785, 2006

Recurrent Events at 4 Years

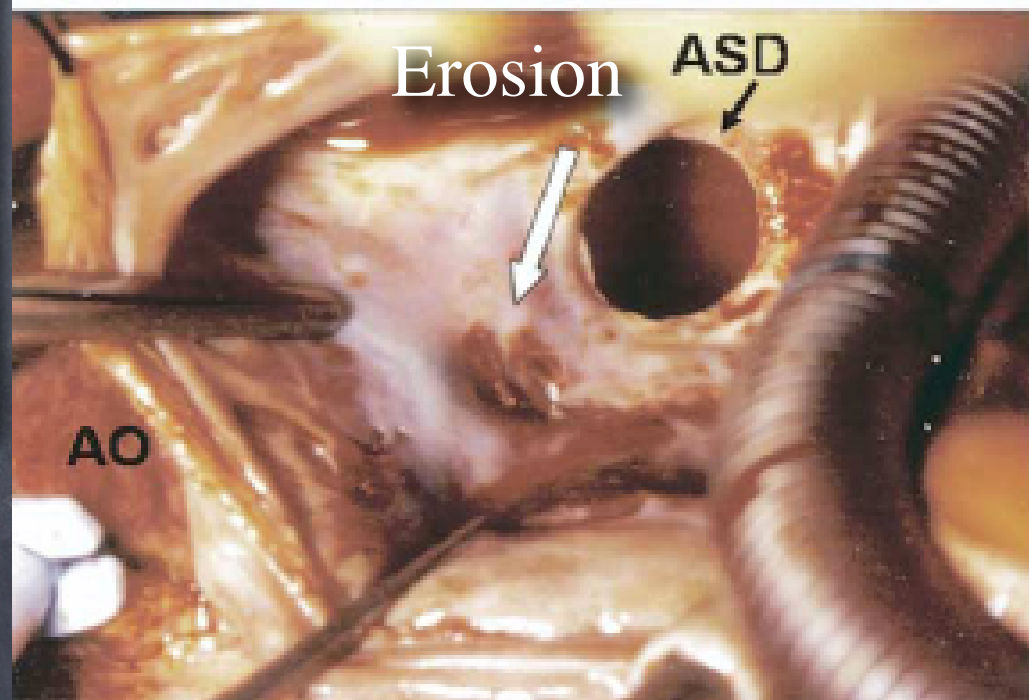
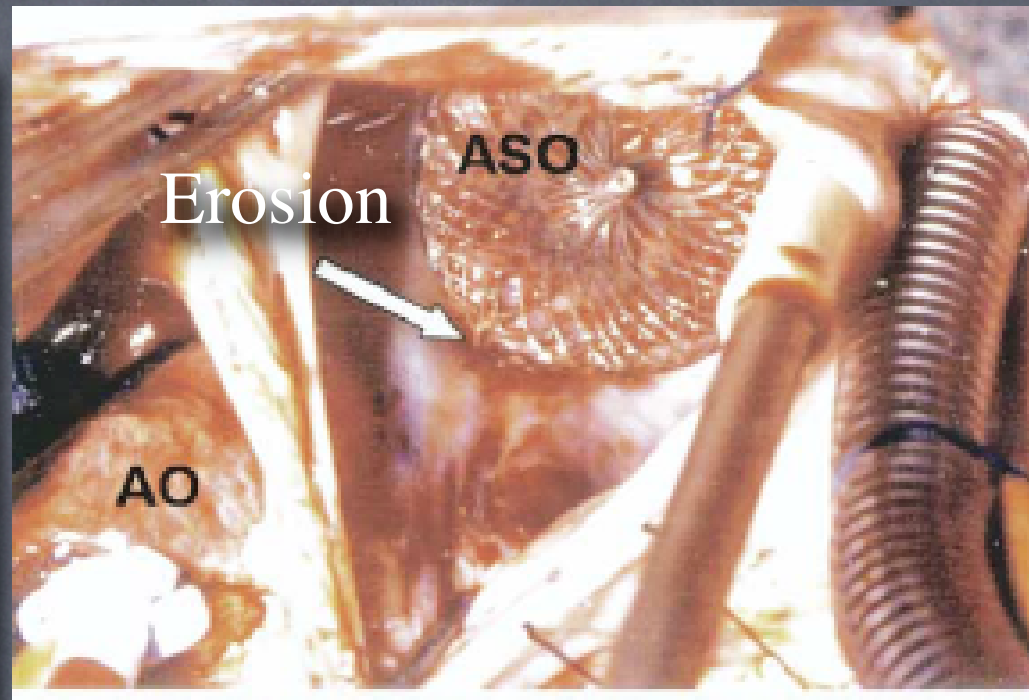
Death, Stroke, TIA



Windecker S et al. *J Am Coll Cardiol.* 2004; 44:750-8

Perforation (Wall Erosion)

Position and Possible Mechanism

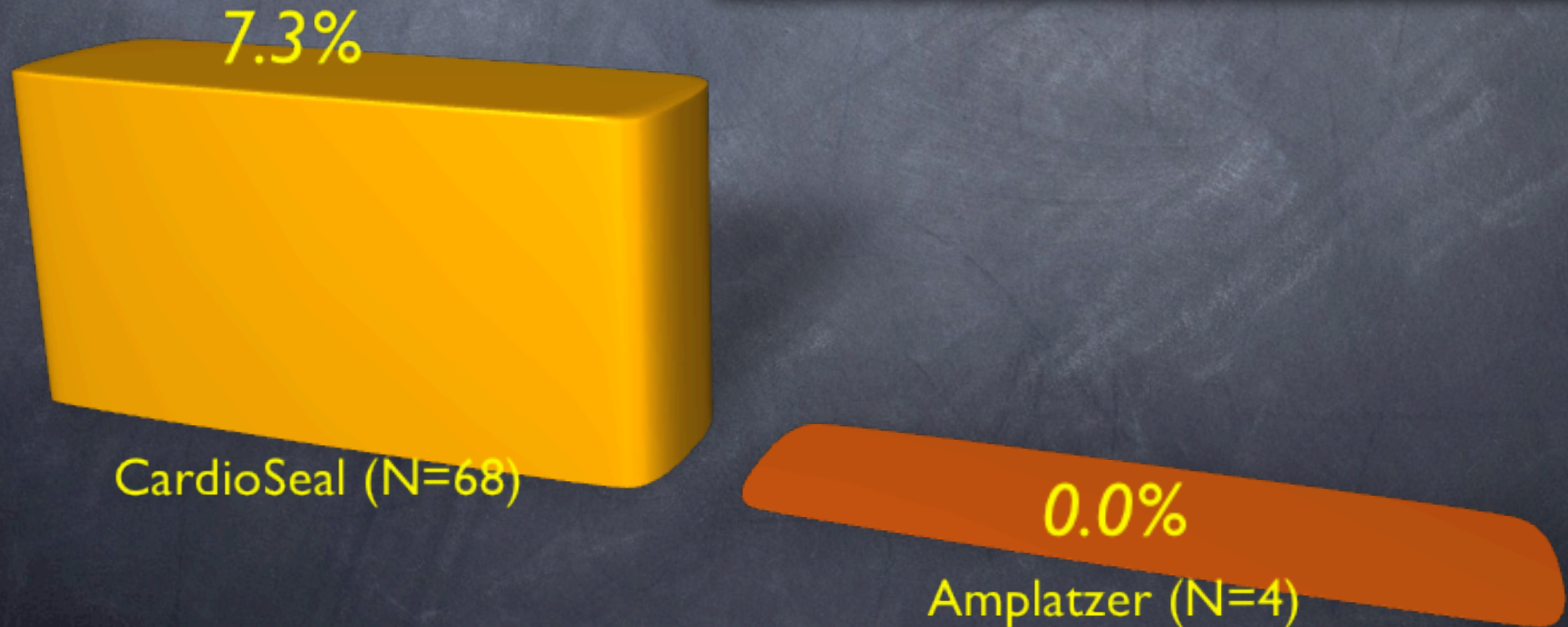


- 47 cases reported to AGA (3 deaths)
- 100,000 devices estimated
- incidence ~ 0.05%
- no fractured wires seen
- 2 with PFO devices, latest at 5 weeks

Atrial Fibrillation/Flutter (AF) After PFO Closure

Alaeddini J, J Invas Cardiol 2006;18:365-368

- Clinical symptoms for detection
- Mean time of occurrence: 6 months
- No influence of ASA
- Age: minimal 30, average 58 years
- Only 20% spontaneous conversion



Closure of Patent Foramen Ovale (PFO) for Cryptogenic Cerebral Embolism

Randomized Trials

Acronym	Place	Device	Patients	Status
• PC	global	Amplatzer	~400/425	recruiting
• PEPSIS	Germany	various	1/600	stopped
• CLOSURE I	US	CardioSEAL	~800/1500 (900)	recruiting
• RESPECT	US	Amplatzer	~350/500	recruiting
• CARDIA	US	PFO STAR	?/300	recruiting

Closure of Patent Foramen Ovale (PFO) for Migraine

Randomized Controlled Trials

Acronym	Place	Sham	Device	Status
• MIST	UK	+	CardioSEAL	reported
• MIST II	US	+	BioSTAR	recruiting
• PRIMA	global	-	Amplatzer	recruiting
• PREMIUM	US	+	Amplatzer	recruiting
• ESCAPE	US	+	PREMERE	recruiting
• STOPAIN	EU	+	PREMERE	recruiting

Transseptal Puncture after PFO Closure

