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# Acute and Chronic Complications in ASD Closure

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# The common thinking

- Complications of ASD closure are extremely rare, because
  - it is such a mature – almost boring - technique
  - We do this since decades
  - The devices are so good
  - We are so good

# The reality is ...

- ... complications of ASD closure are surprisingly frequent, because
  - devices are good, but still not perfect
  - We are good, but by far not perfect

# Complications from ASD closure

- Procedural
  - Arrhythmias
  - Air embolism, thrombo-embolism
  - Device malpositioning and embolization
  - Cardiac perforation, tamponade
- Post procedural
  - Arrhythmias
  - Thrombus formation → Stroke/TIA/Embolism
  - Cardiac perforation / device erosion
  - Aortic valve issues
  - Nickel allergy
  - Increased level of cardiac troponin
  - Bacterial endocarditis
  - Frame fracture

# Air Embolism

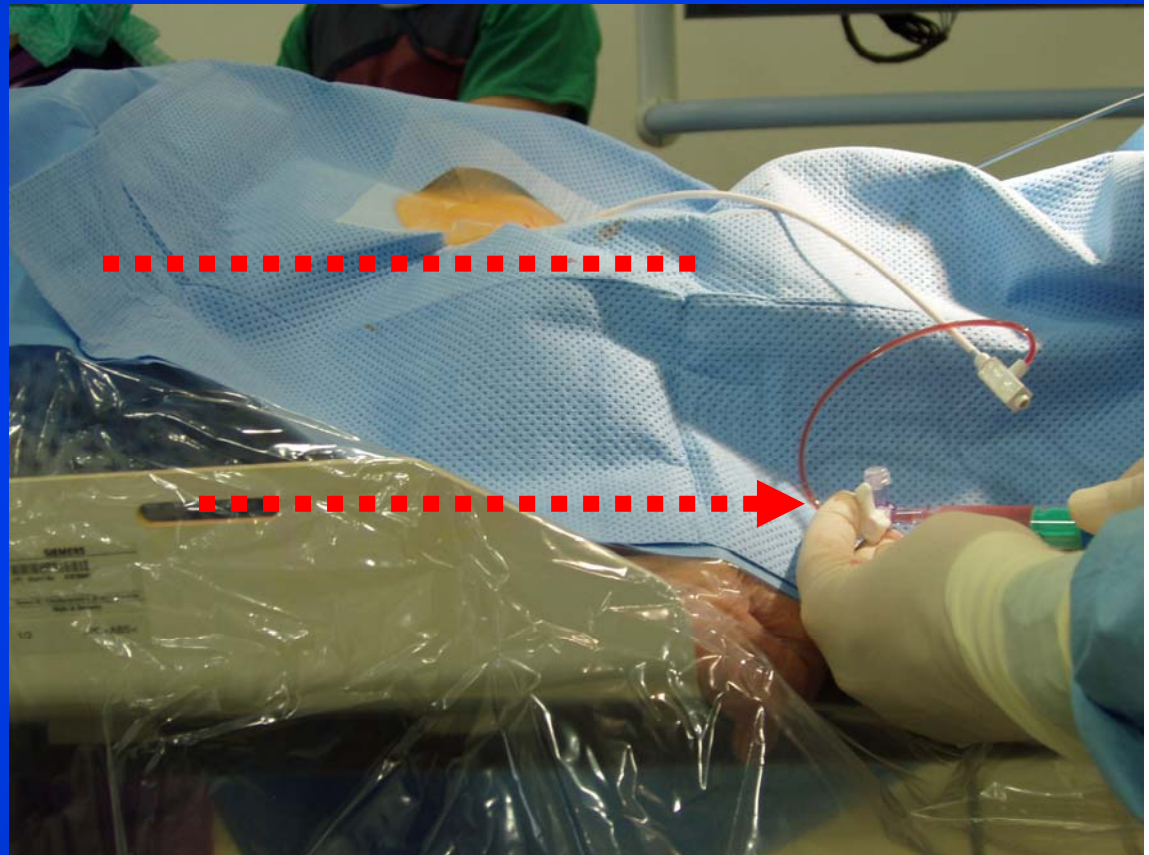
- Probably the most frequent complication of ASD closure
- Predictors:
  - Large sheaths
  - Low LA pressure
  - Agitated patient
- Symptoms
  - ST  $\uparrow$  (air embolism into the RCA)
  - TIA, stroke
  - Death has been reported

# How to avoid air embolism

- Patient should be
  - hydrated (LA- pressure  $> 10\text{mmHg}$ )
  - sedated
- De-air the sheath carefully (including the valve of the sheath)
- Have a continuous infusion of saline solution through the side arm of the introduction sheath (or flush frequently)
- Keep the hub of the catheter/sheath "below zero"
- No "Valsalva" when the catheter/ sheath is open

# How to avoid air embolism

- De-air the sheath
  - To wait for back-bleeding works best
- Stay with the hub below the level of the heart



# Thrombo-embolism

- Rare but much more serious than air embolism
- Due to pre-existing thrombi
- In big sheaths big thrombi may form!
  
- Always flush the sheath!
- Full dose of heparine!
  - 10,000 IU



# Device embolization

- Acute embolization can occur with any device
  - more common with non-self centering devices (1.7-4%) (1,2)
- Late embolization may occur
  - Less frequent, some case reports (3,4)
- Risk factors:
  - Misplacement
  - Undersized device
  - Large defects
  - Lack of rims
  - Septum aneurysm

(1) Chessa M et al *J Am Coll Cardiol* 2002; 39(6): 1061-5

(2) Peuster et al. *Cathet Cardiovasc Interv* 2003; 59:77-82

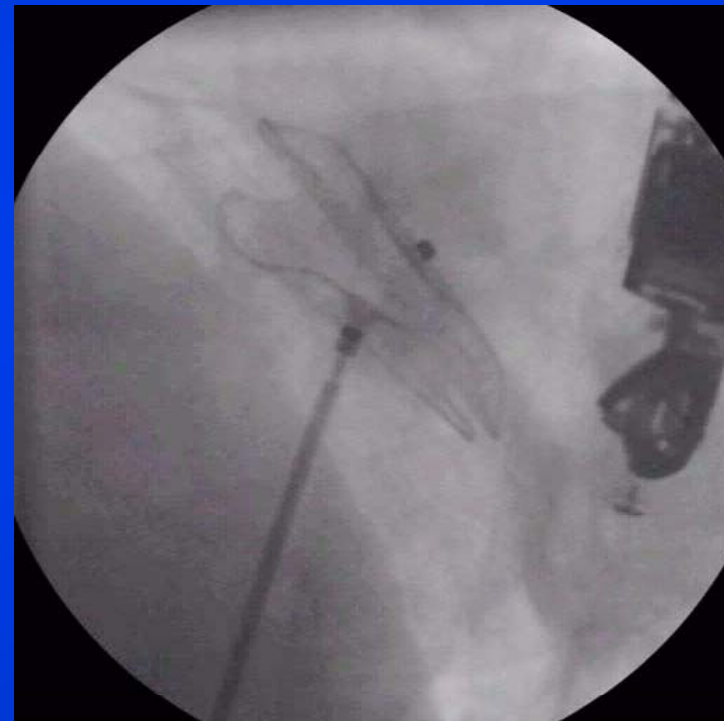
(3) Clikier et al; *Catheter Cardiovasc Interv* 2001; 54: 335-338

(4) Mashman et al. *CCI* 2005;65:588-592

# The good news about device embolization

- Usually only mild symptoms
  - Most often only transient arrhythmias
- More serious events like cardiogenic shock, stroke or death are extremely uncommon
- Most often the device can be retrieved by catheter techniques

# 28 mm ASD Occluder



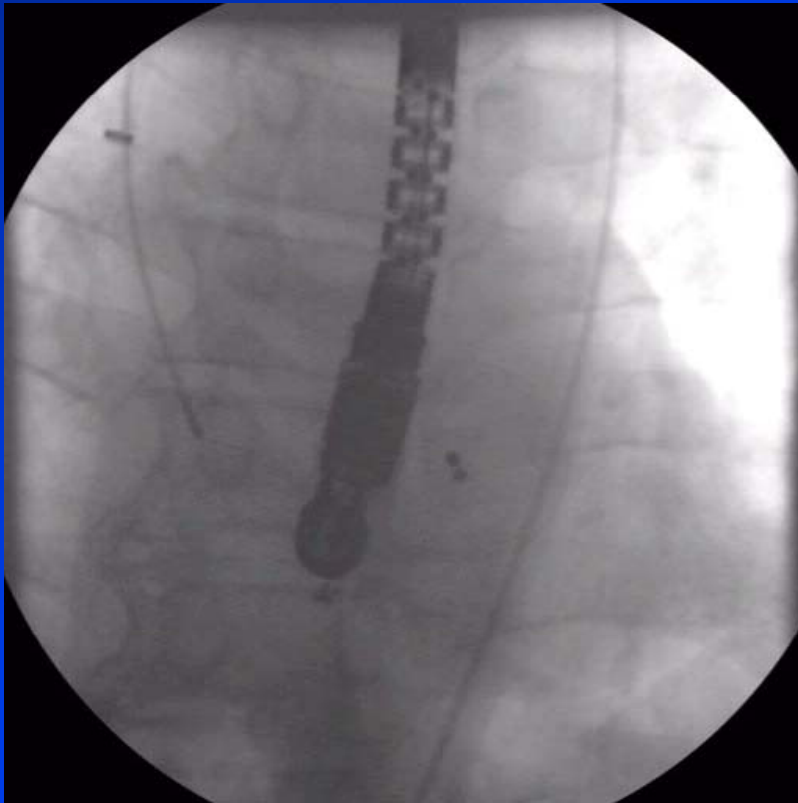
## Tug test

Very important to ensure a stable position before the device is released

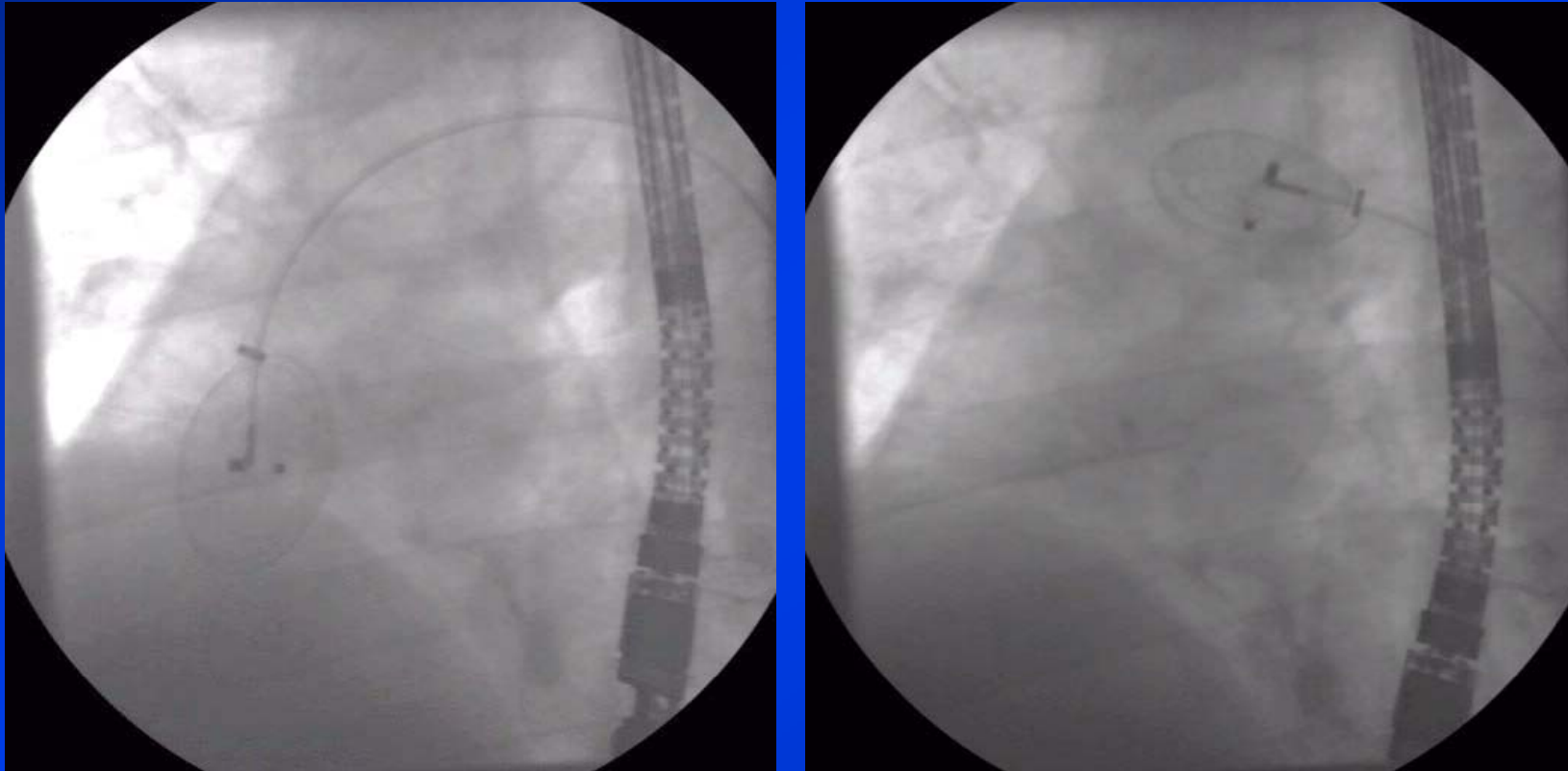
After release  
Looks good!



# Seconds later: Occluder in the LV

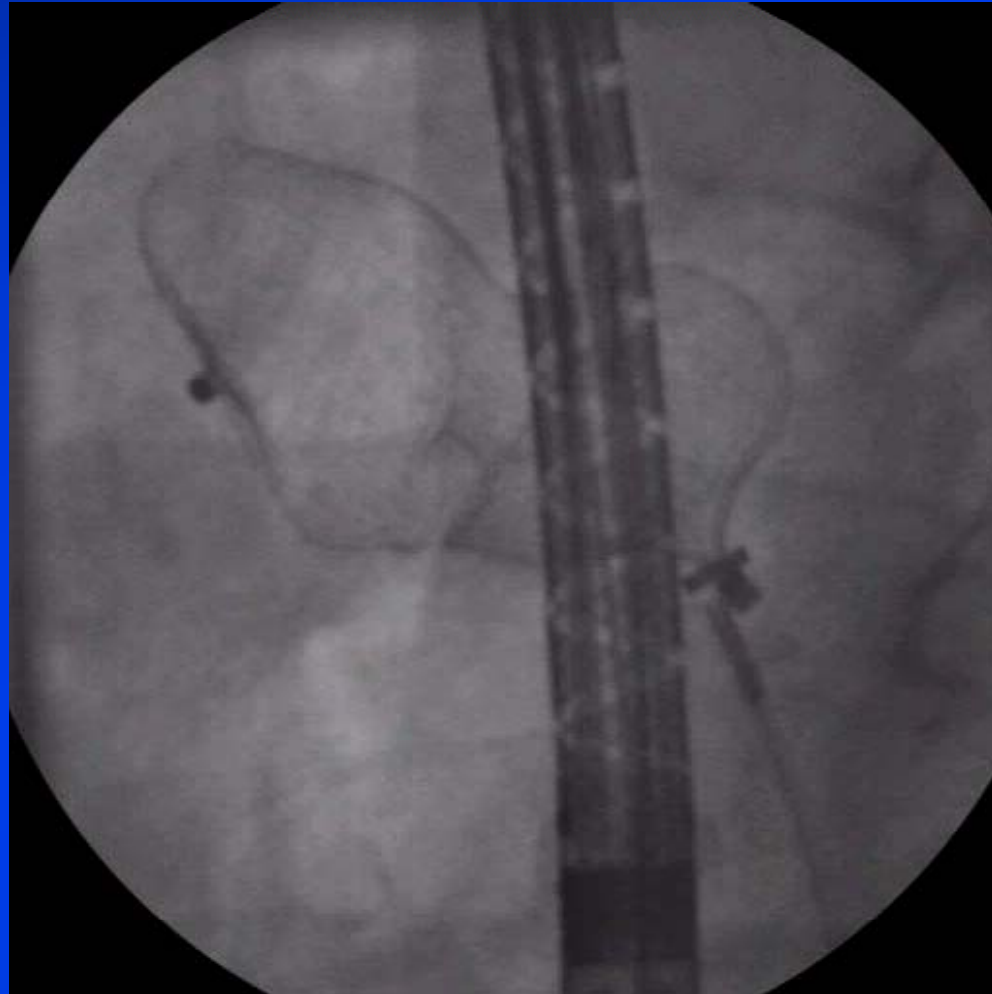


# Retrieval



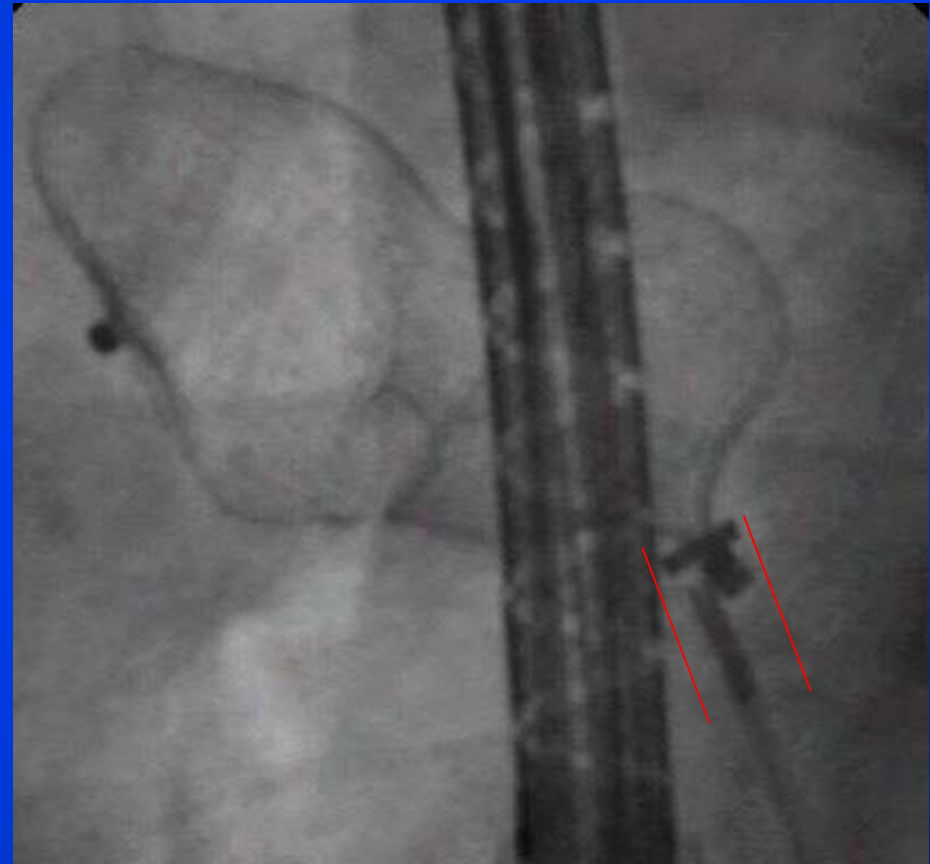
Big sheath + Snare

# Retrieval from the aortic arch



# Device Retrieval

- Big sheath
  - For example 14 F
- Snare
- Grab the proximal hub of the device
- Watch the hub when you pull
  - It has to be inside of the sheath!





# Post Implantation Arrhythmias

- Atrial fibrillation
  - Very frequent (~3%) but most often transient
  - Due to device or natural course of the disease?
    - more frequent in elderly
- AV block
  - Rare, usually transient

*(1) Chessa et al J Am Coll Cardiol 2002; 39: 1061-1065; (2) Murphy et al N Engl J Med 1990; 323: 1645-1650; (3) Gatzoulis et al N Eng J Med 1999; 340: 839-846*

# AV Block after ASD Closure

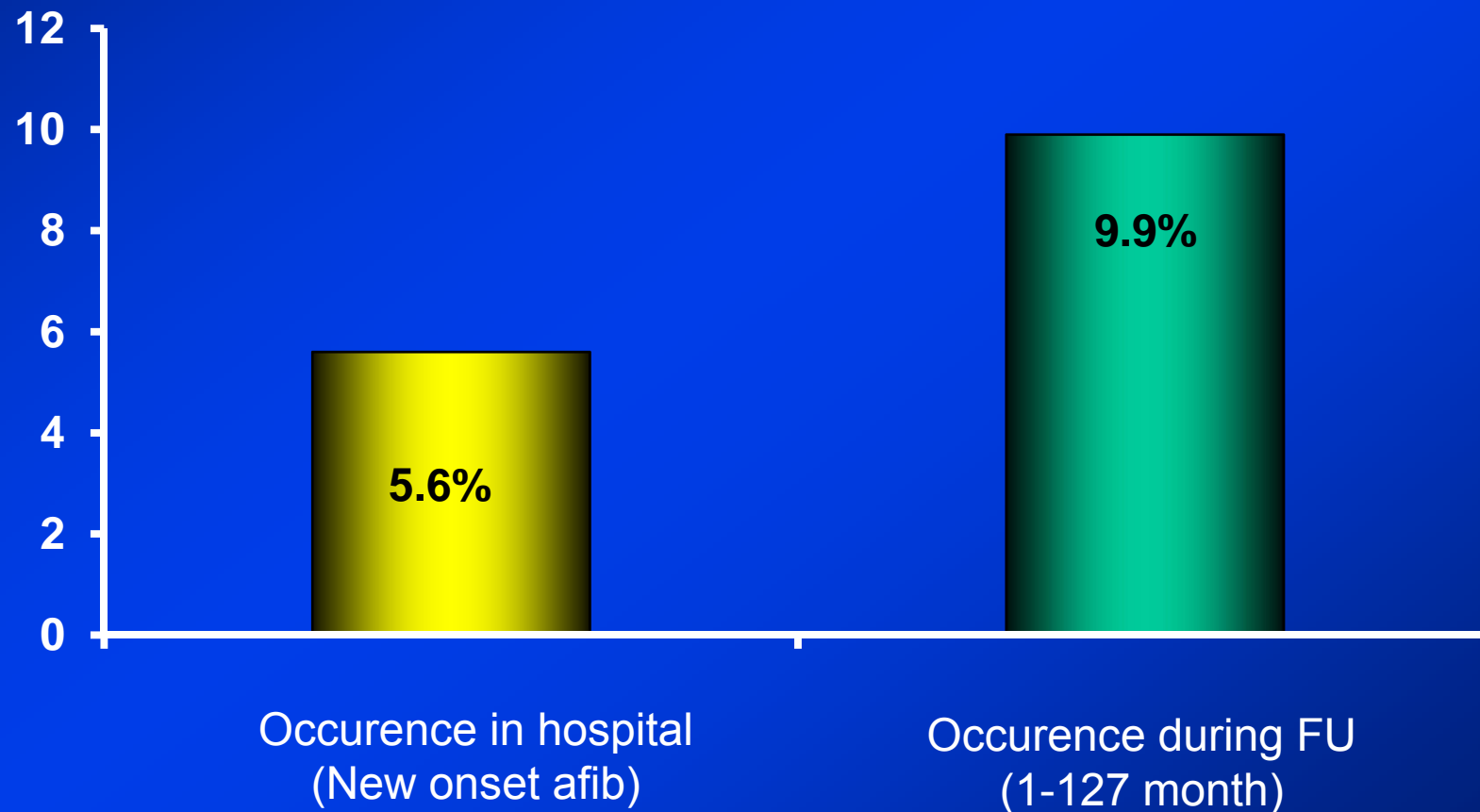
N= 162 pts ASD closure with ASO (Dec 1997- Dec 2001)

- New onset or aggravation of preexisting AVB 6.2 %
  - During procedure 1.9 %
  - Within first week 4.3 %
    - First degree 2.5 %
    - Second degree 2.5 %
    - Third degree 1.2 %
- In 8/10 patients transient

# Post Implantation Arrhythmias

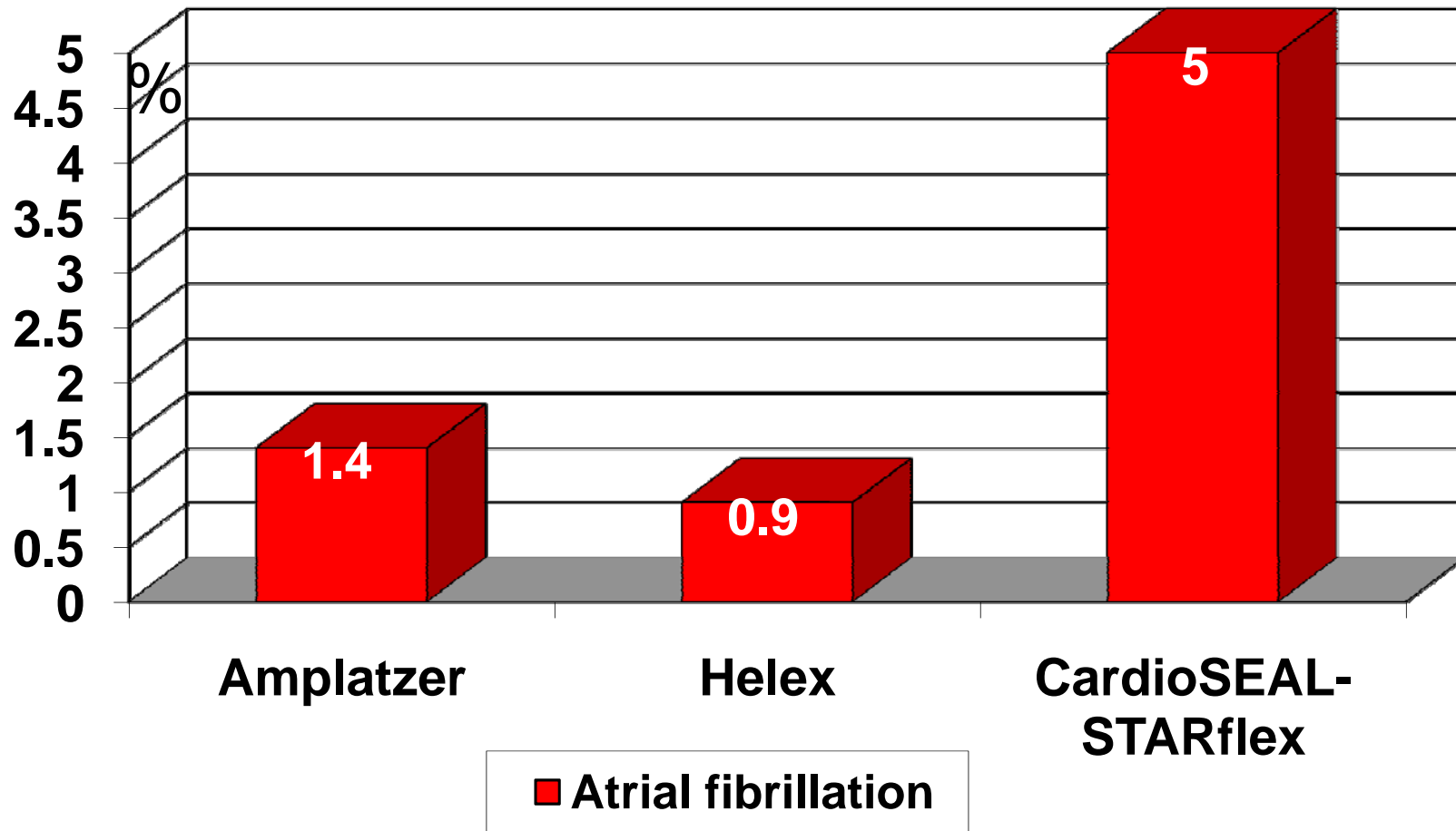
## Occurrence of atrial fibrillation

Frankfurt experience; ASD closure N= 1029 pts ; August 1992- May 2010



# 30 Day Outcome of PFO Closure

660 PFO-Patients, Randomized to 3 Devices



# Afib after ASD Closure

- Most often within the first few weeks/months
- Most often transient
- Good long-term prognosis
  
- You should treat as early as possible
  - Medication, electroshock
- Catheter ablation is not indicated

# Thrombus formation

- N= 1000
- TEE at 4 weeks and 6 months
- Overall incidence 1.2%
- Has occurred on every available device
- 70% of thrombi were found at 1 Mo FU
- Most often in LA
- Thromboembolic events in 20% of pts with thrombus
- Predictors
  - Some devices
  - Atrial fibrillation

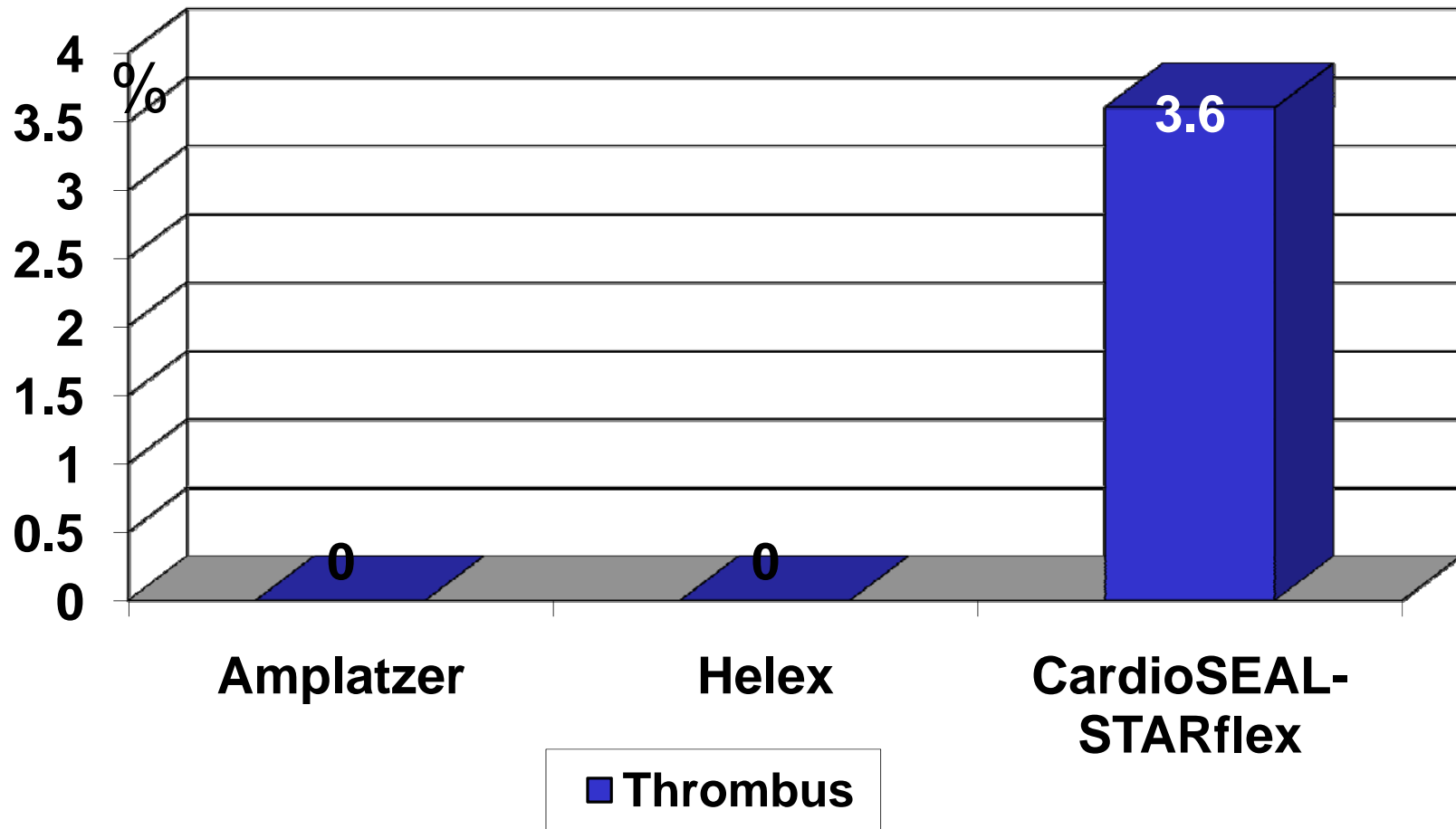
# Thrombus formation

Occluder	n	Thrombus (%)	
		4 weeks	6 months
Rashkind	1	0	0
Butttoned Device	52	0	0
ASDOS	42	3.6	0
Angel Wings	30	0	3.3
CardioSEAL	27	7.1 *	0
StarFLEX	142	5.7 *	0
Amplatzer	418	0*	0.3
PFO-Star	127	6.6 *	1.5
Helex	161	0.8	0

\* Difference between Amplatzer occluder against CardioSEAL, StarFLEX and PFO-Star → significant (p<0.05)

# 30 Day Outcome of PFO Closure

660 PFO-Patients, Randomized to 3 Devices





# How to cope with thrombus formation?

- Prevention:
  - Heparin i.v. (75-100U/kg) during the intervention
  - Antiplatelet therapy for 6 mo after implantation
- Routine follow-up TEE after 4 w and 6 mo
- Treatment:
  - In 85% (17/20) Heparin/Warfarin solved the problem (1)
  - 3/20 pts (15%) underwent surgery

(1) *Krumsdorff et al. JACC 2004; 43: 302-309*

# Thrombus on devices

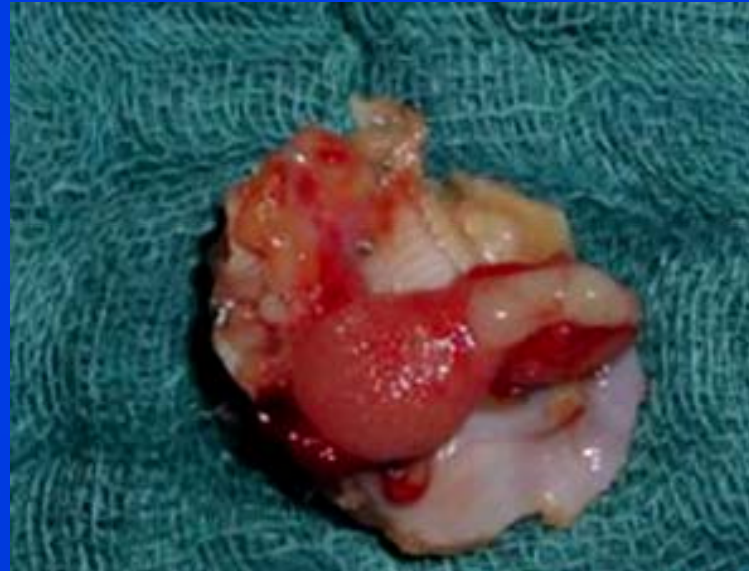
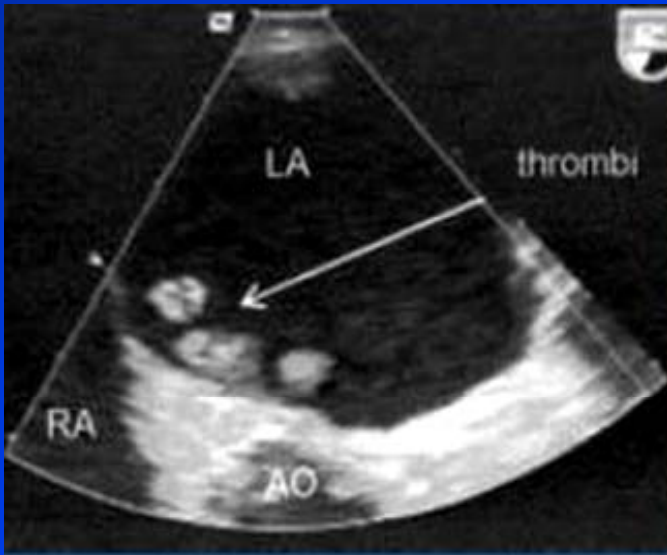


CardioSEAL-STARflex



PFO-STAR

# Thrombus formation



Thrombus on a StarFLEX device  
→ Thrombus was surgically removed with the device

# Thrombus formation

4 yrs after implantation

- Amplatzer ASD occluder
- Thrombus dissolved under anticoagulation



# Perforation

## Occurrence in the cath lab

- During delivery of device
  - Due to guides, wires, sheaths
  - Intrapulmonary bleeding, tamponade
  - Incidence 0.5 % -1.0 % (1,2)
- How to prevent
  - Do not enter the LAA with wires and catheters
  - Use wires with soft J-tip
  - Don't open the device in the pulmonary vein

(1)Chessa et al JACC 2002; 39:1061-5

(2)Egred et al J Interventional Cardiol 2007; Vol 20 (5):395-401

# How to treat tamponade in the cath lab

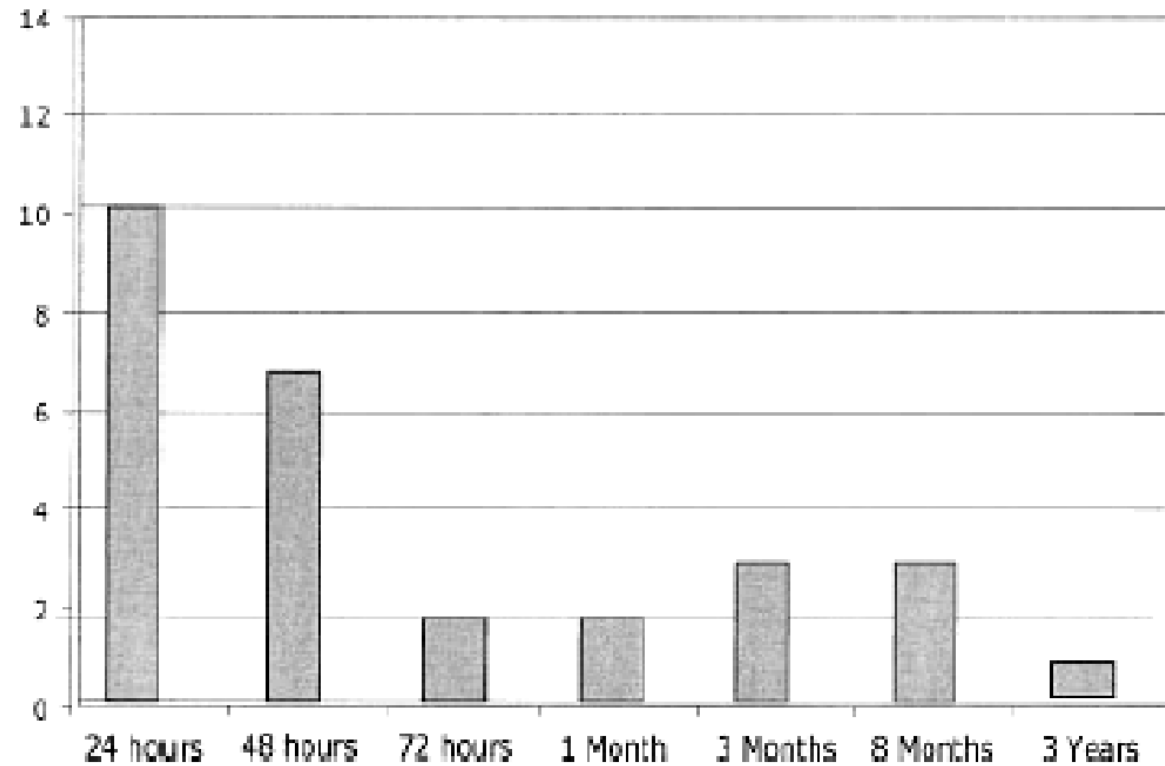
- Reverse anticoagulation
- Pericardiocentesis
  - re-transfuse via venous sheath
- If the perforation was due to catheter manipulation surgery can often be avoided
- If device erosion was the cause surgery is often needed

# Late cardiac perforation/erosion

- ... is the most serious complication of ASD closure
- It results in pericardial effusion, tamponade, hemodynamic collapse and possible death
- The incidence is 0.1- 4% for various devices
- May occur weeks and months after the procedure
- Risk factors
  - pts < 18 years of age
  - deficient aortic / superior rim
  - Oversized devices

# Time to adverse event

(Appearance of hemodynamic compromise - ASD pts only)



*Amin et al. Catheterization and Cardiovascular Interventions 2004; 63: 496-502*



# Device perforation/erosion

- Erosions have been reported with all commonly used devices (1,2,3), except the Helex device
- Nearly all erosions occur at the dome of the atria near the aortic root
- Aortic- right atrial fistula may be the consequence
- Mortality rate is 10%

(1) Amin et al. Catheter Cardiovasc Interv 2004; 63(4):496-502

(2) EHJ 1997; 12: 869-872

(3) J Invasive Cardiol 2009; 21: E39-E41

# Device perforation/erosion

## United States (Amplatz)

Year	Number of Defects Repaired	Reports of HC <sup>1</sup>	Rate	Confirmed Erosion	Confirmed Erosion Rate
1998-2001	1063	1	0.10%	0	0.00%
12-05-2001 (FDA approval)	228	0	0.00%	0	0.00%
2002	2970	8	0.27%	5	0.17%
2003	3599	9	0.25%	7	0.19%
2004	4125	1	0.02%	1	0.02%
2005	4914	4	0.08%	2	0.04%
2006	4812	3	0.06%	1	0.02%
Total	21,711	26	0.12%	16	0.07%

- Erosion of ASO devices occurred in up to 0.19% of implants

*Amin et al. Catheterization and Cardiovascular Interventions 2004; 63: 496-5-2*

# How to avoid cardiac perforation/erosion?

- Careful patient selection (rim assessment- missing anterior rim?)
- Avoid wedging of the device between the aortic and posterior rim
- Pts with small PE on pre- discharge echo should be hospitalized for 24 – 48 hours and should have close follow-up (echo)

# Aortic Valve Issues

- ASD can be close to the aorta/aortic root
- This may result in distortion of aortic frame and impact on the non-coronary cusp
  - Aortic insufficiency
  - Aortic to atrial fistula (1)

(1) Bartus et al. *J Cardiovascular Medicine* 2008; Vol 9, Issue 7: 744-746

# AR after atrial Shunt closure (ASD and PFO)

N=240 (PFO 170/ ASD 70)

Mean device size AGA 25 mm, Cardia 31 mm

	Before	3 Mo-FU	12 Mo-FU
Mild AR	40	49	61
Moderate AR	3	4	6
Severe AR	0	0	0

*Schoen SP. Heart 2008; 94:844-847*

# Frame fractures

- More frequent with older devices
    - ASDOS (1)
    - Buttoned Device (2)
    - StarFLEX →
- Incidence 14% (1,2)
- Incidence up to 15% (3,4)

...but it also happens with newer devices (Helex)

Most often asymptomatic

(1) Sievert et al *Am J Cardiol* 1998, Vol 82, Issue 11: 1405-13

(2) Reddy et al. *In: Am Heart J* (1995 Jan) 129(1):76-82

(3) Krumsdorff et al. *JACC* 2004; 43: 302-309

(4) Carminati et al. *J Interv Cardiol*, published online 8 Jun 2007; Vol14, Issue 3: 319-324

# Nickel Allergy



# Nickel Allergy

- 8-10% of woman and 1-2 % of men are sensitized to nickel
- Complications in patients with nickel allergy
  - higher incidence of paravalvular leaks after surgical valve replacement <sup>(1)</sup>,
  - higher incidence of coronary stent restenosis<sup>(2)</sup>
  - failure of nickel containing orthopedic and dental prosthesis <sup>(3,4)</sup>

(1) Lyell et al, Lancet 1978;2:657-659 (2) Koster R, Lancet 2000; 356: 1895-1897

(3) Counts AL et al.J Orofac Orthop 2002;63:509-515

(4) Gawkrödger DJ. Br J Dermatol 2003; 148: 1089-1093



## Patients with nickel allergy had more migraine and chest discomfort after ASD closure

Table 1. Incidence of Post-Procedural Complications as a Function of the Presence or Absence of Nickel Allergy

	Nickel Test + n = 10 (%)	Nickel Test - n = 27 (%)	p Value
Chest discomfort, palpitations, or MHA/aura	9 (90)	13 (48)	0.028
Chest discomfort or MHA/aura	6 (60)	3 (11)	0.005
New or worsening MHA/aura	4 (40)	2 (7)	0.035
Palpitations	5 (50)	11 (41)	0.7
Chest discomfort	3 (30)	2 (7)	0.1

MHA = migraine headache with or without aura.

New onset or increased frequency and severity of migraine headache after ASD closure was associated with nickel hypersensitivity and large devices

# Endocarditis

- Extremely rare (few case reports!)
  - Avoid implantation within 1 mo after active infection/sepsis

*Sharafuddin et al. Circulation 1997; 95:2162-2168, Bullock et al. 1999; 9: 65-67  
Mitchell et al. 2007; Eur J Echocardiography; 8: 48-49*

Amazing!

Despite all these  
complications

We are still much better  
than surgery