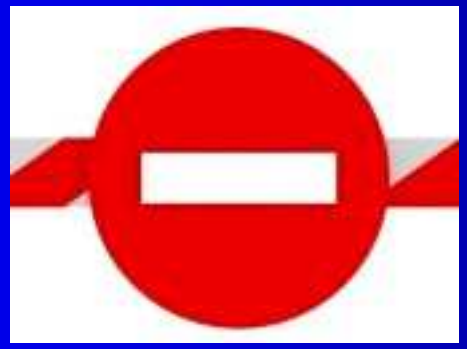
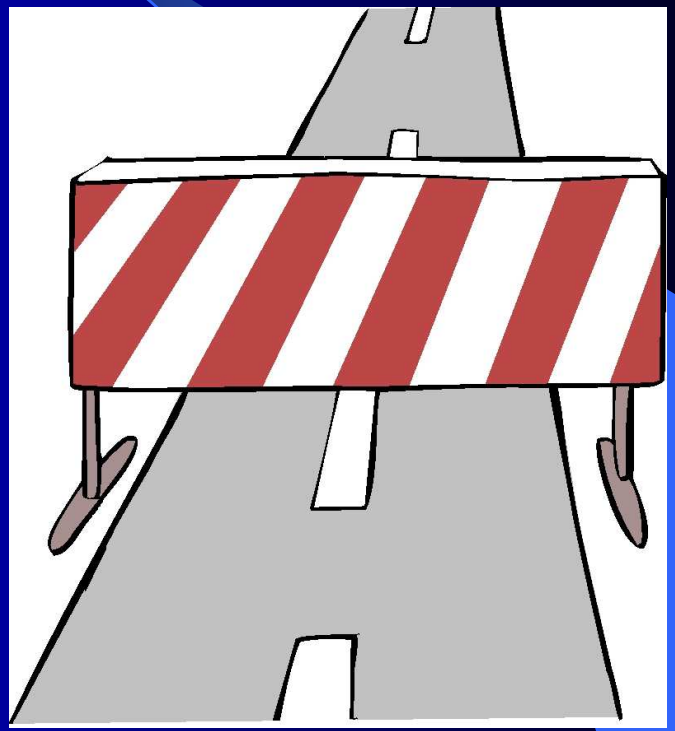
Martedì 21 Ottobre 2014

DALL'ICTUS CRIPTOGENETICO ALLA CHIUSURA PERCUTANEA DEL FORAME OVALE PERVIO

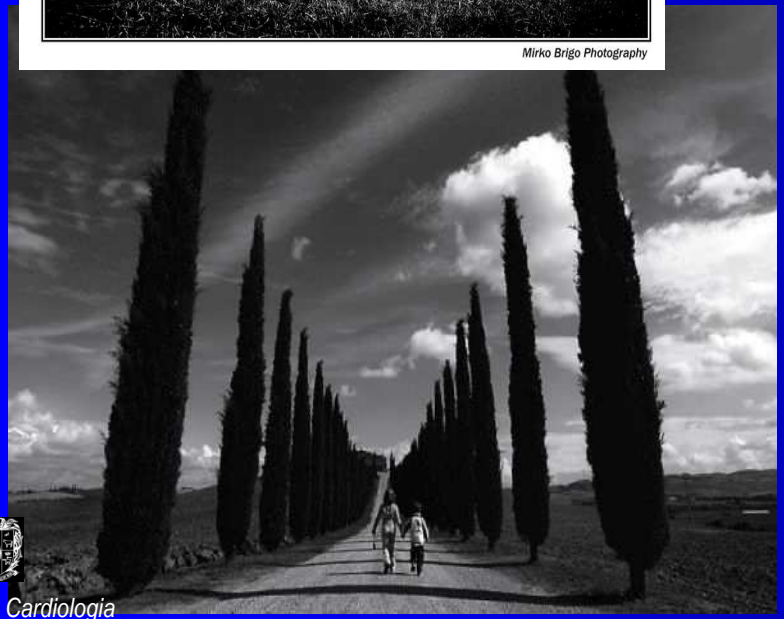
PFO Closure for Cryptogenic Stroke

Le Barriere

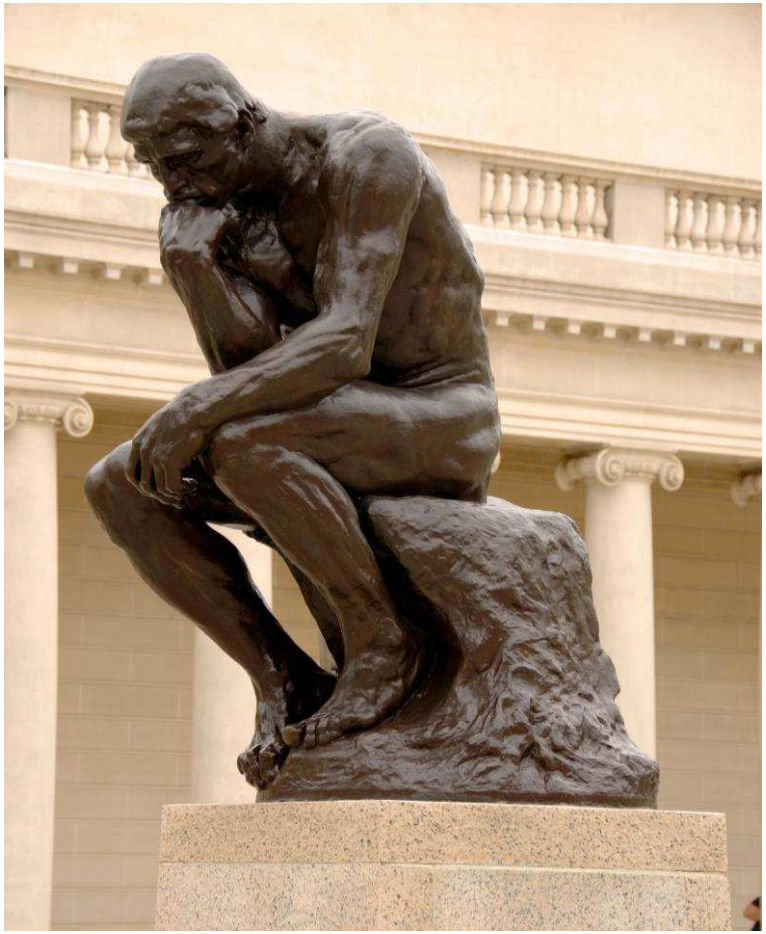


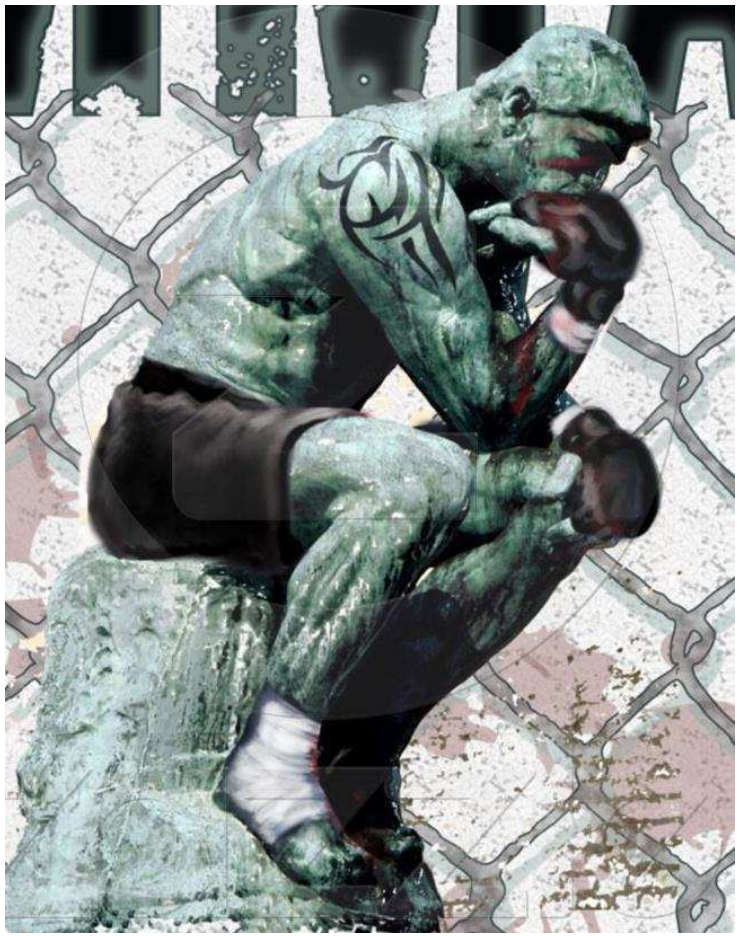


Le Barriere

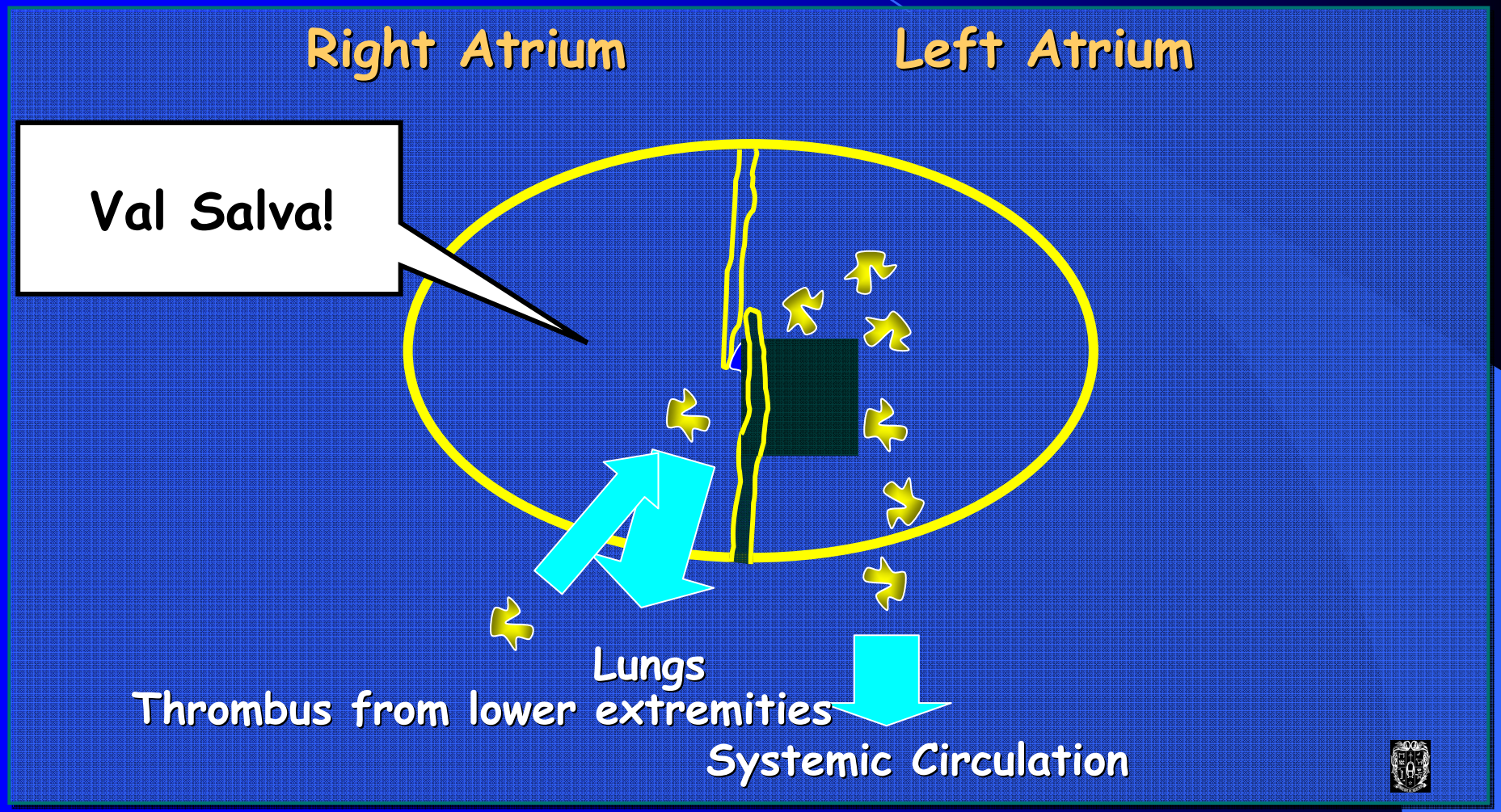


Neurologists

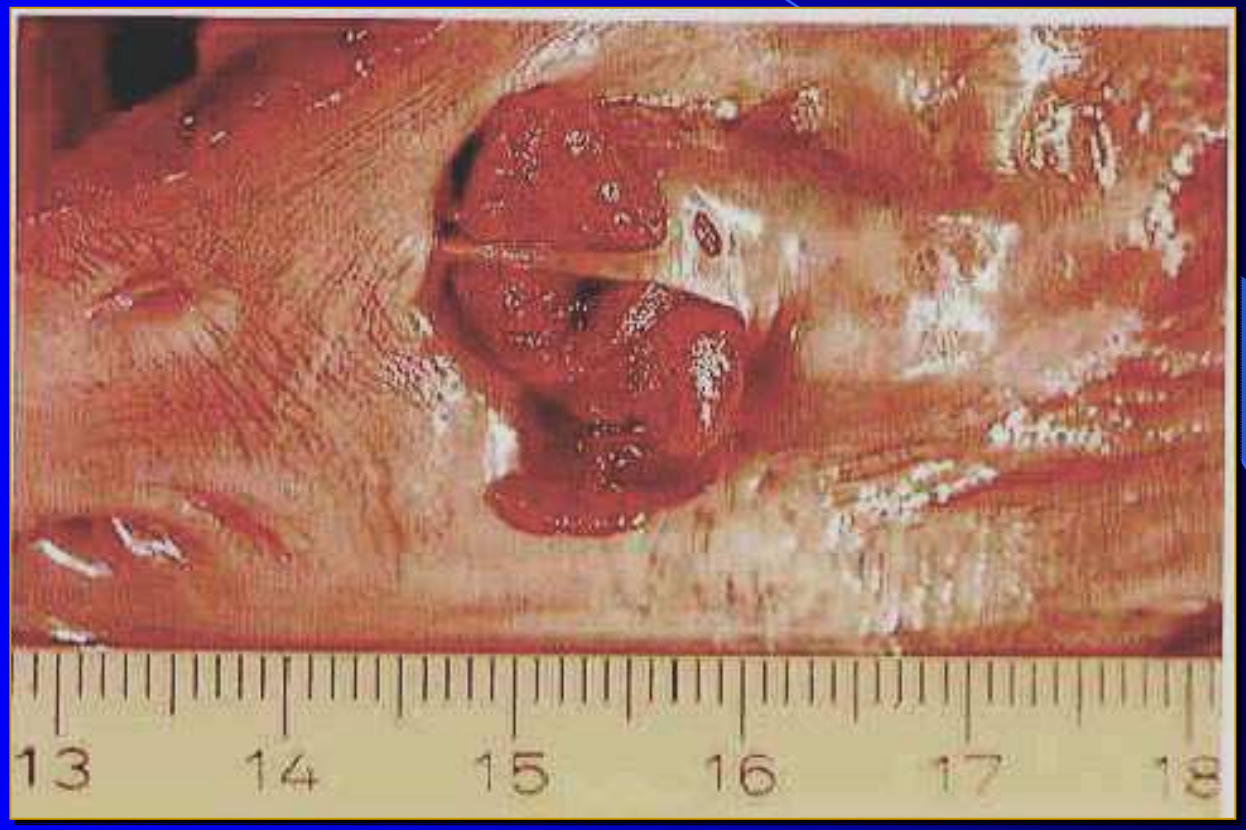




Proposed Mechanism of Paradoxical Embolization 1



Proposed Mechanism of Paradoxical Embolization 2

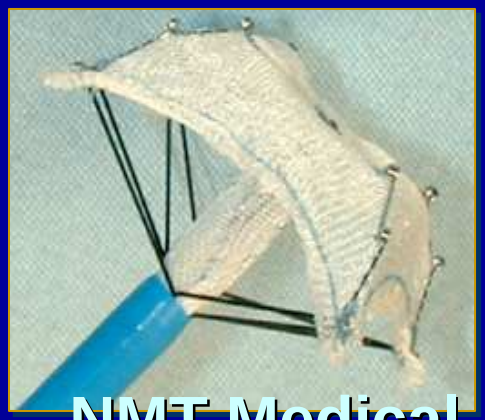


Surgical specimen with thrombus "wedged" in PFO.

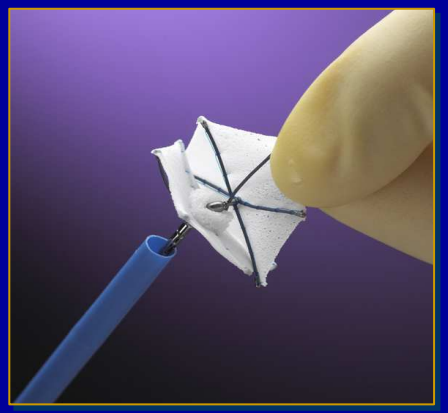
Transcatheter Closure of PFO

Double Occluder Devices in Clinical Use

Amplatzer



NMT Medical



Cardia

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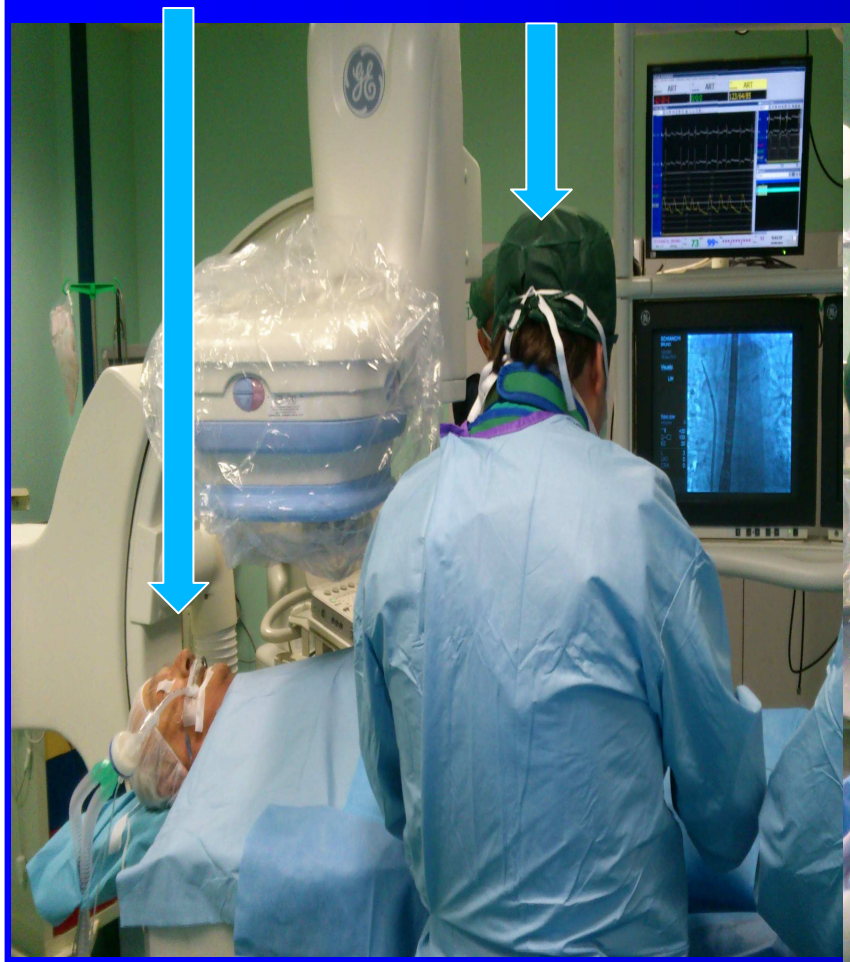
Preparazione dell’occlusore settale

Cath-lab staff

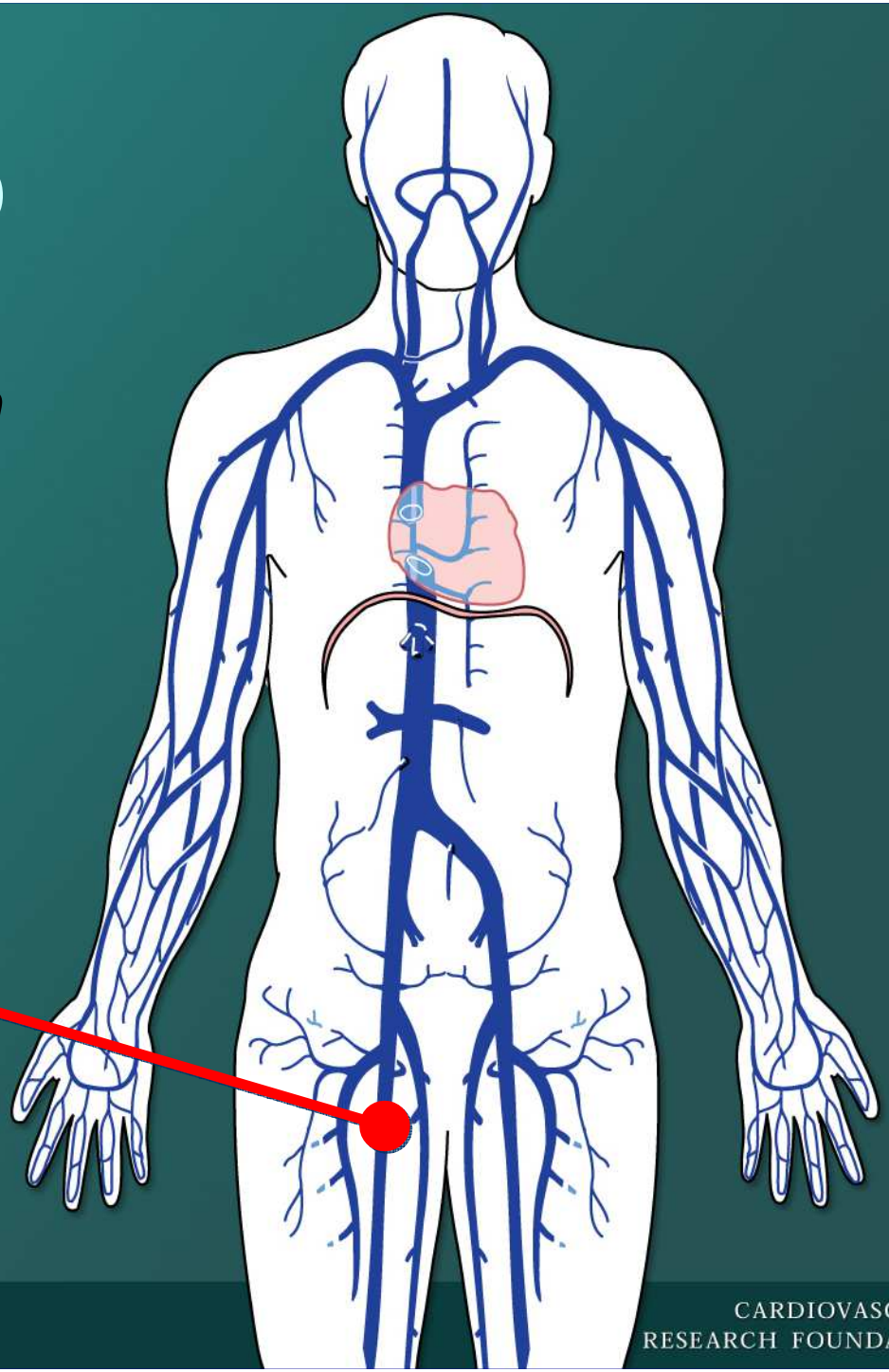


Transcatheter Closure of PFO

Generalized

Current Approach

Site of catheter entry into femoral vein

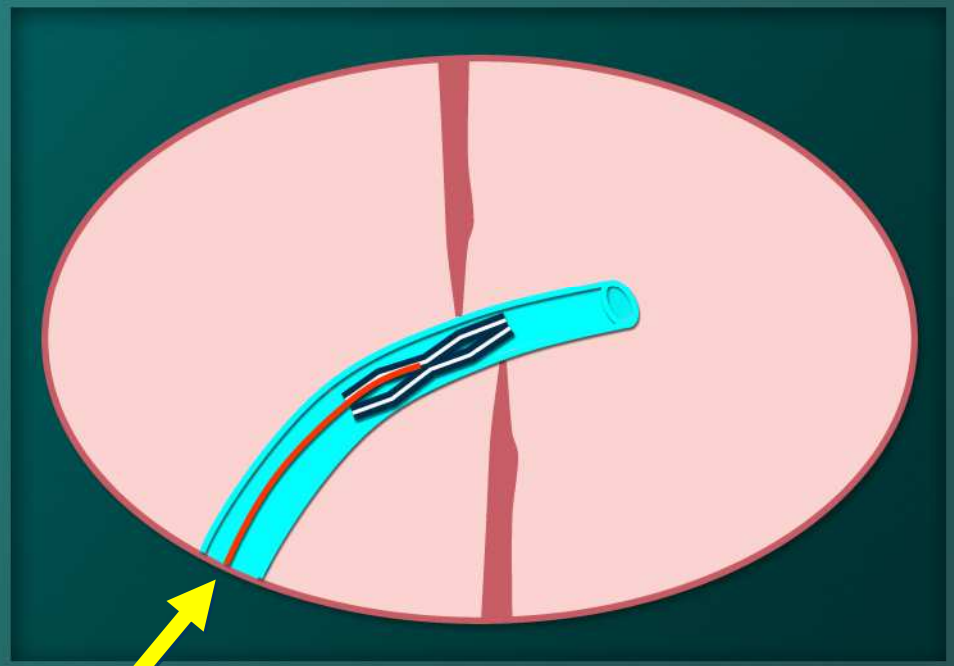


CARDIOVASCULAR RESEARCH FOUNDATION

Transcatheter Closure of PFO

Generalized Current Approach

Right Atrium

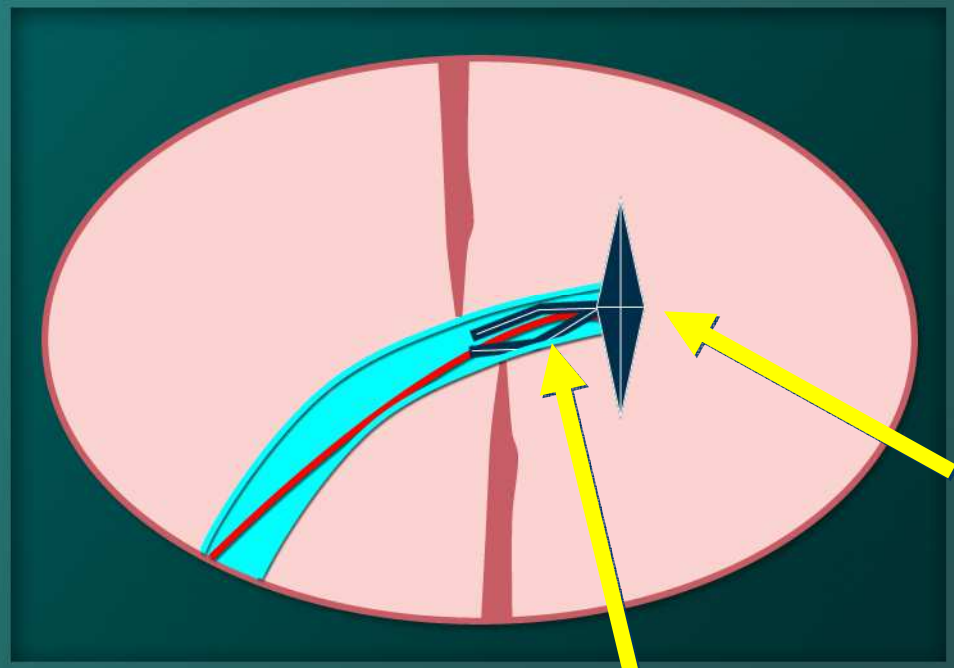


Left Atrium

Catheter delivered from the IVC

Transcatheter Closure of PFO

Generalized Current Approach



Right Atrium

Left Atrium

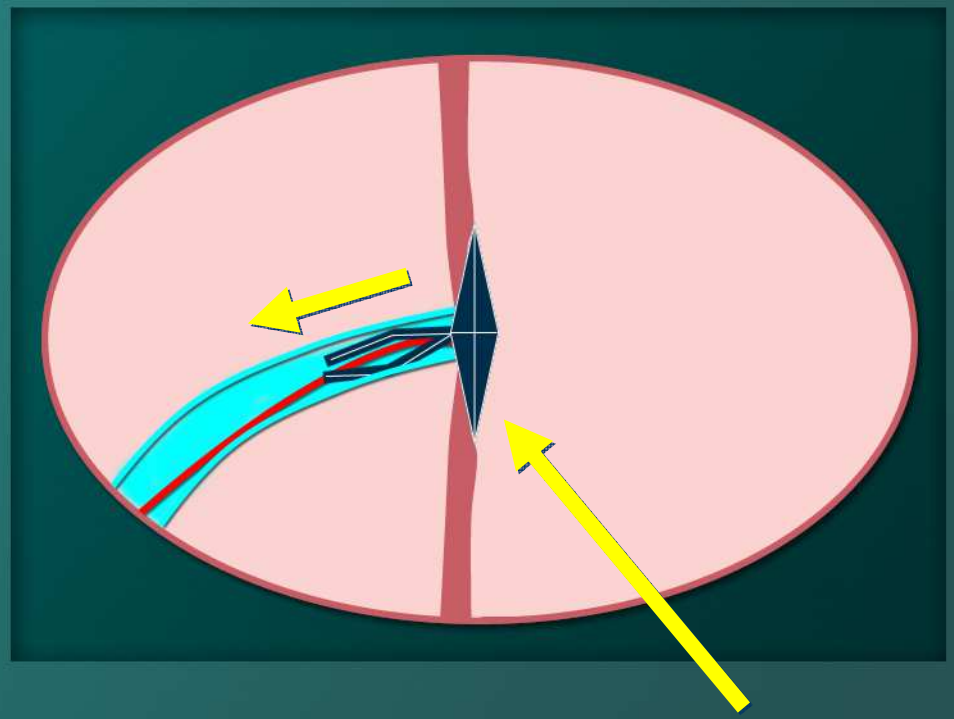
Left-sided occluder opened in LA.

Right-sided occluder remains folded within delivery catheter.

Transcatheter Closure of PFO

Generalized Current Approach

Right Atrium



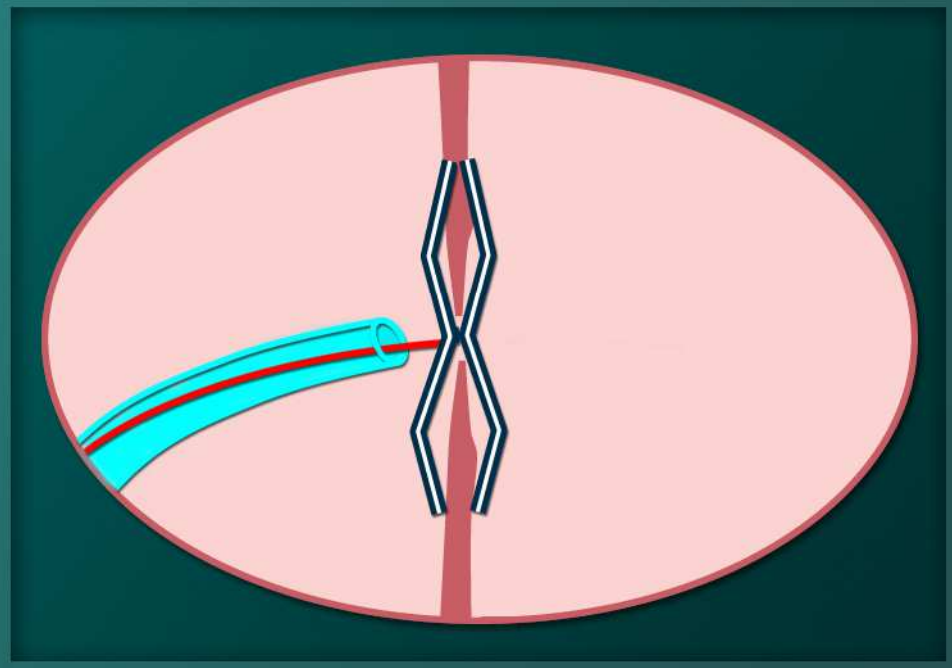
Left Atrium

Left-sided occluder pulled back against flap of PFO, sealing it.

Transcatheter Closure of PFO

Generalized Current Approach

Right Atrium



Left Atrium

Right-sided occluder opened,
fixing device position.
Device released.

Transcatheter Closure of PFO

Amplatzer PFO Occluder: AGA Medical

- Device Advantages:
  - Simple delivery/release
  - Easy retrieval before final release
  - Reusable device after retrieval
  - Conforms anatomy to device

Transcatheter Closure of PFO

Procedural Risks

- Serious complications ~1/500 cases, few are life-threatening, but may include:
  - Thromboembolism
  - Air embolism
  - Device embolization
  - Cardiac perforation

Transcatheter Closure of PFO

Late Risks

- Late Arrhythmia:
  - Transient PAC's: probably 50%
  - Paroxysmal Atrial Fibrillation: probably 3-8%
- Device Thrombosis:
  - Risk unknown / device specific, probably < 2%
  - Many pts asymptomatic: echo finding only
- Device Erosion:
  - Risk unknown, device/anatomy specific
  - JACC (2005) 45(8):1213-8

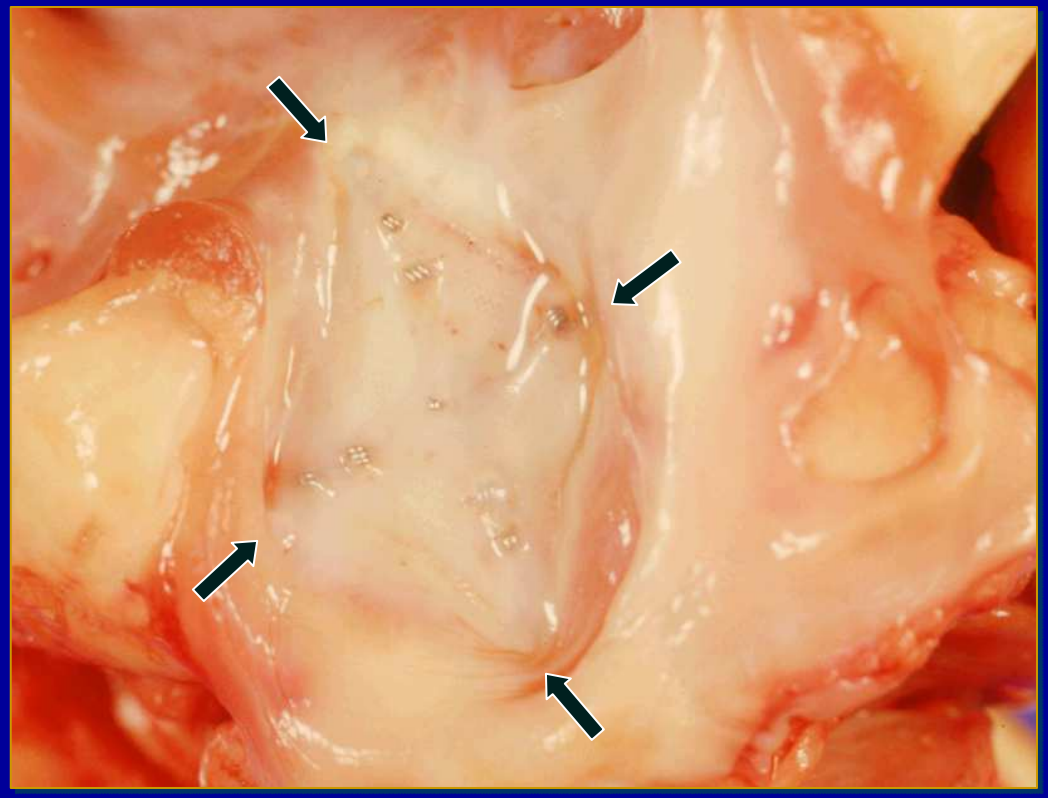
Transcatheter Closure of PFO

Potential Procedural Benefits

- The “Good News”:
  - 30-60 minute procedure
  - Less pain than surgery, no scar
  - No long term anti-coagulation
  - Return to full activity in 5 days

Transcatheter Closure of PFO

Device Endothelialization: CardioSEAL



Device thoroughly endothelialized by 6 months

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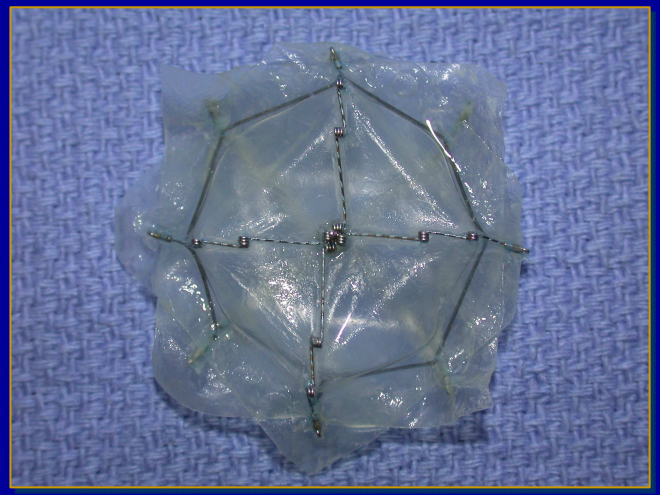
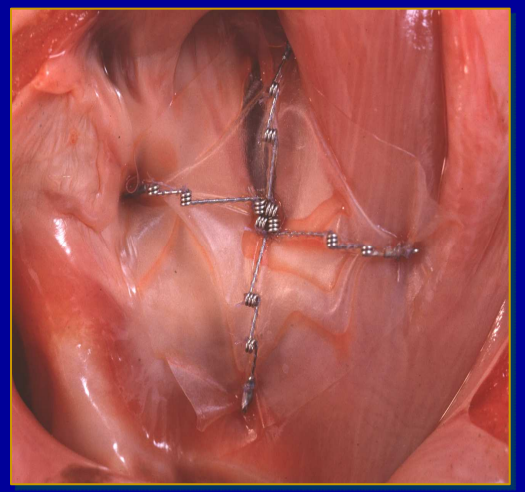
BioSTAR™: NMT Medical

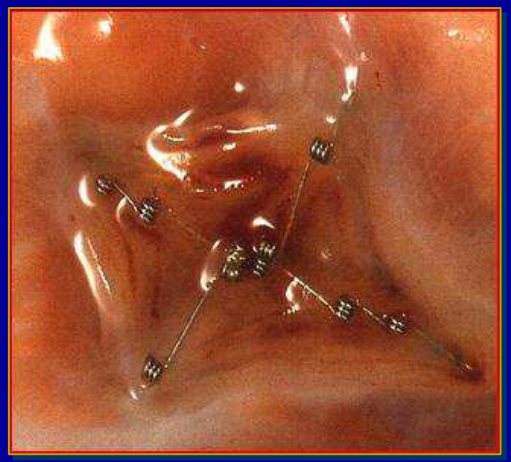
BioSTAR

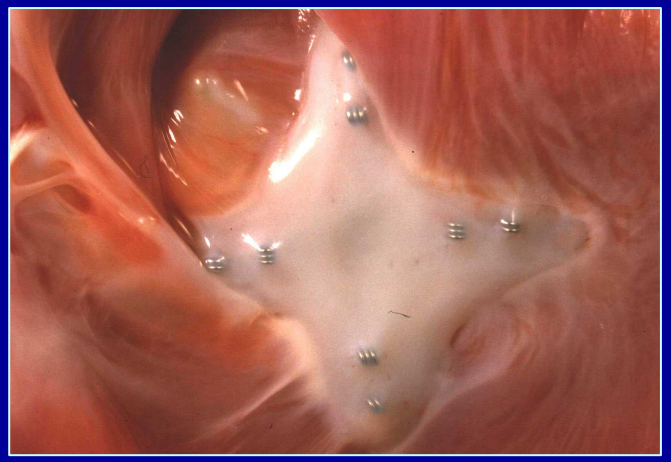




At implant

30 days post implant





90 days post implant

Photos provided by: Dr. Christian Jux, University of Goettingen/Germany and Dr. Peter Wohlsein, Institute of Pathology, School of Veterinary Medicine Hannover, Hannover/Germany

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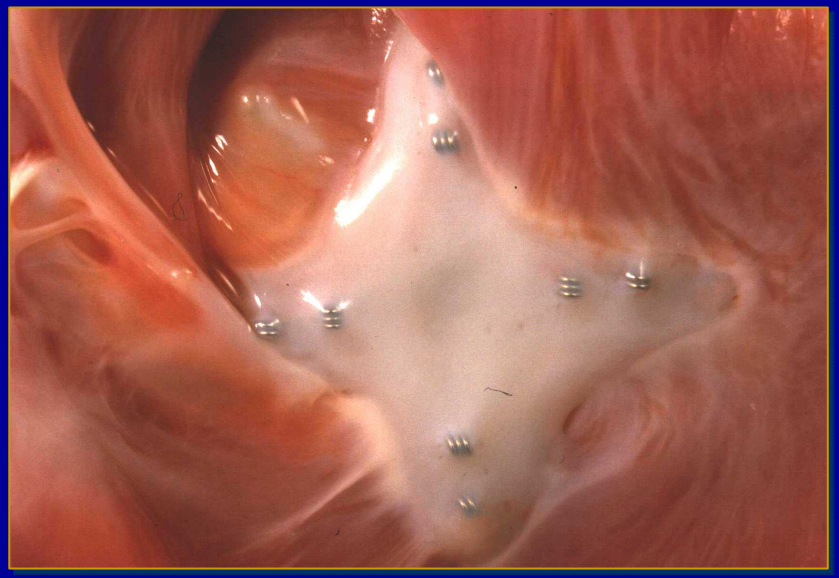
BioSTAR™: NMT Medical

180 Day Results

STARFlex®



BioSTAR™

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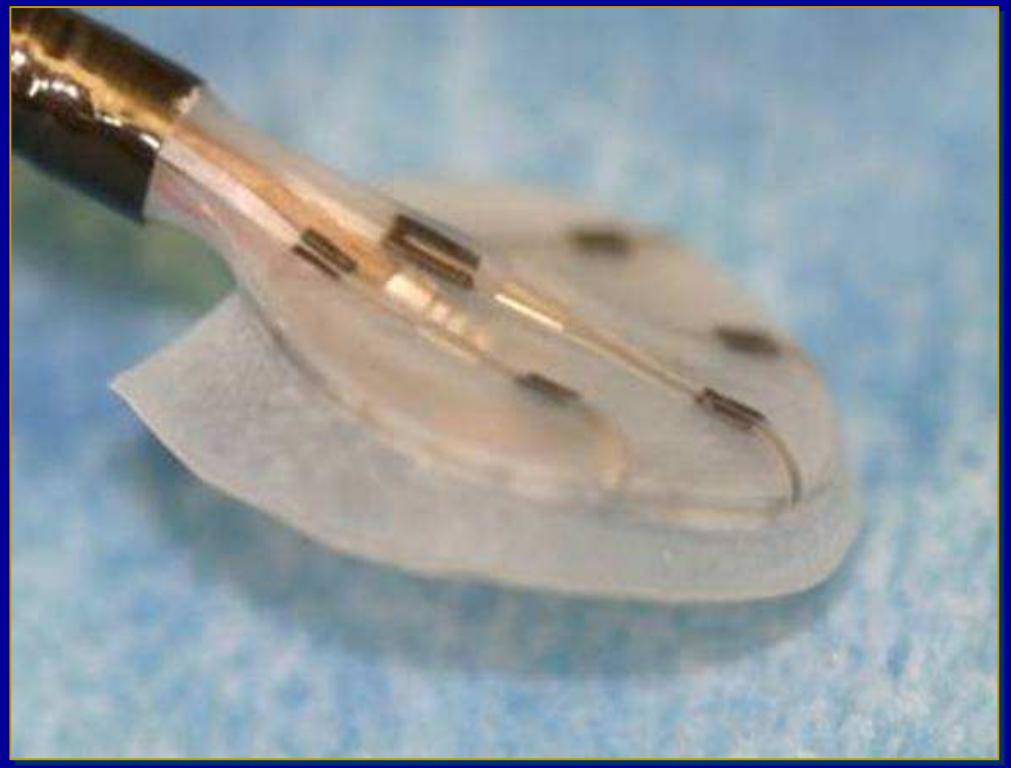
PFX System: Cierra

Radiofrequency Energy Application



Cierra

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The Future of PFO Closure

- The PFO should be viewed not as a hole in the traditional sense of a congenital defect, but as an “enabler” which allows systemic venous blood to bypass the filtration system of the lungs

The Future of PFO Closure

- The clinical manifestations of the failure to filter the blood are largely unknown
- New indications may arise in the next few years, but need to be based on definitive investigative studies

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The Future of PFO Closure

- Within a decade, a variety of catheter techniques will be available such that each may be best applied to specific anatomic variants
- Within a decade, closure procedures for PFO may be second in frequency only to coronary intervention in the cath lab

1

RISCHIO DI MALATTIA DA DECOMPRESSIONE

Riguarda i soggetti, anche asintomatici, che essendo portatori di PFO, corrono rischi embolici per il particolare tipo di lavoro o per l'attività sportiva svolta:

ad esempio soggetti dediti all'immersione subacquea, lavoratori in tunnel con aria compressa, piloti delle grandi altezze, astronauti.

Per questi soggetti può essere indicata la chiusura del PFO sia su richiesta personale , sia per precedenti embolici comprovati

2 SINDROME PLATIPNEA - ORTODEOXIA (SPO):

Si tratta di una desaturazione arteriosa, associata a dispnea, che si produce nel passaggio dal clinostatismo all' ortostatismo.

La SPO sembra essere associata soprattutto alla pneumonectomia , all'aneurisma dell'aorta ascendente, all'obesità ed all'accorciamento della colonna vertebrale.

La presenza di un forame ovale pervio consentirebbe il prodursi di uno shunt Dx-Sin : questo si accentuerebbe in ortostatismo a causa di un disassamento del setto interatriale, comportando la desaturazione.

In una ricerca multicentrica francese su 78 pazienti (P.Guérin) la correzione percutanea del PFO ha ridotto la desaturazione dal 98.3% al 24.2% dei soggetti.

Il rischio del PFO nella fase peri-operatoria di un qualunque intervento chirurgico, non è stata studiata sistematicamente ;

tuttavia è possibile che emboli di varia natura (grasso, aria, coaguli venosi) possano attraversare un forame ovale pervio dando embolia paradossa durante condizioni non fisiologiche di variazioni della pressione intratoracica:

ventilazione assistita,

chirurgia a torace aperto,

stiramenti dei tessuti mediastinici,

chirurgia della fossa cranica posteriore

Valutazione preliminare del problema nei pazienti chirurgici a rischio ?

Ogni causa di significativo aumento di pressione nelle camere cardiache destre può , in presenza di PFO, favorire shunt Dx-Sin , con possibilità di desaturazione ed embolia paradossa :

-Stenosi valvolare polmonare

-Malattia di Ebstein

-Infarto del ventricolo destro

-Malattie polmonari croniche (ostruttive o restrittive)

-Embolia polmonare (acuta o cronica)

-Ipertensione polmonare (primitiva o secondaria).

Scelta terapeutica da caso a caso …

Study Design

161 consecutive pts, since October 2001, pre-treated with Aspirin 100 mg, with signed informed consent

↓

Percutaneous approach by puncture of femoral vein
Peri-procedural heparin with target ACT bet 250 and 300''

↓

TTE post-procedure and at discharge
ASA 100 mg for 1 year and thienopyridines for 3-4 months

↓

1 year Follow up:
- office visit
- Transcranic Eco-Doppler
- TTE or TEE

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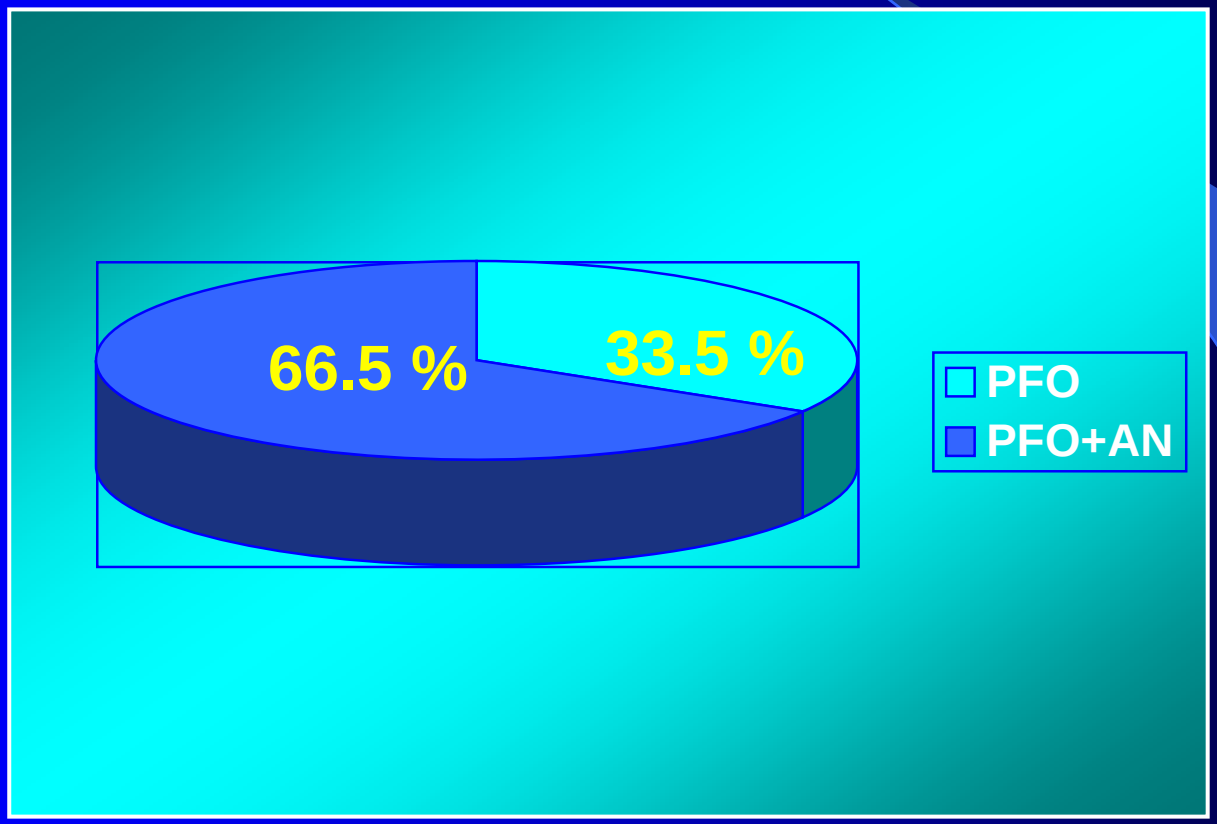
Study Population
Procedure Clinical Indications

	n = 161	%
Indication		
- Stroke	58	36,0
- TIA	95	59,0
- Other	8	4,9

Study Population
Clinical characteristics

	n = 161	%
Age (Mean+/-SD)	49,2+/- 12,9	
Males	84	51,6
Hypertension	61	37,9
Smoke	46	28,6
Diabetes	6	3,7

Study Population
Type of defect



Study Population

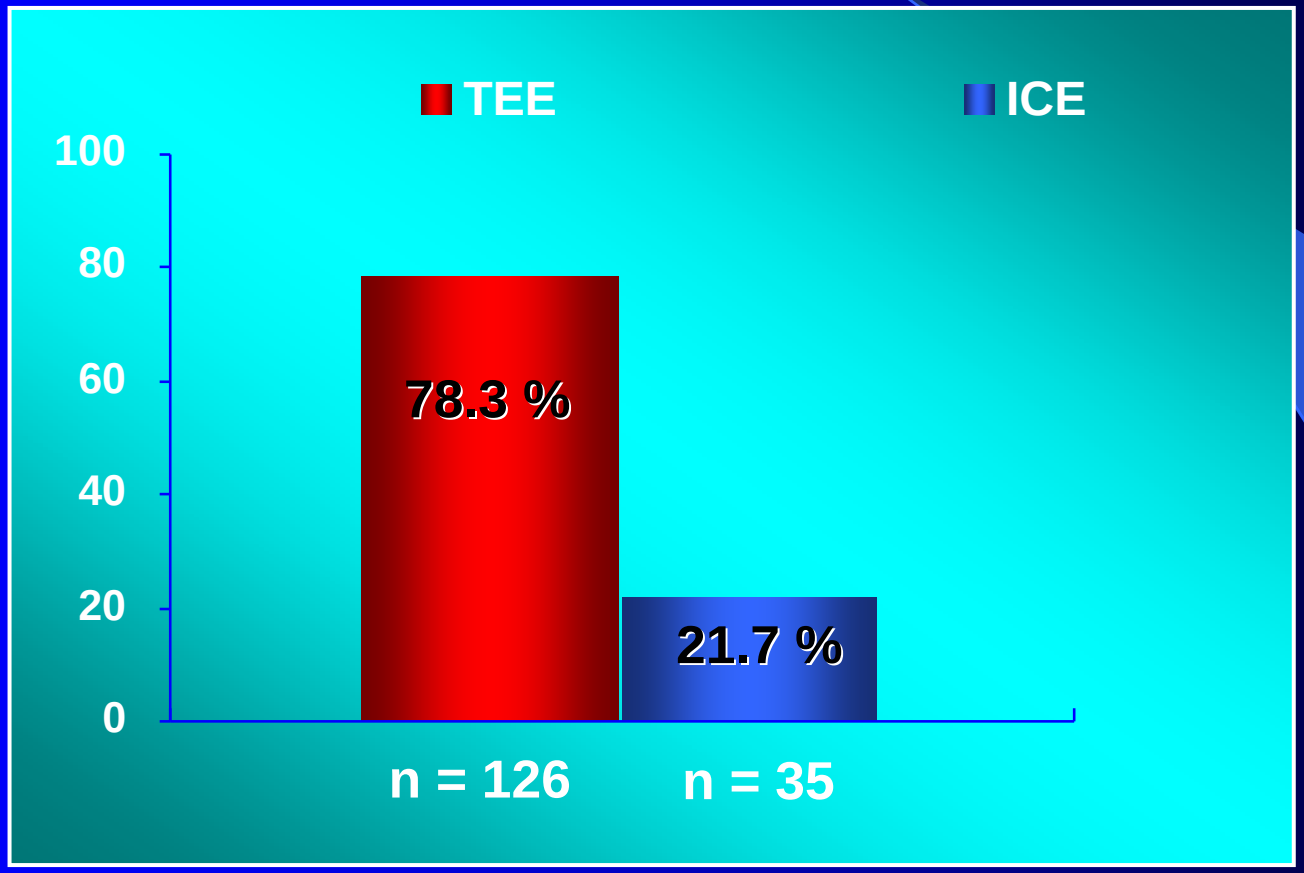
Risk factors distribution between the 2 groups

	Amplatzer (n=127)	Cardia (n=30)	P
Diabetes	5 (6%)	1 (3%)	NS
Hypertension	48 (38%)	13 (43%)	NS
Smoke	41 (32%)	6 (20%)	NS
Type of defect:			
- PFO	79 (62%)	24 (80%)	NS
- PFO + AN	48 (38%)	6 (20%)	NS

Procedural Characteristics
Type of device

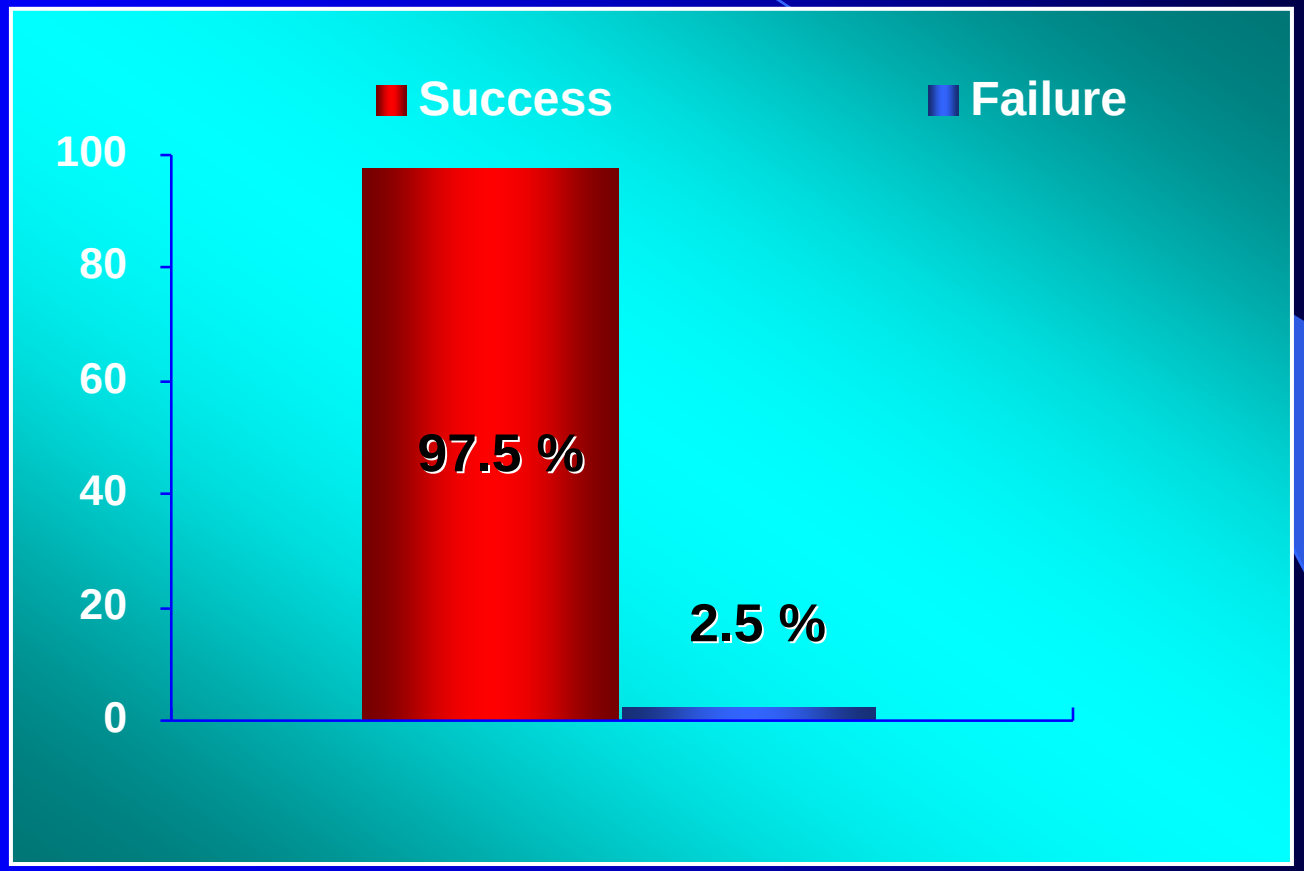
Type of device	N	%
CARDIA 20	5	3,1
CARDIA 25	20	12,4
CARDIA 30	4	2,5
CARDIA Atriasept 2	1	,6
PFO 18	12	6,8
PFO 25	74	46,0
PFO 25 Cribriform	1	,6
PFO 25 Cribriform	27	16,8
PFO 30	3	1,9
PFO 35	6	3,7
PFO 35 Cribriform	4	2,5
Failed	4	1,9

Procedural characteristics
Ultrasound guidance



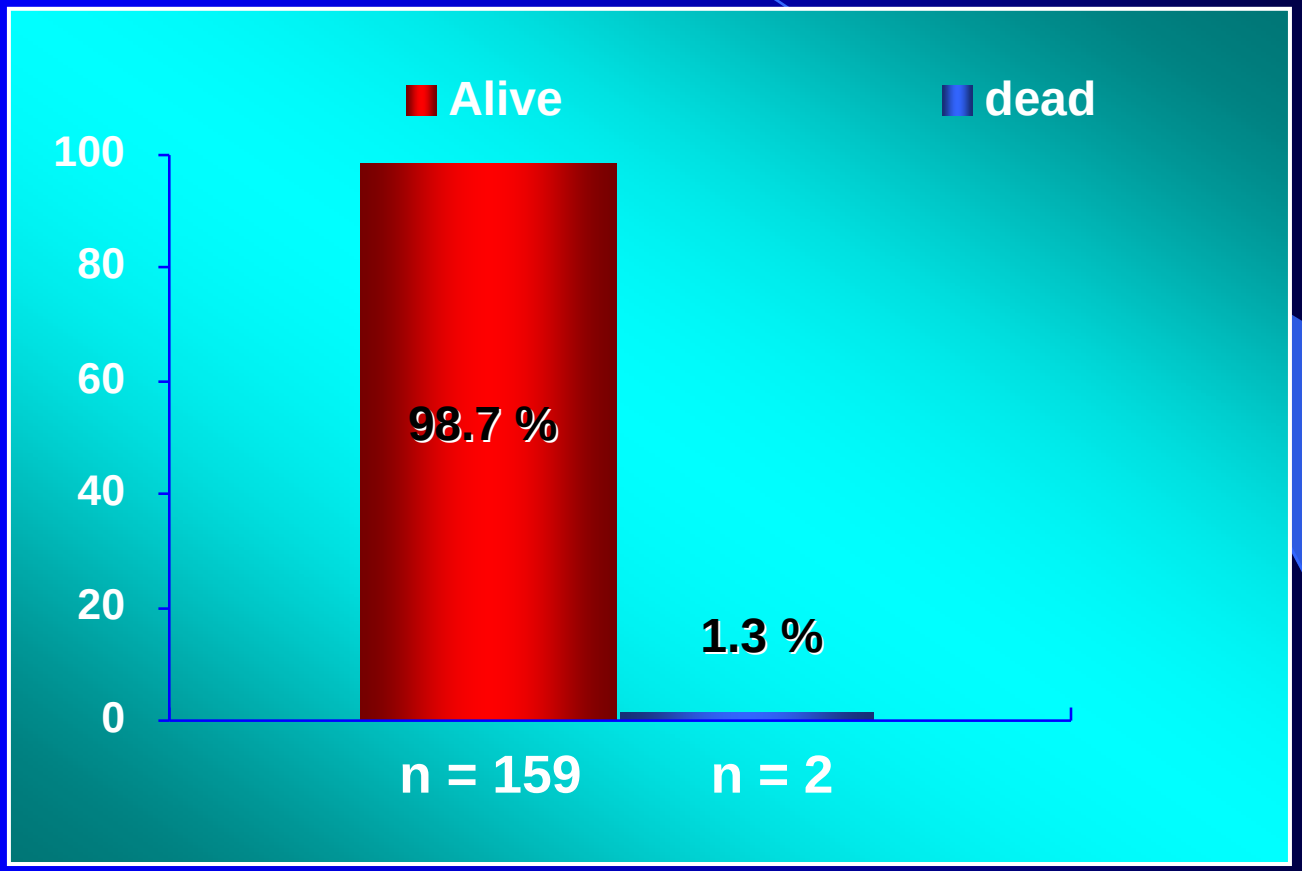
Results

Procedural success



2.48% (4 pts) of peri-procedural complications

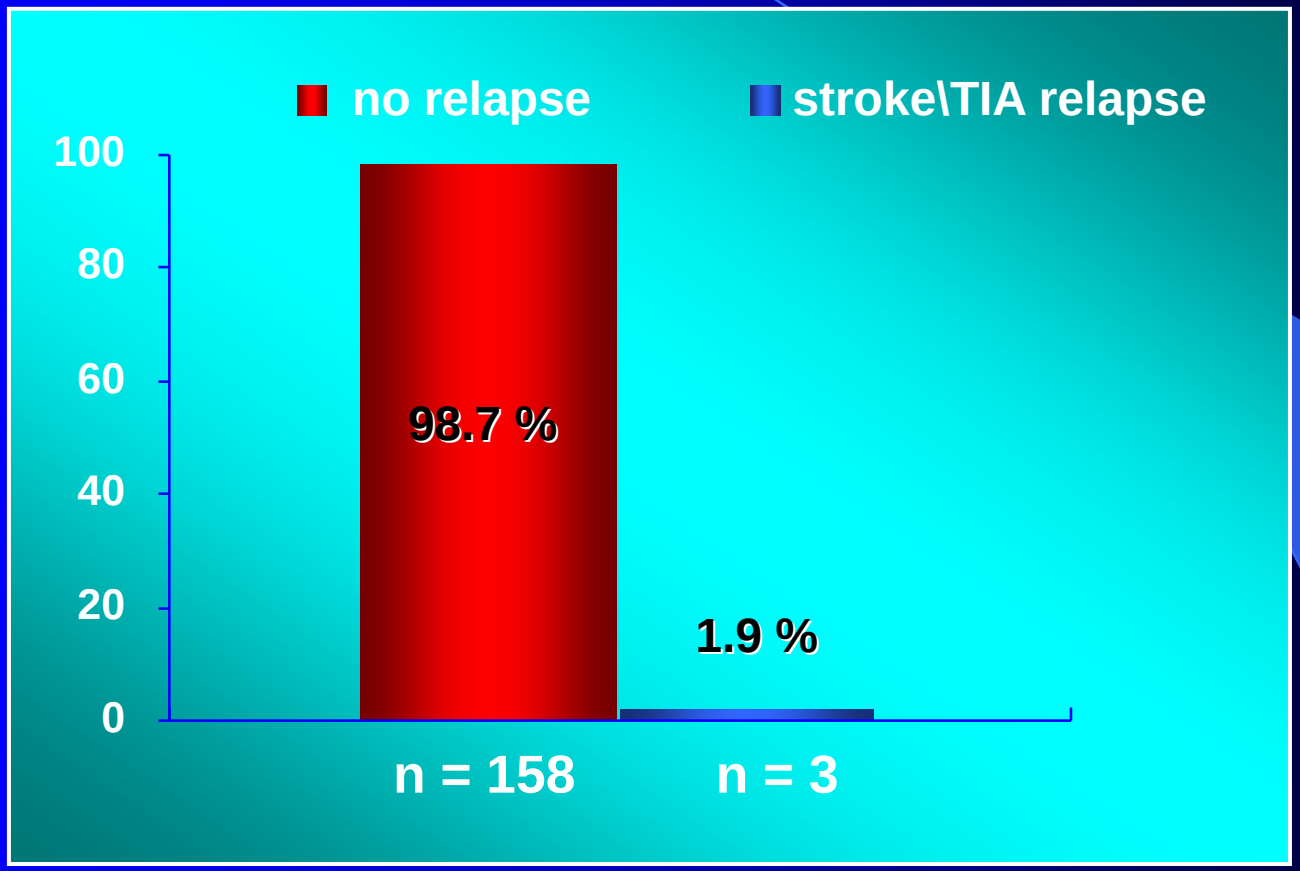
Results
1 year clinical follow up



Completed in 100% of study population at median 42 ± 18 months from index procedure

1-year TTE evaluation in 44% of pts with evidence of optimal closure

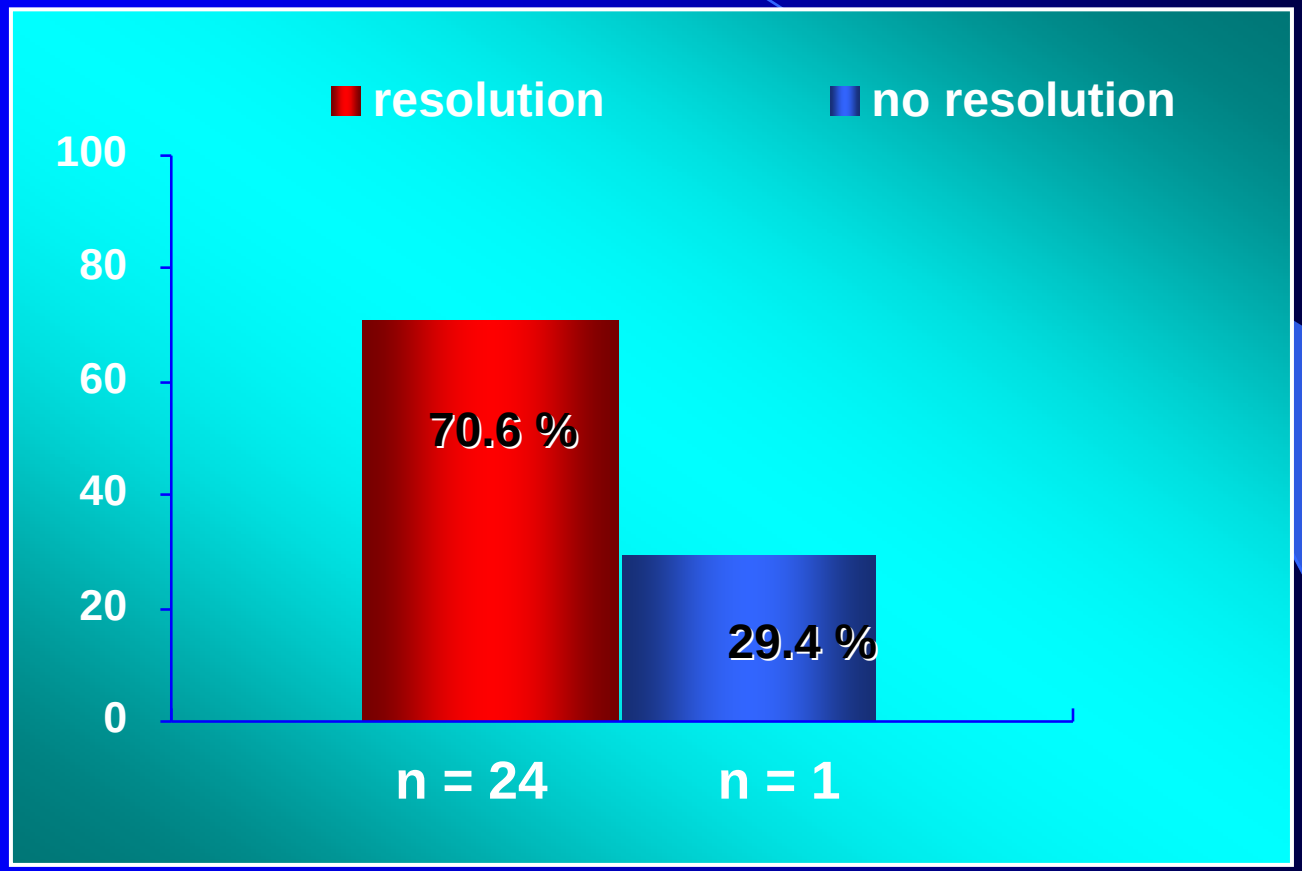
Results
1 year clinical follow up



- At 5 months, 2 and 4 years from index procedure
- Optimal closure with no residual shunt at TTE 1-year evaluation

Results

Migraine resolution in 25 out of 34 pts evaluated



Conclusions

- In our experience percutaneous closure of PFO is safe with 97% of procedural success, 2.4% of peri-procedural complications, 1.9% of overall mortality at 1 year follow up
- 2% of cerebrovascular ischemic events occurred at 1 year follow up, without evidence of residual shunt at TTE control
- Migraine resolution was evident in 70% of the pts evaluated
- The real efficacy of the procedure in the prevention of relapsing neurological events and in migraine resolution is controversial, and deserves further evaluation possibly with adequated sized randomized controlled trials

Casistica Parma Febbraio2014

- **PFO**
- 239 procedure: 5 fallite (3.29%)
- 234 a buon fine (96.71%)
- 234 pazienti soggetti a f.up - 2 decessi extra PFO (3, 12) - 2 persi al f.u.

FLOW CHART DIAGNOSTICO-TERAPEUTICA

- Età ≤ 55 anni
- TIA/ICTUS criptogenetico, infarto emicranico, embolia sistemica criptogenetica

I LIVELLO DIAGNOSTICO

(Ecocardiografia TT/TE con contrasto positivo per shunt dx/sn)
Doppler Transcranico

- **10 BOLLE**
- **> 10 BOLLE**

II LIVELLO DIAGNOSTICO

Ecocardiografia Trans Esofagea (ETE)

Se primo evento ischemico senza fattori di rischio anatomo/clinici

Se primo evento ischemico con uno o piu' fattori di rischio anatomo/clinici

Se recidiva è indicato un work-up completo eziologico da un neurologo preferibilmente con competenze vascolari, comprensivo di studio delle arterie intracraniche ed esclusione di cause cardioemboliche di maggior peso (es. FA parossistica)

Se in corso di terapia antiaggregante

Se in corso di terapia anticoagulante ben condotta (INR 2-3)

TRATTAMENTO

Terapia medica antiaggregante

Chiusura transcatetere FOP proponibile come alternativa a terapia medica

Chiusura transcatetere FOP indicata come alternativa a terapia medica