Percutaneous interventions for patent foramen ovale

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Patent foramen ovale:

- Prevalence of 25% (19-36%).
- Remnant of fetal circulation.
- Mischievous potential.
- Dynamic anatomic structure. (Valsalva)
Atrial septal aneurysm: (ASA)

Prevalence ± 1%.

Prevalence on TEE:
1.9%: excursion > 10mm
0.22%: excursion > 15mm
1. Migraine.
2. TIA – cryptogenic stroke.
3. Orthodeoxia- platypnea syndrome.
4. Decompression sickness in divers.
Scope of the problem - mechanism

1. Chemical mediators?
2. Paradoxal venous embolism.
3. Increased right – left shunting of venous blood.

-> Taking advantage of the PFO
### Scope of the problem - epidemiology

**Overell JR. Neurology 2000;55:1172-9**

<table>
<thead>
<tr>
<th>Study</th>
<th>Cryptogenic n/N</th>
<th>Known cause n/N</th>
<th>OR (95%CI Fixed)</th>
<th>Weight %</th>
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Total(95%CI)

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Chi-square 9.70 (df=8) P: 0.29

#### A

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Chi-square 5.56 (df=2) P: 0.06

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PFO prevalence 40-70% amongst cryptogenic stroke pts
5 fold higher PFO prevalence in young cryptogenic stroke pts
Rationale for intervention

The PFO – ASA trial : (n=581)

Risk of stroke recurrence at 4 yrs.

Mas JL et al. *NEJM* 2001;345:1740-6
Rationale for intervention

• Identified high risk clinical & morphological features for recurrence:

  Hypercoagulable state.
  Previous stroke.
  (Stroke following Valsalva).

  PFO & ASA.
  Spontaneous bubbles passage at rest.
  Long PFO tunnel.
  Eustachian valve vs. PFO.
  > 20 bubbles with large PFO on Valsalva.
How to build up a PFO program

• Be convinced & interested.
• Ask a good friend to perform the imaging.
• Be sure your diagnosis is accurate.
• Build up a multi-disciplinary approach with the neurologist.
  => treat the real cryptogenic stroke.
• Go for training…& start (find pts).
Diagnosis : echocardiography

• Essential :
  Diagnosis & screening.
  Guide during intervention.
  Confirm procedural success during FU.

• Trained, devoted, motivated echographist is a prerequisite for success.

• & an echo-minded interventionalist…
Diagnosis: echocardiography

- Diagnostic steps:
  - Morphology.
  - Functional assessment.
  - Provocative measures.

- Transthoracic:
  - First step. Dynamic screening.

- Transoesophageal:
  - Septal mobility & fine morphology.
Diagnosis: echocardiography

Baseline TTE
Diagnosis: echocardiography

TEE: ASA quantification
Diagnosis: echocardiography

TEE: dynamic measures on Septum 1
Diagnosis: echocardiography

TEE: Eustachian valve
Diagnosis: echocardiography

TEE: dynamic testing
Percutaneous closure

- As many techniques as operators:
  Conscious pt.
  Sedated pt.
  Sleeping pt.

- Primary outcome measures:
  Immediate technical success.
  Complete PFO closure at FU.
  Low or absent neurological recurrence rate.
Percutaneous closure

- Our approach (keep it simple):
  - Awake patient.
  - No contrast.
  - No pressure measurements.
  - No balloon sizing.
  - Principally one device type.
  - Same team...
  - Intracardiac echo guidance.
  - Anatomical screening.
  - Device selection.
Percutaneous closure

A closure device
Percutaneous closure

The intervention:

Loading the device in the Mullins
Percutaneous closure

The intervention:

The Mullins catheter
Percutaneous closure

The intervention:

Deployment of the left side of the device
Percutaneous closure

The intervention:

ICE & fixed device
Percutaneous closure

The intervention:

$\Delta$ in the angle of the septum % sept II thinkness
Percutaneous closure

The intervention:

Δ in the angle of the septum % sept II thinkness
Percutaneous closure

The intervention:

Following deployment  Dynamic testing
Percutaneous closure

The intervention:

Left part of device  Inadequate deployment
Intracardiac echo

Improved image definition
Intracardiac echo

Improved image definition
Unusual case example
Results

- Principally excellent.
- Closure rates >80%.
- Complications: rare.
  - Thrombus: 2-3%.
    (adequate antiplatelet T).
  - Infection: ?
  - Device migration.
  - Perforation.
- Literature is a mixbag of indications, techniques & devices…
A few words of caution

• Meticulous diagnosis.
• Correct indication.
• Beware learning curve, be well trained.
• Teamwork.
• Don’t forget the follow-up.
• Most feared complications:
  Fistulae.
  Thrombus formation.
  Erosion.
• Very long-term not known.
Conclusions & future directions

• At least 2 randomized controlled trials ongoing in cryptogenic stroke.
• One RCT in migraine.
• Awaiting the results, a restrictive policy (high risk pts) is probably indicated.
• The procedure has to be patient-friendly and safe (approaching 0% risk).
• Personal prognosis: migraine may become the first indication in the future.