Percutaneous Closure of Interatrial Septal Defects: An Update

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Davenport, IA

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Learning Objectives

• Review Stroke Etiology and the Concept of Paradoxical Embolization

• Review Techniques in PFO/ASD Closure and Current Applications

• Review Outcome Data in PFO Closure to Prevent Stroke
Epidemiology of Strokes

- 750,000 strokes each year in the USA
- Mortality rate of stroke 27%
- 3rd cause of death after heart disease & cancer
- 4,400,000 stroke survivors in the USA
- Leading cause of morbidity and serious neurologic disease
Lausanne Registry

- Lausanne Stroke Registry - 1988
  - Prospective evaluation of stroke etiology in 891 patients with ischemic stroke
  - Large vessel atherosclerosis – 43%
    - Lacunar infarction – 15%
    - Cardioembolism – 20%
    - Others – 6%
  - CRYPTOGENIC – 8%
Sacco Registry

• Prospective Evaluation of Stroke Etiology in 1273 patients with ischemic stroke (1989)
  • Large vessel atherosclerosis – 9%
    • Lacunar infarct – 27%
    • Cardioembolism – 19%
    • Others – 5%
  • CRYPTOGENIC – 40%
### Association of PFO with Cryptogenic Stroke in Young Adults

<table>
<thead>
<tr>
<th></th>
<th>Patients (n)</th>
<th>Age</th>
<th>PFO (cryptogenic)</th>
<th>PFO (control)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lechat (1988)</td>
<td>26</td>
<td>&lt;55</td>
<td>54% (14/26)</td>
<td>10% (10/100)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Webster (1988)</td>
<td>34</td>
<td>&lt;55</td>
<td>50% (20/40)</td>
<td>15% (6/40)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>De Belder (1992)</td>
<td>39</td>
<td>&lt;55</td>
<td>13% (5/39)</td>
<td>3% (1/39)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Di Tullio (1992)</td>
<td>21</td>
<td>&lt;55</td>
<td>47% (10/21)</td>
<td>4% (1/24)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Hausmann (1992)</td>
<td>18</td>
<td>&lt;40</td>
<td>50% (9/18)</td>
<td>11% (2/18)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Cabanes (1993)</td>
<td>64</td>
<td>&lt;55</td>
<td>56% (36/64)</td>
<td>18% (9/50)</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>202</strong></td>
<td></td>
<td><strong>46% (93/202)</strong></td>
<td><strong>11% (29/271)</strong></td>
<td></td>
</tr>
</tbody>
</table>
PFO and Incidence of Stroke

- 750,000 ischemic strokes per year in the United States
- 10-40% of all strokes are presumed cryptogenic
- prevalence of PFO
  - 50% in patients with cryptogenic stroke

25,000 - 100,000 strokes per year attributable to PFO
Embryological Development of Atrial Septum

- Septum secundum
- Crista terminalis
- Ostium secundum
- Oval foramen
- Septum primum
PFO Anatomy

Direct visualization at autopsy of a PFO. Notice the overlapping nature between septum secundum and primum of the defect structure.

Patent Foramen Ovale

On Valsalva, $P_{RA} > P_{LA}$
Clot in the PFO

Clot in a PFO as seen at surgery

Picture taken from Colour Atlas of the CV System, Thomas et al.

Fig. 6.70 Paradoxical embolism. Embolus in the patent foramen ovale (viewed from the right atrium).
PFO Characteristics Favoring Paradoxical Embolism

- Size
  - Degree of Shunt
  - Atrial Septal Aneurysm
  - Chiari’s network
  - Eustachian Valve
Atrial Septal Defect
Medical Treatment

Traditional therapy is Coumadin

- Difficulty adjusting INR
- Change in life style: diet, travel
- Lifetime therapy
- Continued recurrences

Bleeding side effects can be catastrophic
**Stroke and TIA Recurrence in PFO patients (Medical treatment)**

<table>
<thead>
<tr>
<th>Study</th>
<th>Patients</th>
<th>F/U (mo)</th>
<th>Stroke/TIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mas (95)</td>
<td>132</td>
<td>22</td>
<td>3.4%/year</td>
</tr>
<tr>
<td>Lausanne (96)</td>
<td>140</td>
<td>36</td>
<td>3.8%/year</td>
</tr>
<tr>
<td>DeCastro (00)</td>
<td>86</td>
<td>36</td>
<td>5.5%/year</td>
</tr>
</tbody>
</table>
Homma et al: 28 patients, surgical closure; recurrence of 19.5% at 13 months f/u
Complications: 18%

Dearani et al: 91 patients surgical closure; recurrence 7.5% with mean f/u of 2 yrs
Complications: Afib in 11%; pericardial effusion 6.6%; postop bleed 3.3%
Indications for closure of Interatrial Septal Defects (FDA)

- Prevention of a RECURRENT stroke When conventional therapy fails (PFO closure with CardioSeal Occluder)
Indications for closure of Patent Foramen Ovale (Real World)

- Failure of Coumadin to prevent recurrent strokes
- Contraindication to taking coumadin
- Patient’s preference (Does not want coumadin)
- Not for PRIMARY prevention
ATRIAL SEPTAL DEFECT: Indications For Closure

- Symptoms
- Right ventricular volume overload.
- Qp/Qs ratio >1.5:1
- Arrhythmias.
- Cyanosis.
- Paradoxical Embolism.
Percutaneous Closure

Standard Rt. Heart cath procedure to evaluate right sided pressures and extent of shunt by oxygen saturation analysis
ICE guidance
Local anesthesia
Average time 1 hour
Home within 23 hours
ASA and plavix for 3 months then ASA indefinitely
Follow-up at 1 month, 6 months and 1 year with serial echocardiograms
Long term follow up can be performed with Primary care physician. Recommend an echo every 2 years
AccuNav Siemens ICE System
Characteristics of the AccuNav ICE

• 10 French catheter.
• 90cm insertable length.
• Four-way steering in two planes: anterior-posterior, left-right. 160° in each direction.
• Tension control knob for holding desired catheter curvature.
• Color Doppler for visualization of blood flow direction and velocity. Color Doppler imaging frequencies: 7.0MHz, 6.0MHz, 5.0MHz, 4.0MHz.
• Continuous Wave (CW) Doppler for quantification of flow. CW Doppler imaging frequency: 5.0MHz.
• Pulsed Wave (PW) Doppler for targeted blood flow interrogation. PW imaging frequencies: 5.0MHz, 4.0MHz.
Percutaneous Technique...Step one

Interatrial septum is crossed with a J-wire and using a Multipurpose catheter.
Percutaneous Technique...step two

Balloon sizing of the PFO or ASD
Percutaneous Technique…Step Three

Double Umbrella implant
Framework is MP35n
Fabric is Polyester
Significant clinical history
Amplatzer Septal Occluder

- Low profile, self expanding, double disc device with 4 mm connecting waist
- .0075” Nitinol wire mesh
- Polyester fibers within the mesh
- Size 4-40 mm
- Delivery sheath: 7-12 Fr
Amplatzer Septal Occluder TECHNIQUE

A

LA

RA

SVC

B

C

LA

AO

RA

D

E

F

Yellow arrows indicate the Amplatzer Septal Occluder position.
CardioSEAL at 90 days
PFO
Right-to-Left Shunt During Contrast Echocardiography

Before Device
n=152

- Grade 0: 78%
- Grade 1: 4%
- Grade 2: 18%

After Device (n=150)

- Grade 0: 78%
- Grade 1: 11%
- Grade 2: 7%
- Grade 3: 4%
Stroke and TIA Recurrence in PFO patients (Percutaneous treatment)

80 Patients w/ PFO or PFO with Atrial Septal Aneurysm

5 year follow-up following transcatheter closure

ASA only for up to 6 months.

Annual risk of recurrence:  

<table>
<thead>
<tr>
<th>Event</th>
<th>Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>TIA</td>
<td>2.5%</td>
</tr>
<tr>
<td>Stroke</td>
<td>0%</td>
</tr>
</tbody>
</table>

Meier, et al – Circulation Feb 2000
University of Chicago Experience

- Implantation successful in all 348 patients
  - 2\textsuperscript{nd} attempt during 2\textsuperscript{nd} procedure \( n=6 \)
  - Two devices implanted \( n=12 \)
- Procedure without general anesthesia: 312
- Procedure time: \( 44 \pm 23 \) min
- X-ray time: \( 7.9 \pm 5.9 \) min
- Length of hospital stay: \( 1.3 \pm 1.1 \) days
- Follow-up: 1-71 months \( 13 \pm 16 \) mo.
## University of Chicago Experience

<table>
<thead>
<tr>
<th>Residual Shunt</th>
<th>Immediate</th>
<th>24 hours</th>
<th>3 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade O</td>
<td>51.0%</td>
<td>63.8%</td>
<td>85.3%</td>
</tr>
<tr>
<td>Grade I</td>
<td>34.6%</td>
<td>25.5%</td>
<td>12.2%</td>
</tr>
<tr>
<td>Grade II</td>
<td>8.2%</td>
<td>6.4%</td>
<td>0%</td>
</tr>
<tr>
<td>Grade III</td>
<td>6.1%</td>
<td>4.2%</td>
<td>2.4%</td>
</tr>
</tbody>
</table>
University of Chicago experience

- No mortality
- No recurrent CVA or TIA
- One goin AV fistula repaired surgically, one femoral pseudoaneurysm, no Rx
- 2 patients with atrial fib., medical Rx
Recurrence Rate

- Percutaneous Closure: 3.1%
- Medical treatment: 4%
- Surgical treatment: appears higher recurrence. Main problem is associated substantial morbidity

- Randomized trials are still ongoing to compare Coumadin with percutaneous closure. Until then it is unclear how percutaneous closure compares to medical treatment.

- **Patent Foramen Ovale Is Indicted, but the Case Hasn’t Gone to Trial**