Left atrial appendage occlusion with the Amplatzer Amulet: a case report

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Disclosures: Consultant & Proctor – St. Jude Medical
First LAAO case in Greece

April 26th, 2013
First LAAO case in Greece

- 76 yo male
- Embolic stroke on dabigatran
- CHA$_2$DS$_2$-VASc score 7
- Annual risk for stroke 21.5%
- Unable to take warfarin due to labile INR
- Indication put by neurologist
- Neuro-Heart Team
Case report

LA
AV
LUPV
ostium
Cx
"neck"
LAAO - angiography
LAAO – Lobe deployment
LAAO – Disk deployment
LAAO – angiography testing
LAAO – device release
LAAO – final result
Case report

![Image of medical imaging with annotations]
Multicenter Experience with the Amplatzer Cardiac Plug (ACP)

- To investigate the safety, feasibility, and efficacy of LAAO with the ACP for stroke prevention in patients with AF
- Prospectively collected, retrospectively analyzed nonrandomized, multicenter study
- Real-life experience of 20 European & Canadian centers

<table>
<thead>
<tr>
<th>Participating investigators</th>
<th>(Location)</th>
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<tbody>
<tr>
<td>1. Meier</td>
<td>(Bern, CH)</td>
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<tr>
<td>2. Park</td>
<td>(Hamburg, GE)</td>
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<tr>
<td>3. Sievert</td>
<td>(Frankfurt, GE)</td>
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<td>4. Schillinger</td>
<td>(Göttingen, GE)</td>
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<td>5. Berti</td>
<td>(Massa, IT)</td>
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<td>6. Santoro</td>
<td>(Florence, IT)</td>
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<td>7. Danna</td>
<td>(Milan, IT)</td>
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<tr>
<td>8. Nielsen-Kudsk</td>
<td>(Aarhus, DK)</td>
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<tr>
<td>9. Ibrahim</td>
<td>(Montreal, CA)</td>
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<tr>
<td>10. Kanagaratnam</td>
<td>(London, GB)</td>
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<td>11. Landmesser</td>
<td>(Zurich, CH)</td>
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<tr>
<td>12. Costa</td>
<td>(Lisbon, PT)</td>
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<tr>
<td>13. Vermeersch</td>
<td>(Antwerp, BE)</td>
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<tr>
<td>14. Aminian</td>
<td>(Charleroi, BE)</td>
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<td>15. Kefer</td>
<td>(Brussels, BE)</td>
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<td>16. Budts</td>
<td>(Leuven, BE)</td>
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<td>17. De Potter</td>
<td>(Aalst, BE)</td>
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<td>18. Omran</td>
<td>(Bonn, GE)</td>
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<td>19. Benit</td>
<td>(Hasselt, BE)</td>
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<td>20. Stammen</td>
<td>(Roeselare, BE)</td>
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Tzikas 2014
**DESIGN:** Non-randomized, single-arm, multi-center clinical evaluation of the ACP for stroke prevention in non-rheumatic AF patients

**OBJECTIVE:** To evaluate the acute and long-term safety and effectiveness of the ACP in clinical practice

**PRINCIPAL INVESTIGATOR**
Apostolos Tzikas, Greece

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**Study Flow Chart**

974 consecutive patients from 20 clinical sites in Europe and Canada, treated between December 2008 and August 2013.

- 5 pts missing data
- 27 pts not implanted
- 14 pts lost to F/U

969 patients in study

942 patients in study

928 patients in study

- Stroke risk evaluation (predicted vs actual)
- Bleeding risk evaluation (predicted vs actual)
Anti-thrombotic Medication

<table>
<thead>
<tr>
<th>Anti-thrombotic Medication</th>
<th>Baseline</th>
<th>F/U</th>
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</thead>
<tbody>
<tr>
<td>ASA</td>
<td>37.5%</td>
<td>63.3%</td>
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<tr>
<td>Clopidogrel</td>
<td>2.7%</td>
<td>3.6%</td>
</tr>
<tr>
<td>Warfarin</td>
<td>17.4%</td>
<td>2.2%</td>
</tr>
<tr>
<td>NOAC</td>
<td>1.0%</td>
<td>0.5%</td>
</tr>
<tr>
<td>LMWH</td>
<td>3.9%</td>
<td>2.3%</td>
</tr>
<tr>
<td>No treatment</td>
<td>7.4%</td>
<td>6.3%</td>
</tr>
<tr>
<td>DAPT</td>
<td>19.0%</td>
<td>19.7%</td>
</tr>
<tr>
<td>ASA + Warfarin</td>
<td>7.3%</td>
<td>1.1%</td>
</tr>
<tr>
<td>Triple therapy</td>
<td>2.6%</td>
<td>0.2%</td>
</tr>
<tr>
<td>Other</td>
<td>1.2%</td>
<td>1.0%</td>
</tr>
<tr>
<td>ASA + NOAC</td>
<td>0.5%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Clopidogrel + Warfarin</td>
<td>0.6%</td>
<td>0.5%</td>
</tr>
<tr>
<td>Clopidogrel + NOAC</td>
<td>0.1%</td>
<td>0.0%</td>
</tr>
<tr>
<td>TOTAL</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Results

<table>
<thead>
<tr>
<th>Total Patients</th>
<th>Total Patient Years</th>
<th>CHA$_2$DS$_2$-VASc Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>928</td>
<td>1216.2</td>
<td>4.41</td>
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</tbody>
</table>

**Estimated Stroke Rate per CHA$_2$DS$_2$-VASc**
- 5.62%

**Actual Annual Stroke Rate (N strokes + TIA)**
- 2.06% (25)

**Estimated Bleeding Rate per HAS-BLED**
- 5.49%

**Actual Annual Bleeding Rate (N major bleeds)**
- 2.22% (27)
Summary – Take home message

- Adequate transseptal puncture skills are needed
- Device sizing is based in multimodality imaging
- Implantation technique should follow a strict, pre-specified protocol
- Safe and successful LAA occlusion relies in continuous vigilance in the Cath Lab
- LAA occlusion is a team work
Patient selection and planning

Why do we close the LAA?

- Primary & secondary prevention
- No symptomatic improvement
- We need to do a SAFE PROCEDURE
Case preparation

- Controlled environment – no rush
- Ideally the echocardiographist should be involved in the screening
- General anesthesia is preferable
- All members of the team (echocardiographist, anesthesiologist, nurses, technicians, fellows) should be familiar with the procedure and the patients’ history/background
- Spend 10 – 15’ to explain all the steps of the procedure
- If available, inform your cardio-thoracic surgeon
- Have a pericardial drainage kit and a snare ready
Case preparation

- At the beginning... TEE
  - Check for baseline pericardial effusion
  - Assess the mitral valve
  - Assess the left upper pulmonary vein
Vascular access

- Avoid vascular complications
- Right femoral vein 10F short sheath
- > 1 cm distance between femoral venous & arterial puncture
- Consider
  - No arterial puncture
  - Radial artery
  - Stiff wire for easier
    - delivery sheath insertion
    - septal crossing
Transseptal puncture

TEE Bicaval view (90°)  TEE Short Axis view (45-60°)
Transseptal puncture

AP view

Lateral view

1-3 cm
Transseptal puncture

- INOUE technique 40° RAO projection
Transseptal puncture

Optimal TSP Site: Inferior and posterior TSP site offers good access and good alignment with LAA neck

- Avoid air while removing guidewire or sheath dilator
  - Use a syringe filled with water
  - Remove under water

Cardiac CT Image

Heparin!

ACT ≥ 250 sec
Imaging and sizing

TEE

The Shape of the LAA Orifice

(OSTIUM)

Oval

#1 #2 #3

#4 #5 #6

Round
Imaging and sizing

**TEE**

- Use multiple TEE projections for measurements

60° - 12 mm  
80° - 15 mm  
120° - 14 mm
Imaging and sizing

- Demonstrate the orifice, neck and body of the LAA and the Cx on SAX view (~45°)
- Obtain three key measurements for ACP implant

a. **Orifice of the LAA**: a line between the pulmonary ridge and the Cx
b. **Depth of the LAA neck**: an orthogonal line from the middle of the orifice into the back wall of the LAA
c. **Dimension of the landing zone**: a line between the superior neck ~10 mm inside the PV ridge to the inferior neck ~10 mm inside the Cx
Imaging and sizing

Angiography

- Hand injection close to orifice
- No power injection
  - TSP sheath
  - Pigtail in the TSP sheath
  - Marker pigtail for calibration
Imaging and sizing

Angiography

- Relationship landing zone and anatomy of LAA neck
Imaging and sizing

How to measure dimensions of the LAA

- The projection used for imaging guidance should be the same as used for measurement
- Do not proceed to implant if the orifice and neck of the LAA are not fully demonstrated
Sheath & device manipulation

Avoid air while loading the ACP!

- No air bubbles allowed in the delivery system!
  - Air bubbles inside the device
  - Air bubbles on the surface of the device

- Procedural complications
  - Air embolism: 1-3%*

* Park et al. Catheter and Cardiovasc Interv 2010
1. Keep the sheath aligned with the axis of the LAA neck before starting deployment.

2. Adjust the position of the sheath tip about 5 mm distal to intended landing zone after forming a ball by unsheathing the device.

3. Continue slowly deploying the device lobe with push-pull technique to minimize spring back at the last phase of lobe deployment.

4. Subsequently deploy the disc; check 5 signs of stability before release.
Sheath & device manipulation
Sheath & device manipulation
Sheath & device manipulation
Sheath & device manipulation
How to properly deploy ACP Disc

Correct Deployment:
Keep slight tension on the delivery cable while deploying the disc from the LA to achieve the cupping effect on the orifice of the LAA

Incorrect Deployment:
The cable is being pushed while deploying the disc. As a result, the disc is placed inside the LAA, leaving a space between the LAA orifice and the disc
Sheath & device manipulation
Sheath & device manipulation

Evaluation of Device Size

- **Correct Size**: "Tire" shaped: Proper tension on the device by the LAA
- **Undersized**: "Hockey Puck" shaped: No tension on the device
- **Excessively Oversized**: "Strawberry" shaped: Inward folding stabilizing wires

Stable

Unstable

Unstable
Sheath & device manipulation

Additional Useful Tips

• If a device lobe is unstable, wait for 5 minutes to allow the lobe to “settle”; the lobe becomes more stable because of its self-expanding nature

[Images: Lobe: good shape and acceptable position, but unstable. Waiting for 5 min before deploying the disc. Note the lobe further expanding. Better engagement of stabilizing wires.]

• If you are not sure whether the device is stable, you may gently pull the disc for 5 min before release
Device release

- There are two ways to assess whether you have achieved occlusion of the left atrial appendage:
  
  A. Contrast injection
  B. Color-flow Doppler echocardiography
Device release

5 signs of stability

1. Orientation of the device lobe has to be consistent with the axis of the landing zone
2. Device lobe should be slightly compressed
3. The disk must have a concave shape
4. The disk must be separated from the lobe
5. At least 2/3 of the device lobe should be distal to the left circumflex artery
Device release

5 signs of stability

1. Orientation of the device lobe has to be consistent with the axis of the landing zone
Device release

5 signs of stability

2. Device lobe should be slightly compressed

Tire Shaped  Puck Shaped  Strawberry Shaped

Correct  Incorrect  Incorrect

Stable  Unstable
Stabilizing wires engaged  Stabilizing wires unengaged
Device release

5 signs of stability

3. The disk must have a concave shape
4. The disk must be separated from the lobe
Device release

5 signs of stability

5. At least 2/3 of the device lobe should be distal to the Cx
Don’t do that!
Take it easy...
Congratulations!

Device release

Congratulations!