How to deal with residual shunt after PFO/ASD closure?

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Kardiologisches Zentrum Darmstadt, Germany
Questions to answer

- Do we have residual shunt?
- Why do we see residual shunt?
- How frequent are residual shunts?
- Is residual shunt associated with events and what are the predictors of recurrent events?
- What is the risk/benefit of a re-do closure procedure?
Questions to answer

• Do we have residual shunt?
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• Is residual shunt associated with events and what are the predictors of recurrent events?
• What is the risk/benefit of a re-do closure procedure?
Do we have residual shunt?

Routine Follow up`s
1, 6 month, 1 year, than annually if not closed

- TTE Transthoracic Echo
- TCD Transcranial Doppler
- TEE Transesophageal Echo

- "Gold standard"
If we have residual shunt... 
...the mechanism is crucial!

Use TEE!
Questions to answer

• Do we have residual shunt?
• Why do we see residual shunt?
• How frequent are residual shunts?
• Is residual shunt associated with events and what are the predictors of recurrent events?
• What is the risk/benefit of a re-do closure procedure?
Why do we see residual shunt?

- Additional defects
- Occluder does not endothelialise
- Suboptimal device position
  - Device is not in close contact with septum
  - Device is splayed around aorta leaving a gap
  - Device splints open a PFO
Residual shunt due to an additional defect

LAX view 124°- STARFlex occluder in the PFO- additional defect caudal
Residual shunt due to an additional defect

TEE 0°
Amplatzer occluder in a superior defect - Residual defect inferiorly

TEE 30°
Residual shunt due to an additional defect

3D TEE zoom

Amplatzer occluder in a superior defect- Residual defect inferiorly
Amplatzer occluder
Suboptimal device position
Implantation of a 25 mm Spider occluder

Deliberated device
6-Mo-FU
Suboptimal device position

25mm Occlutech occluder- 6 mo FU

No relevant aortic rim

Occluder slipped into PFO tunnel
Suboptimal device position
25 mm Occlutech occluder - 6 mo FU
Suboptimal device position
Atypical LA Membrane

35mm Amplatzer PFO occluder

Additional 16 mm Amplatzer ASD occluder
Questions to answer

- Do we have residual shunt?
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- How frequent are residual shunts?
- Is residual shunt associated with events and what are the predictors of recurrent events?
- What ist the risk/benefit of a re-do PFO closure procedure?
## Residual Shunt after PFO closure

<table>
<thead>
<tr>
<th>Author</th>
<th>No. of pts after PFO device closure</th>
<th>Mean FU</th>
<th>Closure rate (%)</th>
<th>Residual shunt (%)</th>
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</thead>
<tbody>
<tr>
<td>Majunke et al</td>
<td>1677</td>
<td>37± 25</td>
<td>94%</td>
<td>6%</td>
</tr>
<tr>
<td>Fischer et al</td>
<td>140</td>
<td>At 1 y 91%</td>
<td></td>
<td>At 1 y 9%</td>
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<tr>
<td>Cifarelli et al</td>
<td>154</td>
<td>26 ± 18</td>
<td>At 6 mo 97%</td>
<td>At 6 mo 3%</td>
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<tr>
<td>Wahl et al</td>
<td>1930</td>
<td>At 6 mo 88%</td>
<td>At 1 y 96%</td>
<td>At 6 mo 12% 4%</td>
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<tr>
<td>Wallenborn et al</td>
<td>424</td>
<td>At 6 mo 95%</td>
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<td>At 6 mo 5%</td>
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</tbody>
</table>

Residual shunt at 1 year after closure procedure → ~4%(Echo), ~ 9%(TCD)
Why higher incidences with TCD?

Ballon occlusion of PFO + Power M Mode Transcranial Doppler

- 84 pts (66 pts completed study)
  - Cardioseal 76 pts, Amplatzer 7 pts, Helex 1 pt
- Saline contrast injection during sizing balloon inflation in PFO → flow obliteration confirmed by ICE
- Calibrated Valsalva
- Repeated after device placement and in FU (antecubital vein injection)

20% of patients had a R-L Shunt with balloon inflated in PFO tunnel and confirmation of occlusion by ICE.
Residual shunt decreases over time

- Anzola et al. 140 PFO pts (FU-TCD)
  - 1 month 31/140 (22%)
  - 3 month 15/120 (13%)
  - 6 month 9/112 (8%)
  - 12 month 9/104 (9%)

Anzola et al Stroke 2004; 35: 2140-2144
Residual shunt decreases over time

- N=1930 pts (1994 - 2009) PFO closure with different devices

<table>
<thead>
<tr>
<th></th>
<th>6 month</th>
<th>12 month</th>
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<tr>
<td>Follow-up</td>
<td>N= 1726</td>
<td>N= 1599</td>
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<tr>
<td>Closure rate (%)</td>
<td>87.6%</td>
<td>96%</td>
</tr>
<tr>
<td>Minimal residual shunt (%)</td>
<td>7.8</td>
<td>2%</td>
</tr>
<tr>
<td>Moderate-large residual shunt (%)</td>
<td>4.6%</td>
<td>2%</td>
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</table>

Residual shunt after ASD closure with the Amplatzer Septal Occluder

Dec 2004- Jul 2008: n= 58 adult pts, mean FU 32.5 ± 18.5 mo

<table>
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<th>FU- period</th>
<th>Residual shunt</th>
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<td>24h after procedure</td>
<td>11 (21%)</td>
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<tr>
<td>1 month</td>
<td>3 (5.8%)</td>
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<td>6 months</td>
<td>2 (3.8%)</td>
</tr>
<tr>
<td>12 months</td>
<td>2 (3.8%)</td>
</tr>
</tbody>
</table>

Behjati et al. J Teh Univ Heart CTr 2011; 6(2): 79-84
Questions to answer

• Do we have residual shunt?
• Why do we see residual shunt?
• How frequent are residual shunts?
• Is residual shunt associated with events and what are the predictors of recurrent events?
• What is the risk/benefit of a re-do closure procedure?
Is residual shunt associated with recurrent events?

237 pts → PFO closure with CardioSeal or Amplatzer (Complete closure or only minimal residual shunt in 66%)

Age was only predictor of recurrent events
Is residual shunt associated with recurrent events? FU up to 6 years, no 2nd procedure

A residual shunt after PFO closure was a predictor for recurrence (RR 5.3, 95% CI 1.3 to 21.0; p= 0.02)

Is residual shunt associated with recurrent events?  
Retrospective analysis

- Follow up:
  - TEE or TTE after 1, 6 and 12 months
  - ECG after 1, 6 and 12 months
  - Questionnaire every 12 months

<table>
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<tr>
<th>Follow-up</th>
<th>6 months n = 1930</th>
<th>12 months n = 1930</th>
<th>Last FU n = 1930</th>
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<tr>
<td>No RS</td>
<td>87.6 %</td>
<td>96 %</td>
<td>92 %</td>
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<tr>
<td>Minimal RS</td>
<td>7.8 %</td>
<td>2 %</td>
<td>5.5 %</td>
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<tr>
<td>Moderate – large RS</td>
<td>4.6 %</td>
<td>2 %</td>
<td>2.5 %</td>
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</tbody>
</table>

PFO Closure Results

• Device implantation technically successful
  – 1st attempt  98.6 %
  – 2nd attempt 100 %

• 68 patients underwent percutaneous closure of a residual shunt

• 8 patients underwent surgery
  residual shunt (3), thrombus (3), pericardial tamponade (2)

Results

• Follow-up 1 – 167 (mean 39) months

• Annual recurrence rate: 1 %
  – 63 events in 6211 patient years

• Death n=36
  – One possibly due to paradoxical embolism
    (mesenterial infarction)

## Prognostic Factors

### A residual shunt was not a risk factor!

<table>
<thead>
<tr>
<th>Variable</th>
<th>p-value</th>
<th>HR</th>
<th>95% CI</th>
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<tbody>
<tr>
<td>Age in years</td>
<td>0.007</td>
<td>1.03</td>
<td>1.01-1.06</td>
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</tbody>
</table>

| Diabetes mellitus      | 0.034   | 2.4  | 1.1-3.2      |
| Sideris device         | 0.007   | 5.5  | 1.6-18.6     |

*AF* new onset of atrial fibrillation after device implantation  
*No. of events* Number of events before PFO closure
If we say residual shunt is relevant...

Is an additional closure procedure safe?
Questions to answer

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• What ist the risk/benefit of a re-do closure procedure?
Second closure devices

- 525 pts
- TEE > 6 months 86% complete closure
- 14 patients second device

Wahl et al. Heart published online 16 July 2007
Complications

- 5 devices or parts thereof embolized
- Air embolism in 3 pts
- Tamponade in 3 pts
- Access complications in 4 pts
- Laceration of femoral artery in 1 pt

No procedural complication had long-term sequelae

Wahl et al. Heart published online 16 juli 2007
Second closure devices

- 308 pts treated, 8 different devices
- 6 month closure rate 79% (11% minimal, 10% moderate shunt- all offered a 2nd device)
- 10 received a 2nd device

<table>
<thead>
<tr>
<th>Grade of shunt at baseline</th>
<th>First device</th>
<th>Grade of residual shunt</th>
<th>Second device</th>
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<td>Sideris</td>
<td>Moderate</td>
<td>Sideris</td>
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<tr>
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<td>Angel Wing</td>
<td>Moderate</td>
<td>CardioSEAL</td>
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<tr>
<td>Large</td>
<td>Sideris</td>
<td>Large</td>
<td>Sideris</td>
</tr>
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<td>Large</td>
<td>PFO Star</td>
<td>Moderate</td>
<td>Amplatzer PFO</td>
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<tr>
<td>Large</td>
<td>PFO Star</td>
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<td>Amplatzer PFO</td>
<td>Large</td>
<td>Amplatzer ASD</td>
</tr>
</tbody>
</table>

Schwerzmann M et al. Catheterization and Cardiovascular Interventions 2004;495:490-63
Second closure devices

- No procedural complications
- Fluoroscopy only

FU 3.5 yrs no complications

Schwerzmann M et al. Catheterization and Cardiovascular Interventions 2004;495:490-63
Second closure devices

1,677 consecutive patients underwent percutaneous PFO closure.

- 5 patients were lost to follow-up

107/1,672 patients with a persistent residual shunt

- 8 patients with residual shunt due to additional atrial septal defects were excluded

99 patients with residual shunt due to incomplete PFO closure

- 50 patients with a small residual shunt

- 49 patients with a moderate or large residual shunt

- 5 patients in whom a first PFO closure device was implanted in an external center

- 14 patients declined to be retreated with a second device

40 patients underwent second procedure

Majunke et al. EuroIntervention 2010 Feb; 5(7): 8333-7
Second closure devices

- Technically success in 39/40 pts (98 %);
- Devices:
  - Premere (n=20)
  - Amplatzer PFO (n=13)
  - STARFlex (n=4)
  - Helex (n=1)
  - Angelwings (n=1)
- Mean follow-up of 36 ± 29 months
- Residual Shunt:
  - None: 27 (69 %)
  - Small: 9
  - Moderate: 1 (third device)
  - Large: 2 (1x surgery, 1x third device)

1 death 21 days post closure → Cardiac Tamponade

Majunke et al. EuroIntervention 2010 Feb; 5(7): 8333-7
Second closure devices

- 424 pts underwent PFO closure
- 21 patients with moderate to large residual shunt→
  - 1 patient → surgery
  - 20 patients → second device

1 device embolization requiring surgical removal

Diaz et al. Catheterization and Cardiovascular Interventions 2010; 76: 145-150
Summary

- Routine Follow-up`s for detection of residual shunts
- Evaluation of the mechanism of residual shunts → TEE (based on the mechanism: individualized approach)
- Trend across studies toward increased events related to residual leaks (but not consistent)
- The rate of complications after 2nd device might be higher
- Wait at least 12 mo before a 2nd procedure → closure rates improve with time
Case 1

68 y old male patient

6/2008-1st procedure

Ballon sizing: 14 mm

30 mm Helex device
Case 1

68 y old male patient- 2nd procedure 2/2010

Tunnel-like residual shunt
Table 2. Patients in whom implantation of a second closure device was attempted.

<table>
<thead>
<tr>
<th>Patient</th>
<th>Age (yrs)</th>
<th>Gender</th>
<th>PFO size* (mm)</th>
<th>First device (size)</th>
<th>Residual shunt grade (TEE)</th>
<th>Recurrent event</th>
<th>Second device (size)</th>
<th>Last TEE after procedure (months)</th>
<th>Residual shunt grade (TEE)</th>
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<td>7</td>
<td>Premere (20mm)</td>
<td>Moderate</td>
<td>No</td>
<td>Premere (20mm)</td>
<td>7</td>
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</tr>
<tr>
<td>34</td>
<td>23</td>
<td>w</td>
<td>15.5</td>
<td>Amplatzer (25mm)</td>
<td>Moderate</td>
<td>No</td>
<td>Premere (20mm)</td>
<td>7</td>
<td>Closed</td>
</tr>
<tr>
<td>35</td>
<td>52</td>
<td>m</td>
<td>--</td>
<td>PFO-Star</td>
<td>Large</td>
<td>Yes</td>
<td>Amplatzer (25mm)</td>
<td>--</td>
<td>--</td>
</tr>
<tr>
<td>36</td>
<td>69</td>
<td>m</td>
<td>8.1</td>
<td>Helex (20mm)</td>
<td>Moderate</td>
<td>No</td>
<td>Amplatzer (25mm)</td>
<td>7</td>
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<tr>
<td>37</td>
<td>46</td>
<td>m</td>
<td>17.1</td>
<td>Solysafe (20mm)</td>
<td>Large</td>
<td>No</td>
<td>Premere (20mm)</td>
<td>7</td>
<td>Small</td>
</tr>
<tr>
<td>38</td>
<td>60</td>
<td>m</td>
<td>5</td>
<td>Helex (15mm)</td>
<td>Large</td>
<td>Yes</td>
<td>Premere (20mm)</td>
<td>6</td>
<td>Small</td>
</tr>
<tr>
<td>39</td>
<td>41</td>
<td>m</td>
<td>10.4</td>
<td>Helex (15mm)</td>
<td>Large</td>
<td>No</td>
<td>Premere (30mm)</td>
<td>6</td>
<td>Small</td>
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<tr>
<td>40</td>
<td>76</td>
<td>m</td>
<td>5.3</td>
<td>Helex (15mm)</td>
<td>Moderate</td>
<td>No</td>
<td>Premere (25mm)</td>
<td>6</td>
<td>--</td>
</tr>
</tbody>
</table>

^ denotes an event requiring a second device.
Case 1

68y old male patient - 2nd procedure

2nd device: 20 mm Premere occluder
Case 1
No procedural complication

No residual shunt after the release of the Premere occluder
How to deal with residual shunt?

Editorial Comment

Now you are in a predicament. If the shunt is small and zigzagging through the device, there is little risk that a clot might trespass. However, how to tell the patient, let alone the initially reluctant referring physician, that you meant to close the hole but the hole is still there. Of course, you can try to convince them that the initial hole was dangerous and the current hole is not, but will they buy that?

If it is a residual shunt directly in the inflow of the inferior vena cava that remains unimpeded by the initial device you have to follow your initial line of thought and go for a second closure attempt. Pair the psychological situation with the ease of implanting a second device and most residual shunts qualify for an encore.

B. Meier
Second device after ASD closure?

Indication to close a residual shunt after ASD closure

- QP:QS > 1.5
- or paradoxical embolism
Thank you for your attention!
Comparison of Medical Treatment With Percutaneous Closure of Patent Foramen Ovale in Patients With Cryptogenic Stroke

Stephan Windecker, MD,* Andreas Wahl, MD,* Krassen Nedeltchev, MD,† Marcel Arnold, MD,† Markus Schwerzmann, MD,* Christian Seiler, MD, FACC,* Heinrich P. Mattle, MD,† Bernhard Meier, MD, FACC*

Bern, Switzerland

Figure 4. Probability of recurrent stroke or transient ischemic attack stratified for medical treatment (continuous line) and percutaneous patent foramen ovale (PFO) closure (dashed line) in the subgroup of patients with complete PFO occlusion.
High prevalence of right-to-left shunt in patients with symptomatic great saphenous incompetence and varicose veins

David D. Wright, MB, FRCS, a Kathleen D. Gibson, MD, b Jean Barclay, BS, c Alexander Razumovsky, PhD, d Janet Rush, MD, e and Charles N. McCollum, MD, FRCS, f London and Manchester, United Kingdom; Bellevue, Wash; Conshohocken, Pa; and Cockeysville, Md (J Vasc Surg 2010;51:104-7.)

Table I. Spencer grading of right-to-left shunt at rest and with Valsalva a

<table>
<thead>
<tr>
<th>Spencer grading system</th>
<th>No. of HITS</th>
<th>No. with Spencer grade</th>
<th>At rest</th>
<th>After Valsalva</th>
</tr>
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<tbody>
<tr>
<td>Grade</td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td>0</td>
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<td>136</td>
<td>106</td>
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<td>29</td>
<td></td>
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<tr>
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<td>4</td>
<td>51-150</td>
<td>9</td>
<td>24</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>&gt;150</td>
<td>9</td>
<td>28 b</td>
<td></td>
</tr>
</tbody>
</table>

HITS, High-intensity transient signals.

a Some patients positive after Valsalva were negative at rest, and vice versa.

b One patient grade 5 at rest did not have the test repeated with Valsalva.
Residual Shunt

Table 1. Devices used during first procedure and the number of devices in which a residual shunt persisted.

6.4% had residual shunt

<table>
<thead>
<tr>
<th>Device</th>
<th>Count</th>
<th>Residual Shunt</th>
</tr>
</thead>
<tbody>
<tr>
<td>Angelwings</td>
<td>5</td>
<td>1</td>
</tr>
<tr>
<td>PFO-Star</td>
<td>4</td>
<td>1</td>
</tr>
<tr>
<td>BioStar</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Cardia-Star</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
Multiple Amplatzer septal occluder devices for multiple atrial communications: immediate and long-term follow-up results.


33 patients (mean age 38.9 years and mean weight 68 kg)
67 devices were deployed in 33 patients.
Mean diameters 12.9 and 7.7 mm,
Mean device diameters 19.0 and 13.4 mm

Complications included a Device embolization within 24 hr
Indication for PFO Closure

- Stroke: 42%
- TIA: 52%
- Peripheral Embolism: 4%
- Migraine: 0.6%
- Diver: 1%
- Other: 1%