PDA: Closure Using Coils
Indications, Technique the & Outcomes

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Disclosure Information

PDA: Closure Using Coils
- Indications, Technique & Outcomes

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As a faculty member for this program, I disclose the following relationships with industry:

(GRS): Grant/Research Support (C): Consultant (SB): Speaker’s Bureau
(MSH): Major Stock Holder (AB): Advisory Board (E): Employment
(O): Other Financial or Material Support

pfm Medical: C
Atrium Medical: C
Neurosigma Vascular: AB
NIH Challenge Grant, AHA Innovative Research Grant
What is a Patent Ductus Arteriosus?
Closing PDA’s

Transcatheter occlusion
Began in the late 1971

Though newer techniques
Were developed which
made the procedure easier
to perform

In 1991, smaller PDA’s were
closed with coils.
In 2002 larger PDA’s were
able to be closed with the
Amplatzer PDA and the Nit-Occlude devices
PDA: History of Coil Closure

• Moore et al – first description of a coil occluded PDA
• “all the rage” in the 1990’s
• Bioptome delivery
• Coils tied together
• 0.052’ Coils delivered by sheathes and guide catheters
• Many coils packed in together
Closing Patent Ductus Arteriosus

Gianturco Coil 1991  Amplatzer Duct Occluder I 2004  Amplatzer Duct Occluder II 2012
How Common are PDA’s?

- Depends on age
  - < 2,000 gram premature infants (18%)
  - Other studies are as high as 70%
  - Term infants (ie > 3,500 gram) ranges from 0.9-20.6/10,000 in the US

- US Birthrate in 2009 was 4,130,655
  - Calculates to on average 6-7,000 babies born with PDA every year in the US

- the 2 most common interventional procedure performed (35-50/year)
PDA’s in infants wreak havoc in the Neonatal Intensive Care Units (NICU’s)

- Most common group to have PDA’s
- Most likely to be symptomatic
- Can cause severe lung damage/persistent need for ventilator

Most common finding in children/adults over 1 year of age is heart murmur

- Not infrequently mis-diagnosed with asthma
- Prolonged LA/LV enlargement can cause long-term ventricular dysfunction
PDA: Indications for PDA closure

- Symptoms
- Left-sided heart enlargement by ECHO
- “significant” sized PDA by ECHO
- PDA with an audible murmur
- Any PDA on ECHO
  - The Silent Ductus
PDA: Assessment

- Angiogram
  - RAO, LAT
  - High frame rate
  - Hold for levophase
- ECHO helps
  - Predicts size of shunt
  - "Guesstimates" size
- Angiogram is gold standard
  - Detailed anatomy
  - Ampulla size
  - Distensible?
  - Coarctation?
- PA anatomy
Not all PDA’s are Created Equal
PDA: Angiography: LAT
PDA: Angiography: RAO
PDA: Measurements

“Measure the frame on which it looks biggest not the frame on which you see it the best”

- Length (least critical)
- Narrowest width
- Aortic Ampulla
- Note distance to PAs
PDA: Coil Size Choices

- Size coil to ampulla
- At least 1.5-2X the size of the PDA’s minimum diameter
- Do not want to get in the way of the aorta or pulmonary artery
PDA Devices: When to use more then the average coil?

• > small PDA
• > 2 mm at narrowest or distensible
• PDAs easily crossed from PA side
  • Retrograde delivery possible
• Large PDAs that can’t be crossed from PA
  • especially in adults
• Requires snaring of wire in PA
• Most PDAs are now device closed
PDA: Angiography: LAT

- Length (least critical)
- Narrowest width
- Aortic Ampulla
- Note distance to PAs
PDA: Measurements

“Measure the frame on which it looks biggest not the frame on which you see it the best”

- Length (least critical)
- Narrowest width
- Aortic Ampulla
- Note distance to PAs
PDA: Coil Choices

• Flipper Coil – Cook
  • MREye
  • 3mmX5cm, 5mmX6cm

• Pushable Coils
  • MREye, 0.038’ coils

• Nit-Occlud Coils –
  • pfm Medical

• Micro-Coils
  • Interlock, Axiom, Hydrogel

• RARELY Needed
PDA: Coil Delivery

• ≤ 1 loop in the PA
• Angiography prior to release (optional)
• Check coil orientation
• Prior to release
  • No LPA obstruction
  • No Dao obstruction
PDA: Angiogram After Release

• Do I need more coils?
• Risk of hemolysis?
• Is residual shunt acceptable?
Nit-Occlud Coils
- robust coil
- retrievable
- ideal shape
- “almost” FDA approved

<table>
<thead>
<tr>
<th>REF</th>
<th>Coil diameter</th>
<th>Implantation catheter</th>
<th>Implantation catheter length</th>
<th>Coil length</th>
<th>Type</th>
<th>PU</th>
</tr>
</thead>
<tbody>
<tr>
<td>143106</td>
<td>10 x 6 mm</td>
<td>5 F</td>
<td>105 cm</td>
<td>6.0 mm</td>
<td>Stiff</td>
<td>1</td>
</tr>
<tr>
<td>143126</td>
<td>12 x 6 mm</td>
<td>5 F</td>
<td>105 cm</td>
<td>6.0 mm</td>
<td>Stiff</td>
<td>1</td>
</tr>
<tr>
<td>143146</td>
<td>14 x 6 mm</td>
<td>5 F</td>
<td>105 cm</td>
<td>6.0 mm</td>
<td>Stiff</td>
<td>1</td>
</tr>
<tr>
<td>145044</td>
<td>4 x 4 mm</td>
<td>4 F</td>
<td>85 cm</td>
<td>3.5 mm</td>
<td>Flex</td>
<td>1</td>
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<tr>
<td>145054</td>
<td>5 x 4 mm</td>
<td>4 F</td>
<td>85 cm</td>
<td>3.5 mm</td>
<td>Flex</td>
<td>1</td>
</tr>
<tr>
<td>145065</td>
<td>6 x 5 mm</td>
<td>4 F</td>
<td>85 cm</td>
<td>3.5 mm</td>
<td>Flex</td>
<td>1</td>
</tr>
<tr>
<td>145076</td>
<td>7 x 6 mm</td>
<td>5 F</td>
<td>85 cm</td>
<td>4.5 mm</td>
<td>Medium</td>
<td>1</td>
</tr>
<tr>
<td>145096</td>
<td>9 x 6 mm</td>
<td>5 F</td>
<td>85 cm</td>
<td>5.0 mm</td>
<td>Medium</td>
<td>1</td>
</tr>
<tr>
<td>145116</td>
<td>11 x 6 mm</td>
<td>5 F</td>
<td>85 cm</td>
<td>6.0 mm</td>
<td>Medium</td>
<td>1</td>
</tr>
</tbody>
</table>
HOW IT WORKS……..
Delivery System  Y Connector  Transport. Sheath

Safety Clip  Pusher Ball  Rotation Screw

Coil  Handle

PUL.  AORTA  PDA

D1  L3  0  D2

P  D  Lc
<table>
<thead>
<tr>
<th>D1</th>
<th>D2</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>1mm</td>
<td>≤ 3mm</td>
<td>4x4</td>
</tr>
<tr>
<td>1mm</td>
<td>4mm</td>
<td>5x4</td>
</tr>
<tr>
<td>1mm</td>
<td>≥ 5mm</td>
<td>6x5</td>
</tr>
<tr>
<td>2mm</td>
<td>≤ 5mm</td>
<td>6x5</td>
</tr>
<tr>
<td>2mm</td>
<td>6-7mm</td>
<td>7x6</td>
</tr>
<tr>
<td>2mm</td>
<td>≥ 8mm</td>
<td>9x6</td>
</tr>
</tbody>
</table>

Table: Selection of the Nit-Occlud® PDA Coil (according to angiographic PDA dimensions)

<table>
<thead>
<tr>
<th>D1</th>
<th>D2</th>
<th>Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>3mm</td>
<td>≤ 7mm</td>
<td>7x6</td>
</tr>
<tr>
<td>3mm</td>
<td>8-9mm</td>
<td>9x6</td>
</tr>
<tr>
<td>3mm</td>
<td>≥ 9mm</td>
<td>9x6 or 11x6</td>
</tr>
<tr>
<td>4 or 5mm</td>
<td>9mm</td>
<td>11x6 or 10x6</td>
</tr>
<tr>
<td>4 or 5mm</td>
<td>10-11mm</td>
<td>11x6 or 12x6</td>
</tr>
<tr>
<td>4 or 5mm</td>
<td>≥ 12mm</td>
<td>11x6 or 14x6</td>
</tr>
</tbody>
</table>

HOW IT WORKS
HOW IT WORKS
HOW IT WORKS........
Step: 05 Final Coil Adjustment

Marker

Transportation Sheath

HOW IT WORKS........
Step: 06  Coil Release

HOW IT WORKS
Case 1: Nit Occlud PDA Occlusion
Case 1: Nit Occlud PDA Occlusion
Case 1: Nit Occlud PDA Occlusion
Case 1: Nit Occlud PDA Occlusion
Case 2: Nit Occlud PDA Occlusion
Case 2: Nit Occlud PDA Occlusion
Case 2: Nit Occlud PDA Occlusion
Case 2: Nit Occlud PDA Occlusion
Case 2: Nit Occlud PDA Occlusion
Case 3: Nit Occlud PDA Occlusion
Case 3: Nit Occlud PDA Occlusion
Case 3: Nit Occlud PDA Occlusion
PDA: Microcatheter coiling?

- Premature infants
- Next frontier
- 2.7-3 Fr system is desirable
- PDAs too small to cross
- Really need to close these?
Detachable Coils: IR and NeuroIR

- GDC
- Axiom
- Interlock
The Premie Duct
PDA with a Micro-coil
PDA with a Micro-coil
PDA with a Micro-coil
What is the Optimal PDA Closure Device?

MRI Compatible

Retrievable/Repositionable

Easily Retrievable if Device Should Embolize

Minimal Residual Shunt @ Follow-up

Low Profile

Cheap
Catheterization and Cardiovascular Interventions 76:687–695 (2010)

PEDiatric and CONGENITAL HEART DISEASE

Original Studies

Trans-Catheter Closure of Patent Ductus Arteriosus—What Is the Best Device?

## TABLE I. Comparison of Four PDA Closure Devices

<table>
<thead>
<tr>
<th>Type of Device</th>
<th>Gianturco 120 (22%)</th>
<th>Flipper 119 (22%)</th>
<th>Amplatzer 152 (28%)</th>
<th>Nit-Occlud 155 (28%)</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yrs)</td>
<td>4.7 ± 5.1</td>
<td>4.3 ± 5.1</td>
<td>6.8 ± 10.1&lt;sup&gt;a&lt;/sup&gt;</td>
<td>6.5 ± 8.6&lt;sup&gt;b&lt;/sup&gt;</td>
<td>0.01</td>
</tr>
<tr>
<td>≤1 yr 140 (%)</td>
<td>27 (19.3)</td>
<td>38 (27.1)</td>
<td>36 (25.7)</td>
<td>39 (27.9)</td>
<td>NS</td>
</tr>
<tr>
<td>&gt;1–≤5 yrs 233 (%)</td>
<td>59 (25.3)</td>
<td>50 (21.5)</td>
<td>66 (28.3)</td>
<td>58 (24.9)</td>
<td>NS</td>
</tr>
<tr>
<td>&gt;5 yrs 169 (%)</td>
<td>34 (20.1)</td>
<td>31 (18.3)</td>
<td>47 (27.9)</td>
<td>57 (33.7)</td>
<td>NS</td>
</tr>
<tr>
<td>Male: Female</td>
<td>33: 87</td>
<td>44: 75</td>
<td>53: 99</td>
<td>49: 106</td>
<td>NS</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>20.4 ± 21.2</td>
<td>18.8 ± 6.4</td>
<td>20.5 ± 19.2</td>
<td>19.8 ± 16.6</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Narrowest PDA diameter (mm)</td>
<td>2.2 ± 0.8</td>
<td>2.2 ± 1.0</td>
<td>3.2 ± 1.5</td>
<td>2.3 ± 1.4</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>PDA type</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>A 355 (%)</td>
<td>91 (25.6)</td>
<td>88 (24.8)</td>
<td>94 (26.5)</td>
<td>82 (23.1)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>B 40 (%)</td>
<td>8 (20)</td>
<td>2 (5)</td>
<td>17 (42.5)</td>
<td>13 (32.5)</td>
<td></td>
</tr>
<tr>
<td>C 45 (%)</td>
<td>7 (15.6)</td>
<td>14 (31.1)</td>
<td>14 (31.1)</td>
<td>10 (22.2)</td>
<td></td>
</tr>
<tr>
<td>D 11 (%)</td>
<td>2 (18.2)</td>
<td>4 (36.4)</td>
<td>3 (27.2)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>E 84 (%)</td>
<td>12 (14.3)</td>
<td>11 (13.1)</td>
<td>13 (15.5)</td>
<td>48 (57.1)</td>
<td></td>
</tr>
<tr>
<td>Unknown 11 (%)</td>
<td>–</td>
<td>–</td>
<td>11 (100)</td>
<td>–</td>
<td></td>
</tr>
<tr>
<td>No. of coils/device</td>
<td>87</td>
<td>89</td>
<td>152</td>
<td>143&lt;sup&gt;c&lt;/sup&gt;</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>1</td>
<td>2</td>
<td>22</td>
<td>–</td>
<td>3&lt;sup&gt;d&lt;/sup&gt;</td>
<td></td>
</tr>
<tr>
<td>≥3</td>
<td>12</td>
<td>8</td>
<td>–</td>
<td>–</td>
<td></td>
</tr>
</tbody>
</table>

<sup>a</sup>Significant compared with Gianturco and Flipper group.

<sup>b</sup>Significant compared with Flipper group.

<sup>c</sup>Nine patients in whom a Nit-Occlud coil was initially tried eventually received an Amplatzer duct occluder for PDA closure—not included in the table.

<sup>d</sup>Amplatzer duct occluder was the second device used in three patients with residual shunts after PDA closure with Nit-Occlud coils.

All data expressed as sample number (n) and percentage (%) or mean and standard deviation (SD); Yrs, years; kg, kilograms; mm, millimeter; NS, not significant; No, number; PDA type - based on Krichenko's classification.
What is the Optimal PDA Closure Device?

<table>
<thead>
<tr>
<th>Type of Device</th>
<th>Gianturco</th>
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<th>Nit-Occlud</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (percent)</td>
<td>120 (22%)</td>
<td>119 (22%)</td>
<td>152 (28%)</td>
<td>155 (28%)</td>
<td></td>
</tr>
<tr>
<td>Immediate R.S.</td>
<td>42 (35)</td>
<td>38 (32)</td>
<td>66 (43.4)</td>
<td>80 (51.6)</td>
<td>0.004</td>
</tr>
<tr>
<td>R.S. at 6 months</td>
<td>15/96 (15.6)</td>
<td>12/95 (12.6)</td>
<td>5/150 (3.3)</td>
<td>3/143 (2.1)</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Embolization</td>
<td>11 (9.2)</td>
<td>3 (2.5)</td>
<td>0</td>
<td>3 (2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Coarctation</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1 (0.7)</td>
<td>NS</td>
</tr>
<tr>
<td>LPA stenosis</td>
<td>2 (1.7)</td>
<td>0</td>
<td>1 (0.7)</td>
<td>0</td>
<td>NS</td>
</tr>
</tbody>
</table>

\(^a\)Six-month follow-up echocardiographic data available only in these patients.

\(^b\)No interventions required to date.

All data expressed as sample number (n) and percentage (%) in parenthesis; R.S, residual shunt; LPA, left pulmonary artery; NS, not significant.