Transcatheter PDA Closure Using Devices

Matthew J. Gillespie MD
The Children’s Hospital of Philadelphia

SCAI Fellows Course
December 9, 2014
Matthew J. Gillespie, MD
No Disclosures
PDA closure

• Transcatheter PDA closure
  – Dr. Portsmann, 1967

• Transcatheter intervention = first line therapy for almost all PDAs

• PDA devices
  – Larger PDAs
  – Large PDAs in small patients
Tools: Coils
Tools: PDA “Devices”

- FDA approved 2003
- FDA approved 2004
- FDA approved 2007
- FDA approved 2012

- Nitocclude PDA-R
ADO device description

- CE Mark 1998
- FDA approval 2003
ADO device description

Amplatzer "10/8"
Device

10 mm 8 mm

14 mm

JACC Vol. 44, No. 3, 2004 Pass et al. 515
August 4, 2004:513–9
Multicenter USA Amplatzer Patent Ductus Arteriosus Occlusion Device Trial

Initial and One-Year Results

Robert H. Pass, MD,* Ziyad Hijazi, MD,† Daphne T. Hsu, MD,* Veronica Lewis, RN,* William E. Hellenbrand, MD*

New York, New York; and Chicago, Illinois
ADO device outcomes

- September 1999 – June 2002
- 484 pts; 25 US centers
- Median weight = 11kg
- Median age 1.8 years
- Median PDA diameter = 2.6 (1-11.2)mm
- No procedural deaths
  - 1 late death likely unrelated to device (Tri 18)
- 2 pts with mild LPA stenosis on follow up
- 98% complete occlusion @ 1 year
ADO case demonstration
ADO case demonstration
ADO case demonstration
ADO case demonstration

• Sizing parameters and device selection

  – General rule:
    • Pulmonary arterial end of device approximately 2mm > than narrowest diameter
    • Room for aortic retention disk
## ADO 1 Sizes

<table>
<thead>
<tr>
<th>Device Diameter at Descending Aorta</th>
<th>Device Diameter at Pulmonary Artery</th>
<th>Length</th>
<th>Minimum Recommended Sheath Size (AMPLATZER® TorqVue® Delivery System)</th>
<th>Minimum Recommended Sheath Size (AMILATZER® Delivery System)</th>
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</thead>
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<tr>
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ADO case demonstration
ADO case demonstration
ADO case demonstration
ADO2 Device

• CE mark 2013
• FDA approval August 2013

Transcatheter closure of the patent ductus arteriosus using the new Amplatz duct occluder: Initial clinical applications in children

Basil Thanopoulos, MD, PhD, Nikolaos Eleftherakis, MD, Konstantinos Tzannos, MD, and Christodoulos Stefanadis, MD, PhD. Athens, Greece.

Background In spite of recent advances in transcatheter management, the occlusion of certain anatomic types of patent ductus arteriosus (PDA), especially in infants and small children, remains a challenge. The aim of the study was to report initial human experience with transcatheter closure of PDA in 25 patients using the new Amplatz duct occluder (ADO II).

Methods The median age of the patients was 3.2 years (range 0.1-5 years), and the median weight was 10.5 kg (range 3.1-8 kg). The device used is a modified ADO II made of braided fine Nitinol wire net in a very-low-profile disk with an articulated connecting waist. Both disks are 6 mm larger than the diameter of the connecting waist. Connecting waist diameters range from 3 to 6 mm.

Results The mean PDA diameter was 3.6 ± 1.3 mm (range 0.6-5 mm). The mean device diameter (waist diameter) was 4.3 ± 1.4 mm (range 3-6 mm). Complete echocardiographic closure of the ductus at 1-month follow-up was observed in 24 (96%) of 25 patients. Immediately after the procedure, there was a mild left pulmonary stenosis (Doppler gradient of 15 mm Hg) in 2 of the 25 patients. No other complications were observed.

Conclusions The ADO II is a promising addition to our armamentarium for PDA closure. Further studies are required to document its efficacy, safety, and long-term results. (Am Heart J 2008;156:917.e1-917.e6.)
## ADO2 Device

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<th>Reorder Number</th>
<th>Waist Diameter (mm)</th>
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ADO2 CASE
AVP 2 device for PDA occlusion
Long, Tubular PDA
AVP2 Case Example
AVP2 Case Example
AVP2 Case Example
AVP2 Case Example

RAO

LAT
The Amplatzer Vascular Plug and Amplatzer Vascular Plug II for Vascular Occlusion Procedures in 50 Patients With Congenital Cardiovascular Disease

Matthew Schwartz, MD, Andrew C. Glatz, MD, Jonathan and Matthew J. Gillespie, MD

Objective: To describe the use of the amplatzer vascular plug (plug 1 and vascular plug II (plug 2) in patients with congenital cardiovascular disease. Background: Plugs 1 and 2 have recently been made available. We describe describing plugs 1 and 2 in patients with CCVD highlighting a need for these devices. Methods: All patients with CCVD who underwent a vascular occlusion procedure at the Children's Hospital of Philadelphia between August 30, 2009, with plug 1 or 2 were included. A retrospective review of medical records was performed. Results: Fifty patients underwent a vascular occlusion procedure with a median age of 2.0 years (range 1 day to 47 years) and a median weight 3.1–66 kg. Fifty-eight plugs (43% plug 1, 57% plug 2) were placed in these vessels, 20 (38%) were patent ductus arteriosus (PDA), 14 (27%) atrio-ventricular collaterals, 5 (10%) aorto-pulmonary collaterals, 4 (8%) modified Blalock-Taussig shunts, and 6 (12%) miscellaneous structures. Conclusions: Plugs 1 and 2 are safe and effective devices used in a variety of vascular occlusion procedures in patients with CCVD. Plug 2 is preferred for high-flow arterio-venous malformations and closure of high-flow, tubular structures, especially type C PDA's. Key words: pediatric interventions; collaterals; embolization; congenital heart disease.
• FDA approval 2012

• Post Approval Study
  – Test 5-year safety and efficacy
## Nit-Occlud® PDA

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<th>REF</th>
<th>Coil diameter</th>
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<td>85 cm</td>
<td>6.0 mm</td>
<td>Medium</td>
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</table>
PDA closure: where are we heading?

- Transcather PDA closure
  - Dr. Portsmann, 1967

- Transcather intervention = first line therapy for almost all PDAs

- Premie PDAs = next “frontier”??
**Conclusions:** There was a high incidence of occurrence of UVCP (67%) associated with PDA ligation in ELBW infants.

Unilateral vocal cord paralysis following PDA ligation does seem to be associated with increased requirements for tube feeding, respiratory support, and hospital stay in these ELBW infants.

Why bother with premie PDA?

LPA inadvertently clipped during surgery
Why bother with premie PDA?

• **Avoidance of operative morbidities**
  – Compromised respiratory mechanics in premies with severe BPD (pneumothorax, effusion)
  – Vocal cord issues
  – Branch PA distortion/ interruption

• **Forward march of technology** ……
  – Feasibility given new devices
  – Ongoing pursuit of least invasive solution to structural issue

• **$$ Financial considerations $$**
  – Potentially cheaper
Why bother with premie PDA?
Financial incentive

<table>
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<tr>
<th>Outcomes and hospital course</th>
<th>Study Group (n = 20)</th>
<th>Control Group (n = 18)</th>
<th>( p ) Value</th>
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<td>Age (day)</td>
<td>51.8 ± 21.1</td>
<td>39.9 ± 20.7</td>
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<td>Body weight (kg)</td>
<td>4.24 ± 1.19</td>
<td>3.79 ± 0.88</td>
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<td>PDA diameter (mm)</td>
<td>4.13 ± 0.61</td>
<td>4.42 ± 0.92</td>
<td>0.26</td>
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<td>Hospital stay (day)</td>
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<td>14.7 ± 7.7</td>
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<tr>
<td>ICU stay (day)</td>
<td>0.9 ± 1.3</td>
<td>3.4 ± 2.1</td>
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Closure of Large Patent Ductus Arteriosus in Infants

Chu-Chuan Lin, MD, Kai-Sheng Hsieh, MD*, Ta-Cheng Huang, MD, and Ken-Pen Weng, MD

<table>
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<tr>
<th>Wound infection</th>
<th>Study Group (n = 20)</th>
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<td>7/18 (38.9%)</td>
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<td>Diaphragm paralysis</td>
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<td>1/18 (5.6%)</td>
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<td>Echocardiography follow-up</td>
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<tr>
<td>Residual shunt</td>
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<td>1/18 (5.6%)</td>
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<tr>
<td>Right peripheral pulmonary stenosis</td>
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<td>0/18 (0.0%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Left peripheral pulmonary stenosis</td>
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<td>1/18 (5.6%)</td>
<td>1.00</td>
</tr>
<tr>
<td>Coarctation of aorta</td>
<td>2/20 (10%)</td>
<td>0/18 (0.0%)</td>
<td>0.49</td>
</tr>
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</table>

*(Am J Cardiol 2009;103:857–861)*

* \( p <0.05 \).
NTD = New Taiwan dollars.
Where are we now?

- Current “threshold” for transcatheter PDA closure?
  - Moving target
    - Reflecting adaptation of newer technologies
  - $\geq 10$ kg...........no problem
  - 6kg – 10kg...........no problem (usually)
  - $< 6$kg? (most would say yes, but.....
  - How small is too small?
Early experience with the Amplatzer ductal occluder for closure of the persistently patent ductus arteriosus.


N = 106
Weight: 21 (+18)

Infant PDA: Published experience

N = 439 patients
Age: 1.8 y (0.2 – 70)
Weight: 11kg (4.5 – 165)

99.7% success
Low morbidity
Zero mortality

N = 29 patients
Age: 8 (+3 months)
Weight: 6.4kg (+1.5)

86% success at 1 year
Low morbidity

N = 20 patients (≤ 3 months)
Age: 39 (13-82 days)
Weight: 4.2 (2.7-7.1 kg)

N = 62 patients (≤ 6kg)
Age: 4.7 (+2.8 months)
Weight: 4.6 (+0.9 kg)

94% success
Low morbidity
Zero mortality
How small can we go?

Transcatheter Occlusion of Patent Ductus Arteriosus in Pre-Term Infants

Edwin Francis, DM, Aril Kumar, DM
Raman Krishna Kumar, DM
Kochi, India

Objectives The aim of this study was to report the occlusion of patent ductus arteriosus (PDA) in pre-term infants weighing less than 1.5 kg.

Background Transcatheter treatment of PDA has become an attractive option in recent years, and therefore often not considered for pre-term infants less than 1.5 kg, requiring medical treatment.

Methods Coil occlusion was offered to eight (N = 8 patients) pre-term infants weighing on average 1.1 kg (0.9 – 1.8 kg) and the anticipated coil size required for PDA occlusion was achieved with catheter manipulation within the catheterization laboratory.

Results Eight pre-term infants weighing 1.1 kg (0.9 – 1.8 kg) were included in the study. Complete occlusion of the duct was achieved with no complications and the expected results were achieved. No complications were noted during the procedure.

Conclusion It is technically feasible to occlude PDA using pre-cut coils in selected symptomatic pre-term infants weighing less than 1.5 kg.

Weight = 1.1 (0.9 – 1.8 kg)
Femoral venous access only
Coils
Success 7/8 (88%)
No complications
Figure 2. Angiographic Demonstration of the PDA Before and After Coil Occlusion

(A) A lateral-view angiogram of the patent ductus arteriosus (PDA) obtained by hand injection through the side arm of a 4-F introducer sheath placed across the PDA with a guidewire in the descending aorta (Online Video 2). This allows precise definition of the duct anatomy with small volumes of contrast. The white arrows indicate the pulmonary arterial end of the PDA. Retaining the guidewire allows precise and stable positioning of the sheath tip in the duct ampulla. The PDA is first crossed, before positioning the sheath, with a glide-wire alone (Online Video 1). This technique eliminates the need for an arterial puncture to obtain angiograms of the duct before coil occlusion. (B) Shows a lateral-view aortic angiogram obtained by a forceful injection of diluted contrast in the femoral arterial cannula after deployment of the coils (Online Video 5). The coil delivery sequences are shown in Online Videos 3 and 4. The coil mass in ampulla is seen. There is minimal protrusion of the coil in the pulmonary artery. Excessive protrusion of coils in the pulmonary artery can potentially result in stenosis of the origin of left pulmonary artery. Abbreviations as in Figure 1.
Our Approach evolved along with Devices

- Amplatzer family of devices

- Amplatzer Duct Occluder
  - FDA approved 2004

- AVP 1

- AVP2
ADO 1 case

Aortic retention
disc = 9-10 mm

<table>
<thead>
<tr>
<th>Device Diameter at Descending Aorta</th>
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Case example Amplatz Ductal Occluder

3 kg
Ex 23 week premie
Tri 21
Severe BPD
PHN
Failed indocin
Oscilator
ADO case

10mmHg gradient
ADO case

20mmHg gradient
### AVP 1

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<td>100 cm</td>
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FDA Approved 2004
2.3 kg
Ex 23 week premie
Severe BPD + Numerous comorbidities
Failed indocin
Conventional ventilator with high MAP
AVP 1 case

2.3 kg
Ex 23 week premie
Severe BPD + Numerous comorbidities
Failed indocin
Conventional ventilator with high MAP
2.3 kg
Ex 23 week premie
Severe BPD + Numerous comorbidities
Failed indocin
Conventional ventilator with high MAP
AVP 1 case

brisk flow through 6mm AVP 1
PEDIATRIC AND CONGENITAL HEART DISEASE

New Device for Percutaneous Closure of Aorti

INTRODUCTION

A variety of techniques/devices for congenital heart disease have been developed and applied in different parts of the world to correct congenital heart disease. Recently, infantile congenital heart disease therapy has been a focus of attention among pediatric cardiologists around the world. The Amplatzer Occluder (AOG Medical, Golden Valley, MN), a non-surgical, percutaneous device, is used to close atrial septal defects (ASD). This device consists of a nitinol wire and a nitinol mesh, which are attached to the ends of the wire. The wire is then advanced through the catheter to the desired position in the heart, where it is anchored. The nitinol mesh is then deployed, creating a seal that occludes the ASD.

Device and Delivery System

The Amplatzer vascular plug (AVP; AOG Medical; Golden Valley, MN) is a self-expanding device made of 144 nitinol wires that are joined together at the tips. The device is currently available in sizes up to 12 mm. The AVP is used to close defects in the aorta, including patent ductus arteriosus (PDA) and ventricular septal defects (VSD). It is delivered through a 9F delivery catheter and is deployed using a snare.

CASE REPORT

A 12-month-old boy weighing 10.5 kg was noted to have a heart murmur in early infancy. At 3 months of age, an echocardiogram confirmed a PDA. The patient was referred for possible closure of the PDA. The AVP was placed through a 9F delivery catheter and deployed using a snare. The PDA was successfully closed, and the patient was discharged the same day.

Case Reports

Novel Use of the Amplatzer of a Patent Ductus

Mark H. Hoye

We report the novel use of an Amplatzer vascular plug device in a small child. The device was used to successfully close a large PDA in a neonate.

Background

The AMPLATZER Vascular Plug (AVP; AOG Medical, Golden Valley, MN) is a percutaneous device for occluding intracardiac defects in the peripheral circulation. It consists of a nitinol wire and a nitinol mesh, which are attached to the ends of the wire. The wire is then advanced through the catheter to the desired position in the heart, where it is anchored. The nitinol mesh is then deployed, creating a seal that occludes the defect.

Conclusion

The AVP is a safe and effective device for closing defects in the aorta, including patent ductus arteriosus (PDA) and ventricular septal defects (VSD). Its use in neonates and infants is increasing, and it is proving to be a valuable tool in the treatment of congenital heart disease.
AVP in infants

Case Reports

Novel Use of the
of a Patent

INTRODUCTION

Transcatheter closure of patent ductus arteriosus (PDA) has become a standard procedure in pediatric interventional cardiologists. Currently, the only device that is designed and approved for use in closing the PDA in the United States is the Amplatz occluder [1]. However, other devices are also available, including the transapical technique, the Amplatz septal (AGA Medical, Golden Valley, MN), and the Gianturco-Russell vascular device (Cook, Bloomington, IN). The Amplatz septal (AGA Medical, Golden Valley, MN) and Gianturco-Russell vascular device (Cook, Bloomington, IN) are FDA-approved devices for closure of the PDA.

CASE REPORT

A 12-month-old boy weighing 10.5 kg was born with a heart murmur in early infancy, and an echocardiogram confirmed a PDA. Initial cardiology evaluation was at 7 months of age, when a grade II/IV murmur and increased pulses were noted. An X-ray showed mild to moderate cardiomegaly.

2 weeks post AVP1

Severe residual left-to-right flow
AVP 1 case: Modified Plug

2006
AVP 1 case: Modified Plug
AVP 1 case:
Modified Plug
AVP 1 case:
Modified Plug

• By echo it worked

• We repeated this procedure a handful of times

• But AVP2 made this unnecessary
<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>3 mm</td>
<td>6 mm</td>
<td>1.42 mm (0.056 in)</td>
<td>4 French</td>
<td></td>
<td>5 French</td>
<td>100 cm</td>
</tr>
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<td>4 mm</td>
<td>6 mm</td>
<td>1.42 mm (0.056 in)</td>
<td>4 French</td>
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<td>100 cm</td>
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<td>4 French</td>
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<td>100 cm</td>
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<td>7 mm</td>
<td>1.42 mm (0.056 in)</td>
<td>4 French</td>
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<td>5 French</td>
<td>100 cm</td>
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<tr>
<td>10 mm</td>
<td>7 mm</td>
<td>1.78 mm (0.070 in)</td>
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<td>6 French</td>
<td>100 cm</td>
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<td>12 mm</td>
<td>9 mm</td>
<td>1.78 mm (0.070 in)</td>
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<td>100 cm</td>
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<tr>
<td>14 mm</td>
<td>10 mm</td>
<td>2.18 mm (0.086 in)</td>
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<td>8 French</td>
<td>100 cm</td>
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<tr>
<td>16 mm</td>
<td>12 mm</td>
<td>2.18 mm (0.086 in)</td>
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<td>8 French</td>
<td>100 cm</td>
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<tr>
<td>18 mm</td>
<td>14 mm</td>
<td>2.49 mm (0.098 in)</td>
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<td>9 French</td>
<td>100 cm</td>
</tr>
<tr>
<td>20 mm</td>
<td>16 mm</td>
<td>2.49 mm (0.098 in)</td>
<td>7 French</td>
<td></td>
<td>9 French</td>
<td>100 cm</td>
</tr>
<tr>
<td>22 mm</td>
<td>18 mm</td>
<td>2.49 mm (0.098 in)</td>
<td>7 French</td>
<td></td>
<td>9 French</td>
<td>100 cm</td>
</tr>
</tbody>
</table>

FDA Approved 2007
AVP 2

2.9 kg
AVP 2

4mm AVP2

2.9 kg
AVP 2

Device release

2.9 kg
AVP 2

Post release

2.9 kg
AVP 2

2.9 kg

Post release: RAO view
AVP 2

4mm
AVP2

2.9 kg
AVP 2 case 2

2.2 kg
AVP 2 case 2

6mm AVP2

2.2 kg
AVP 2 case 2

2.2 kg
AVP 2 case 2

6mm
AVP2

2.2kg
AVP 2: limitations
AVP 2: limitations

8 mm AVP2 causing LPA stenosis

2.4 kg
Percutaneous Closure of Patent Ductus Arteriosus in Small Infants With Significant Lung Disease May Offer Faster Recovery of Respiratory Function When Compared to Surgical Ligation

Anas A. Abu Hazeem, MD, Matthew J. Gillespie, MD, Haley Thun, MPH, David Munson, MD, Matthew C. Schwartz, MD, Yoav Dori, MD, PhD, Jonathan J. Rome, MD, and Andrew C. Glatz, MD, MSCE

Objectives: To describe our experience with percutaneous closure of patent ductus arteriosus (PDA) in small infants and compare outcomes to matched surgical patients. Background: Ligation via thoracotomy has been used to close PDAs in small infants, but has been associated with respiratory and hemodynamic compromise. We hypothesized that percutaneous closure would offer faster recovery of respiratory function. Methods: Patients <4 kg requiring positive pressure ventilation who underwent percutaneous PDA closure between January 2000 and April 2012 were reviewed and matched to contemporary surgical patients on gestational age (GA), birth weight (BW), procedure weight (WT), and ventilation mode. Patients returned to baseline respiratory status when the product of mean airway pressure and FIO2 returned to pre-procedural levels. Results: Eight matched pairs were included. Median BW, GA, and WT were 1.43 kg (0.62–2.97), 28.8 weeks (24–38), and 2.8 kg (2.2–3.8) for catheter patients and 1.55 kg (0.48–5.04), 29 weeks (29–37), and 2.75 kg (2.3–4.2) for surgical patients. Complete PDA closure occurred in all. The median time to return to baseline respiratory status was significantly shorter in the percutaneous group (17 hr (range 0–113) vs. 53 hr (range 13–219), P<0.05). In the percutaneous group, two patients developed mild aortic coarctation, one mild left pulmonary artery stenosis, and four femoral vascular thromboses which all resolved with medical therapy. Surgical complications included significant respiratory and cardiac compromise, rib fractures and urinary retention. Conclusions: Percutaneous closure of PDA in small infants on respiratory support is equivalent in safety and efficacy and may offer shorter recovery time than surgical ligation.

Key words: PDA; catheter; premature
**RSS** = mean airway pressure $\times$ fractional inspired oxygen

Baseline RSS = mean of values calculated at these 5 time points

"Return to baseline" = time from patient return to inpatient unit to time RSS was $\leq$ baseline RSS and remained there for $\geq$ 6 hrs

---

**Fig. 1.** The typical course of respiratory status prior to and after intervention. Time points where RSSs were collected are shown. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]
<table>
<thead>
<tr>
<th>MP</th>
<th>MV</th>
<th>BW (g)</th>
<th>GA (weeks)</th>
<th>PW (kg)</th>
<th>BW (g)</th>
<th>GA (weeks)</th>
<th>PW (kg)</th>
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<tr>
<td>1</td>
<td>BIPAP</td>
<td>520</td>
<td>27.0</td>
<td>2.2</td>
<td>640</td>
<td>25.7</td>
<td>2.3</td>
</tr>
<tr>
<td>2</td>
<td>VENT</td>
<td>850</td>
<td>26.1</td>
<td>2.8</td>
<td>604</td>
<td>26.0</td>
<td>2.8</td>
</tr>
<tr>
<td>3</td>
<td>VENT</td>
<td>530</td>
<td>26.6</td>
<td>3.4</td>
<td>992</td>
<td>26.0</td>
<td>4.2</td>
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<tr>
<td>4</td>
<td>VENT</td>
<td>2,551</td>
<td>39.0</td>
<td>3.9</td>
<td>2,570</td>
<td>37.0</td>
<td>3</td>
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<tr>
<td>5</td>
<td>VENT</td>
<td>2,000</td>
<td>32.6</td>
<td>3.8</td>
<td>2,136</td>
<td>32.0</td>
<td>2.5</td>
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<tr>
<td>6</td>
<td>CPAP</td>
<td>690</td>
<td>24.0</td>
<td>2.7</td>
<td>482</td>
<td>23.0</td>
<td>2.6</td>
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<tr>
<td>7</td>
<td>CPAP</td>
<td>2,965</td>
<td>38.0</td>
<td>2.8</td>
<td>3,040</td>
<td>37.0</td>
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<tr>
<td>8</td>
<td>VENT</td>
<td>2,030</td>
<td>34.1</td>
<td>2.2</td>
<td>2,105</td>
<td>34.6</td>
<td>2.9</td>
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</table>

BIPAP, bilevel positive airway pressure; BW, birth weight; CPAP, continuous positive airway pressure; ELBW, extremely low birth weight; g, gram; GA, gestational age; kg, kilogram; LBW, low birth weight; MP, matched pair; MV, mode of ventilation; PW, procedure weight; VENT, traditional mechanical ventilation; wks, weeks.
### TABLE III. Comparison of Treatment Groups

<table>
<thead>
<tr>
<th></th>
<th>Percutaneous cases (n = 8)</th>
<th>Surgical controls (n = 8)</th>
<th>P</th>
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<tbody>
<tr>
<td>Gestational age (weeks)</td>
<td>29.8 (24–38)</td>
<td>29 (23–37)</td>
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<tr>
<td>Birth weight (kg)</td>
<td>1425 (520–2965)</td>
<td>1549 (482–3040)</td>
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<tr>
<td>Weight at procedure (kg)</td>
<td>2.8 (2.2–3.9)</td>
<td>2.75 (2.3–4.2)</td>
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<tr>
<td>Age at Procedure (months)</td>
<td>3.7 (1–5.3)</td>
<td>1.4 (0.2–4.2)</td>
<td>0.07</td>
</tr>
<tr>
<td>Complete PDA occlusion</td>
<td>8 (100%)</td>
<td>8 (100%)</td>
<td>NS</td>
</tr>
<tr>
<td>Peri-procedural complication</td>
<td>7</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>Baseline RSS</td>
<td>440 (130–1436)</td>
<td>262 (144–606)</td>
<td>0.09</td>
</tr>
<tr>
<td>Time to return to baseline RSS (hr)</td>
<td>17 (0–113)</td>
<td>53 (13–219)</td>
<td>&lt;0.05</td>
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<tr>
<td>Procedural mortality</td>
<td>0</td>
<td>0</td>
<td>NS</td>
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<tr>
<td>Late mortality</td>
<td>2</td>
<td>3</td>
<td>NS</td>
</tr>
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</table>

Data presented as median (range) or count (percentage of total).
h, hours; kg, kilogram; NS, not significant; PDA, patent ductus arteriosus; RSS, respiratory severity score.

Catheterization and Cardiovascular Interventions DOI 10.1002/ccd.
Published on behalf of The Society for Cardiovascular Angiography and Interventions (SCAI).
Fig. 4. Time to return to baseline RSS in percutaneous cases compared to their matched surgical controls. [Color figure can be viewed in the online issue, which is available at wileyonlinelibrary.com.]
AVP4 in PDAs?

<table>
<thead>
<tr>
<th>Device Diameter (mm)</th>
<th>Unconstrained Length (mm)</th>
<th>Diagnostic Catheter*</th>
<th>Required Guidewire Compatibility of Catheter** (inch)</th>
<th>Maximum Length*** (cm)</th>
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</thead>
<tbody>
<tr>
<td>4</td>
<td>10.00</td>
<td></td>
<td>0.038</td>
<td>100</td>
</tr>
<tr>
<td>4 mm</td>
<td>10.5</td>
<td></td>
<td>0.038</td>
<td>100</td>
</tr>
<tr>
<td>6 mm</td>
<td>11.00</td>
<td>4Fr Cordis Tempo® OR 4Fr Cordis Tempo® Aqua™ OR</td>
<td>0.038</td>
<td>100</td>
</tr>
<tr>
<td>8 mm</td>
<td>12.5</td>
<td>5Fr Boston Scientific Imager™ II</td>
<td>0.038</td>
<td>100</td>
</tr>
<tr>
<td>10 mm</td>
<td>13.5</td>
<td></td>
<td>0.038</td>
<td>100</td>
</tr>
</tbody>
</table>
Future Devices (USA)
ADO2 AS?
Catheterization and Cardiovascular Interventions 00:00-00 (2013)

Original Studies

Ductal Spasm During Performance of Transcatheter Ductal Occlusion

Sarosh P. Bativala,1,2,3,4 MD, Andrew C. Glatz,1,2 MD, MSCE, Matthew J. Gillespie,1,2 MD, Yoav Dori,1,2 MD, PhD, and Jonathan J. Rome,1,2 MD

Objectives: Transcatheter patent ductus arteriosus (PDA) occlusion is a staple of pediatric catheterization laboratories. We present the phenomenon of significant PDA spasm to prevent failure to occlude a hemodynamically significant duct. Background: Transcatheter techniques have evolved, allowing safe and effective occlusion of PDAs in younger and smaller patients. Neonatal care is evolving with increasing survival at younger gestational ages. Premature infants often have PDAs, so the proportion of formerly premature children referred for transcatheter ductal occlusion will likely rise.

Methods: We reviewed all transcatheter PDA occlusions performed at our institution since 2001 (N = 331). Retrospective data included: gestational age, age at catheterization, precatheterization echocardiographic parameters, PDA size (after spasm relief), device specifications, and most recent follow-up data. Results: Seven cases were identified. Median age was 12 months, median gestational age was 28 weeks. All were born prematurely. All PDAs were restrictive and six had left-heart volume overload. All patients were examined by the interventional cardiologist and had ductal murmurs. When reascultated (three of seven), murmurs were absent during spasm. None of the patients required additional sedation. All patients accommodated a 6-mm- or larger-Amplatzer device. No significant complications occurred and all patients were well at follow-up. Conclusion: Ductal spasm occurs during transcatheter occlusion and may be an unrecognized cause of procedural failure. The phenomenon seems to occur in children born prematurely, and can occur after infancy. Loss of a continuous murmur confirms the diagnosis. Care should be taken to avoid device undersizing when spasm occurs.

Key words: ductus arteriosus; patent; heart defects; congenital; prematurity; amplatz occluder device
Summary

• Transcather PDA closure is feasible in premature infants
  – down to 2kg with AVP2
  – 1kg with coils (yikes)
  – AVP4 and ADO2 AS may push the amplatzer family of devices into smaller infants.

• Theoretical advantages include
  – No thoracotomy therefore management of CLDz is not set back significantly (NICU staff)
  – Can be performed venous access only to minimize arterial trauma
  – Financials $$
Thank You
CHOP experience 2007 – 2013
< 4kg

- 20 patients
- Age 93 (24-160 days)
- Weight 2.5 (2.0 – 3.9 kg)
- Successful closure in 17 (83%)
  - 13 AVP 2
    - 3 – 8 mm diameter
  - 3 modified AVP 1
  - 1 ADO (6/4)
    - Residual coarctation

Matthew C. Schwartz MD
Jonathan J. Rome MD
Andrew C. Glatz MD
Yoav Dori MD PhD
• Complications
  – Coarctation in 1
  – Femoral artery clot in 2
The Amplatzer Vascular Plug and Amplatzer Vascular Plug II for Vascular Occlusion Procedures in 50 Patients With Congenital Cardiovascular Disease

Matthew Schwartz,* MD, Andrew C. Glatz, MD, Jonathan J. Rome, MD, and Matthew J. Gillespie, MD

Objective: To describe the use of the amplatzer vascular plug (plug 1) and amplatzer vascular plug II (plug 2) in patients with congenital cardiovascular disease (CCVD).

Background: Plugs 1 and 2 have recently been made available. We report our experience describing plugs 1 and 2 in patients with CCVD highlighting the versatility of these devices. Methods: All patients with CCVD who underwent a vascular occlusion procedure at the Children's Hospital of Philadelphia between August 1, 2004 and July 30, 2009 with plug 1 or 2 were included. A retrospective review was performed. Results: Fifty patients underwent vascular occlusion procedure with plug 1 or 2 at a median age of 2.0 years (range 1 day to 47 years) and median weight of 12.3 kg (range 3.1–98 kg). Fifty-eight plugs (49% plug 1, 57% plug 2) were placed in 52 vessels. Of these vessels, 20 (30%) were patent ductus arteriosus (PDA), 14 (27%) venous collaterals, 5 (10%) aorto-pulmonary collaterals, 4 (8%) modified Blalock Taussig shunts, 3 (5%) porto-systemic connections, and 6 (12%) miscellaneous structures. Excluding a patient who was lost to follow-up, complete occlusion was observed in 100% of vessels either at the time of the catheterization or at follow-up. There were two complications (3.8%). Conclusions: Plugs 1 and 2 are safe and effective devices that can be used in a variety of blood vessels in patients with CCVD. Plug 2 is particularly useful in closure of high-flow, tubular structures, especially type C PDA's.

Key words: pediatric interventions; collaterals; embolization; congenital heart disease in adults; patent ductus arteriosus
<table>
<thead>
<tr>
<th>Site of intervention</th>
<th>No. of vessels</th>
<th>No. of devices</th>
<th>Age(^a)</th>
<th>wt.(^a) (kg)</th>
<th>Vessel diameter(^a) (mm)</th>
<th>Device diameter(^a) (mm)</th>
<th>CO on Angio or F/U (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>PDA</td>
<td>20</td>
<td>Plug 1 (n = 6)</td>
<td>1.6 yrs</td>
<td>10.7</td>
<td>3.75(^b)</td>
<td>6</td>
<td>20 (100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plug 2 (n = 14)</td>
<td>(3 mos–4 yrs)</td>
<td>(2.8–17.7)</td>
<td>(2–6)</td>
<td>(3–10)</td>
<td></td>
</tr>
<tr>
<td>Venous Collateral</td>
<td>14</td>
<td>Plug 1 (n = 9)</td>
<td>11.9 yrs</td>
<td>36.9</td>
<td>6</td>
<td>10</td>
<td>13 (93)(^c)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plug 2 (n = 10)</td>
<td>(10 mos–47 yrs)</td>
<td>(7.4–98)</td>
<td>(4–12)</td>
<td>(6–16)</td>
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<tr>
<td>AP Collateral</td>
<td>5</td>
<td>Plug 1 (n = 1)</td>
<td>2.0 yrs</td>
<td>9.7</td>
<td>3.5</td>
<td>7</td>
<td>5 (100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plug 2 (n = 5)</td>
<td>(2 mos–21 yrs)</td>
<td>(3.8–76)</td>
<td>(3–12)</td>
<td>(4–18)</td>
<td></td>
</tr>
<tr>
<td>Modified BT Shunt</td>
<td>4</td>
<td>Plug 1 (n = 2)</td>
<td>2.5 yrs</td>
<td>15.9</td>
<td>2.75</td>
<td>4</td>
<td>4 (100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plug 2 (n = 2)</td>
<td>(14 mos–4 yrs)</td>
<td>(10.7–18.7)</td>
<td>(2.5–4)</td>
<td>(4–6)</td>
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<tr>
<td>Porto-systemic</td>
<td>3</td>
<td>Plug 1 (n = 3)</td>
<td>8 mos</td>
<td>5.5</td>
<td>5</td>
<td>8</td>
<td>3 (100)</td>
</tr>
<tr>
<td>Communication</td>
<td></td>
<td>Plug 2 (n = 0)</td>
<td>(1–8 mos)</td>
<td>(3.5–7.4)</td>
<td>(5–7)</td>
<td>(8–10)</td>
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<tr>
<td>Miscellaneous</td>
<td>6</td>
<td>Plug 1 (n = 4)</td>
<td>4.3 mos</td>
<td>14.8</td>
<td>5</td>
<td>8</td>
<td>6 (100)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Plug 2 (n = 2)</td>
<td>(1 day–21 yrs)</td>
<td>(3.1–76)</td>
<td>(4.5–10)</td>
<td>(6–14)</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>52</td>
<td>58</td>
<td>2.0 yrs</td>
<td>12.3</td>
<td>4.3</td>
<td>6</td>
<td>51 (98)(^d)</td>
</tr>
</tbody>
</table>

Angio, angiography; AP, aorto-pulmonary; BT, blalock taussig; CO, complete occlusion; F/U, follow-up imaging; kg, kilogram; mos, months; PDA, patent ductus arteriosus; Wt, weight; yrs, years.

\(^a\)Median values with range reported.

\(^b\)Mid PDA diameter.

\(^c\)Includes one patient with occlusion of veno-atrial collateral and residual flow on angiography whose subsequent saturations suggest complete occlusion of vessel.

\(^d\)The single patient without complete occlusion had residual flow on angiography and was lost to follow-up.