

AMPLATZER® PDA Occluder Case Study

Transcatheter PDA closure of 68 year-old, 63 years after surgical PDA closure

John L. Bass, M.D.

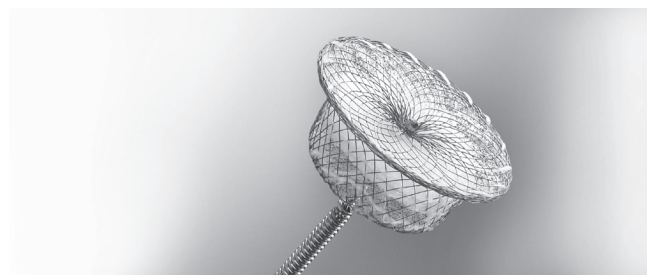
Associate Professor
Department of Pediatrics
University of Minnesota Medical Center, Fairview
Minneapolis, Minnesota

History

In 1943, a then 5 year-old female patient presented with a moderate sized (2 to 4 mm) Patent Ductus Arteriosus (PDA), demonstrating symptoms of fatigue, reduced stamina, and some difficulty breathing with physical activity. The subject was one of the very first patients in the world to undergo open heart surgical closure of her PDA. She underwent the procedure at the University of Minnesota. In that procedure, ligatures were tied around the PDA to occlude the communication. Three years later, she was diagnosed as having a residual patent ductus, presumably from re-canalization caused by loosening of the ligature and/or growth of the heart structures. She underwent further diagnostic studies at age fifteen, but it was determined her condition did not warrant further intervention at that time.

Physical Exam

Currently, the 68 year-old patient weighs 67 kg, height of 147 cm. Heart beat was 72/min with respiration of 14/min at rest. Blood pressure was 159/64, and she was warm and well perfused. A 2/6 systolic murmur was evident at the upper left sternal border.



Second heart sound was physiologically split with a normal pulmonary component and peripheral pulses at 2+, equal bilaterally. Left-side cardiac structure was enlarged. The patient was alert and in no distress. PDA closure was recommended to resolve her fatigue, reduce volume load and reduce risk of bacterial endocarditis.

Procedure

The patient was prepped for access at the right and left groins, fasting with conscious sedation. FiO₂ was 0.21. Buffered Xylocaine was injected locally and the left femoral artery was entered with a 5Fr sheath. Right femoral vein access was gained using a 7Fr sheath. 2,000 units of heparin was administered intravenously. A 7Fr endhole balloon catheter was advanced through the right femoral access to the superior vena cava. Pressure oximetry series were performed sampling the superior vena cava, right atrium, right ventricle, left pulmonary artery, and wedge positions.

A 4Fr pigtail catheter was inserted via the left arterial access and advanced to the left ventricle. Pressure at the descending aorta was measured during withdrawal, the pigtail was removed and replaced with a 4Fr JB1 glide catheter. A 0.025" Bentson guidewire was advanced through the ductus into the main pulmonary artery. The Bentson guidewire was snared using a 20mm AMPLATZ GOOSE NECK® Snare

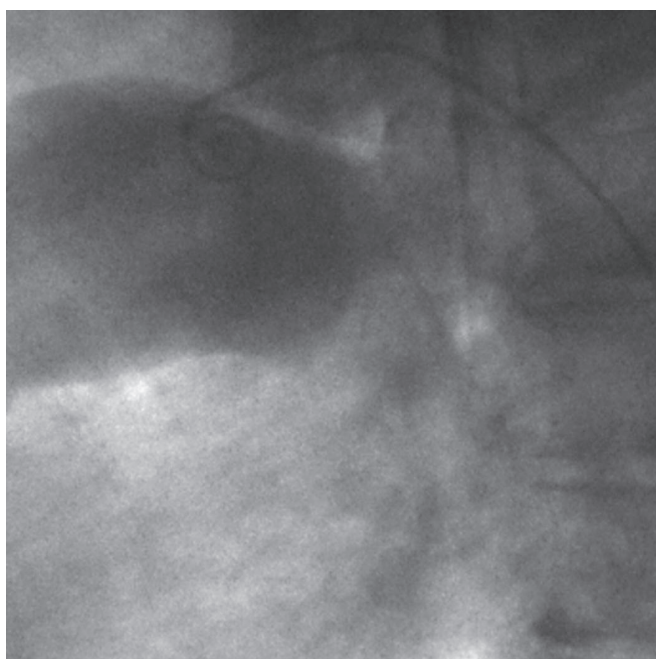
from the main pulmonary artery. The 4Fr JB1 catheter was replaced by a 4Fr pigtail catheter, which was pulled through the ductus to the right ventricle. An 0.035" guidewire was advanced through the pigtail catheter, snared and pulled out the left femoral sheath creating an arteriovenous loop. The 5Fr sheath at the left access point was removed, and an AMPLATZER® 6Fr Delivery Catheter was advanced over the guidewire through the ductus to the descending aorta. After confirmation of the distal delivery catheter position, the 0.035" guidewire and dilator were removed.

An 8 mm AMPLATZER® Duct Occluder, with an 8 mm diameter at the distal edge and 6 mm diameter at the proximal edge (8/6) device was advanced to the distal end of the delivery catheter using the delivery cable with screw attachment for AMPLATZER occlusion devices. The distal retaining skirt and distal portion of the device were expanded by pulling back on the delivery catheter under fluoroscopy. The catheter and delivery cable were pulled back together to seat the retaining

skirt in the aortic ductus ampulla, and the delivery catheter was then pulled back to expand the Duct Occluder proximal portion in the ductus.

An aortogram was performed with vertical tube 30° RAO and horizontal tube 90° lateral with injected 20cc Optiray 350 at 15 cc/sec. Imaging showed complete occlusion at the PDA site. The Duct Occluder was released by unscrewing the delivery cable from the device. A second aortogram was performed with vertical tube 30° RAO and horizontal tube 90° lateral with injected 20cc Optiray 350 at 15 cc/sec, confirming occlusion at the aortic ampulla location.

A 7Fr endhole balloon catheter was advanced to the left pulmonary artery. Oximetry was performed sampling from the left and main pulmonary arteries and the aorta. 8 mg Protamine was injected and an ACT was performed for 153 seconds. Sheaths and catheters were removed and hemostasis was achieved at both access sites with compression.



Contrast to main pulmonary artery.

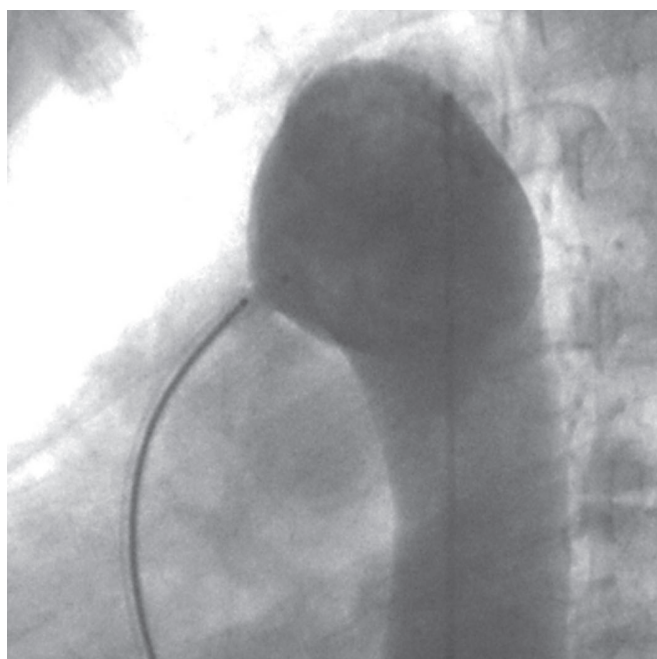


Shunt to Pulmonary Artery observed pre-procedure.

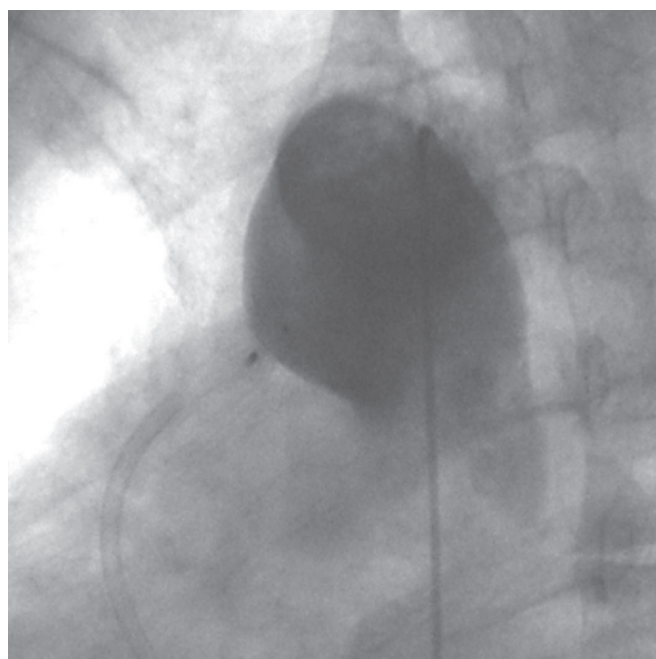
Post Procedure and Follow-Up

Comparative calculations of key measures pre and post procedure indicated successful closure and improvement to bloodflow, cardiac output and oxygenation.

Hemodynamic Tests	Baseline Pre-PDA Closure	Directly Post-PDA Closure
QpQs	1.55/1	1.0/1
SVC O2 Saturation	69%	72%
MPA	53/23, m=35 O2 Sat 79%	32/11, m=19
LPA	53/22, m=36	35/12, m=20 O2 Sat 70%
LLLW	a=18, m=14	a=8, m=6
Dao/Ao	DAo 191/71, m=117 O2 Sat 97%	Ao 188/79, m=120 O2 Sat 92%



Distal portion of Duct Occluder expanded and in the ampulla.



Entire Occluder expanded in the communication with cessation of shunt.

PDA Case Study: A Patient's Perspective

Merrilyn Dawson clearly remembers her life before her first surgical PDA closure, and the surgery itself. Because the surgery was one of the first done around the world, the story made the St. Paul newspaper when the surgery was performed in June of 1943.



"I spent a lot of time getting oxygen and laying in bed, and I was frequently ill before I had that first surgery" says Merrilyn, "The doctors didn't think that I would live beyond a few years old." Merrilyn remembers how difficult and painful the first surgery was in 1943, but she also remembers the huge difference it made in her life.

"The surgery was scary and I was in a lot of pain directly afterward, but after my recovery from the surgery, I was able to be a pretty normal little girl. Before, my heart pounded like a hammer, and even a tiny bit of extra movement felt like I had run a marathon. After the surgery, I was very active and could play like other kids."

At age eight, a check-up after a bad case of measles showed her PDA had re-opened, but with further tests at age 15 using an early version of a catheterization procedure, it was decided to not treat her for the condition at that time. The duct was partially open but not to the degree it was at her surgery, and the risks seemed higher than the benefits of doing another surgical closure. "That catheter procedure when I was fifteen was really horrible. I had a bad reaction to the contrast they used, and it was really uncomfortable with a burning sensation in my whole body."

Merrilyn, now a retired school teacher in the Twin Cities, Minnesota, began to feel fatigued and prone to shortness of breath as she moved into her sixties, but just considered it a sign of growing older. Her family encouraged her to get it checked out. "My daughter was really the one who pushed me. With all the advances in medicine, she told me there was no reason to not get it looked into."

After the diagnosis that the partially open ductus arteriosus was causing her symptoms, she was a little apprehensive about another catheter procedure, but decided to proceed. "I've had a number of other treatments for other health reasons, and Dr. Bass walked me through this procedure. It sounded pretty straightforward and might do some good, so I went for it."

The catheter placement of the AMPLATZER Duct Occluder went very well, and Merrilyn was home the same day after the morning procedure. She had only mild discomfort from the femoral access and a much milder reaction to the contrast injections. "The doctors and staff at the University of Minnesota Clinic were wonderful too," relates Merrilyn, "They were efficient and attentive, and made me feel very confident they were doing everything they could to keep me comfortable. I wish every time I saw a doctor, it was as good as that!"

Merrilyn now does the activities she wants to do. "I'm taking brisk walks with my husband, up on my feet a lot more and just feel a lot more energetic all around. I sing in my church choir, and I used to have to gulp for air after even a couple verses. I'm keeping up with the choir a lot better now, and it's great to jump up to be with my family and friends without a second thought."



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Via Nerviano, 31
20020 Lainate (Mi)
tel. +39 02 93305.1
fax +39 02 93305.400
www.abmedica.it

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