Surgery for PDA via a thoracotomy or videoscopic approach is safe, with no mortality. However, there is significant morbidity (scar, hospitalization for 2 to 4 days, and recurrent laryngeal nerve palsy) and the closure rate is not 100 percent.

The era of nonsurgical transcatheter closure of PDA began in 1967 using an Ivalon plug. The large introducer size needed to insert the plug (18F) precluded the use of this device in most pediatric patients. However, the feasibility of nonsurgical closure of PDA was demonstrated. Subsequently, few devices have been used to close the ductus, including the Rashkind umbrella and the buttoned device; all had relatively good results. However, the incidence of residual shunting and the high cost of these devices discouraged cardiologists from using them and they were not approved by the US Food and Drug Administration.


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Nonsurgical Closure of the Persistent Patent Ductus Arteriosus

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Patent ductus arteriosus (PDA), a communication between the aorta and pulmonary artery, is a common form of congenital heart disease that accounts for approximately 10 percent of all forms of this disease. It can present in infancy with congestive heart failure, can be an incidental finding in children and young adults, and can cause congestive heart failure and pulmonary vascular obstructive disease in the adult population. The annual risk of bacterial endocarditis in patients with PDA is estimated to be 0.45 percent per year.

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Figure 1. The Amplatzer duct occluder is mushroom shaped, made from nitinol wire, and available in many different sizes. This device is user/patient friendly; can be repositioned and retrieved prior to its release from the cable; requires a small delivery catheter; and achieves a high rate of complete closure in patent ductus arteriosus.
Recently, we reported on a new technique of nonsurgical device closure of PDA with very good results.\(^5\) The Amplatzer duct occluder, (AGA Medical, Golden Valley, Minn.) was the device used. It is mushroom shaped, made from nitinol wire, and available in many different sizes (6-4 mm; 8-6 mm; 10-8 mm; 12-10 mm; 14-12 mm; and 16-14 mm). The device requires a 5 to 7F sheath for delivery (Figure 1, p.11). This device has major advantages when compared with any other similar device: It is user/patient friendly; can be repositioned and retrieved prior to its release from the cable (a very important feature); requires a small delivery catheter (an important feature in small infants); and achieves a high rate of complete closure.

The procedure usually starts in the morning after local anesthesia is given in the groin, where catheters are inserted. Pressure measurements and angiograms are performed to assess the size and shape of the ductus. Then the proper-size device is chosen and inserted under x-ray guidance via the same catheters into the ductus. Repeat measurements and angiograms are done to verify closure before the patient leaves the laboratory. Figure 2 shows the large PDA of a 13-month-old infant. The PDA measured approximately 4 mm at its narrowest diameter. The infant had been experiencing pulmonary artery hypertension and failure to thrive. This ductus was closed completely using the Amplatzer device.

After ensuring complete closure, catheters are taken out and hemostasis is obtained with a bandage. The procedure, on average, takes 10 minutes of fluoroscopy. Then the patient recovers for approximately 3 to 4 hours and is discharged from the hospital on the same day of the procedure. Patients usually can resume their normal activities the following day. We follow up with patients after 6 weeks, and yearly thereafter.

I have performed more than 300 nonsurgical closures of PDA using devices and coils, with excellent results and a complete closure rate of 98 percent. Our patients range in age from 2 weeks to 70 years and in weight from 2.3 kg to 95 kg. Complications are very rare. Loss of femoral pulse is the most common complication. This occurs in smaller infants. We have not had any device embolization. No patient has required any blood transfusion.

We have taught this technique to physicians in the United States and abroad. A phase II clinical trial of PDA closure using the
UPDATE: The Amplatzer Duct Occluder device has been FDA-approved for the nonsurgical closure of patent ductus arteriosus (PDA).

Amplatzer device is under way. The University of Chicago Children’s Hospital is the only medical center in Illinois involved in this trial approved by the Food and Drug Administration.

Dr. Hijazi is the chairman of the phase II clinical trial. To refer patients, please call Dr. Hijazi at (773) 702-6172.

REFERENCES