



New and Emerging Techniques - Surgical

Rapid Review

Intraluminal Closure of Patent Ductus Arteriosus in Infants

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**Australian
Safety
and Efficacy
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Surgical**

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College of Surgeons**

NET-S Rapid Review Summary

Intraluminal Closure of Patent Ductus Arteriosus in Infants

- Patent Ductus Arteriosus (PDA) is where the ductus arteriosus, a blood vessel that connects the pulmonary artery to the aorta (necessary *in utero*), does not close after birth.
- Small PDAs may produce no symptoms, but larger PDA can lead to heart failure, pulmonary vascular obstructive disease or bacterial endocarditis.
- Surgical ligation was the ‘gold standard’ for treatment of PDA, but intraluminal or transcatheter closure of PDA is becoming more common, with its minimal invasiveness an advantage.
- There are several different closure devices including the Rashkind Umbrella device, the Sideris buttoned device, the Botallocluder, Gianturco and Cook coils and the Amplatzer Duct Occluder.
- The Amplatzer Duct Occluder is useful in the closure of large PDAs, but is generally not suitable for infants under 5 kg.
- Coils have been used in infants as small as 2.3 kg.
- There is an increased embolisation risk with coils, but this has been improved with the Gianturco coils being modified, allowing more controlled positioning and release.
- Devices cannot be used in premature babies, so if closure of the PDA cannot wait until the child is older, surgical ligation is the best method of closure.
- There are risks involved with device closure for example, embolisation of the device, residual shunts, stenosis and possible reversion to surgery.
- Both the Amplatzer Duct Occluder and Cook coils are available in Australia.

Background

The ductus arteriosus is a blood vessel that connects the pulmonary artery to the aorta, allowing blood to bypass the lungs during foetal development. Normally, the ductus narrows in the first few hours or days after birth, and closes within one to eight weeks. Patent ductus arteriosus (PDA) is where the ductus arteriosus does not close (“patent” means “open”).

If the ductus arteriosus remains open, it connects the pulmonary circulation to the systemic circulation and oxygenated blood can flow from the systemic circulation into the pulmonary circulation, resulting in increased blood flow to the lungs. Small PDAs may produce no symptoms and can go undetected until later in childhood or in adulthood. Larger PDAs, however, can cause several pathological consequences in babies, including heart failure and pulmonary vascular obstructive disease (from large PDAs). The abnormal flow patterns of blood across the ductus can also create an increased risk of bacterial endocarditis (from smaller PDAs) of the heart and ductus, which may be fatal.

The Technology

In PDAs large enough to need occlusion, surgical ligation, where the ductus was tied at either end and cut in the middle, has been the usual method of treatment.¹ Initially, surgical ligation was performed with open thoracotomy, but it is now performed thoroscopically^{2,3}, with reversion to open surgery if needed. Although the mortality rate for surgery is very low, the morbidity of anaesthesia and thoracotomy, scarring from the surgery and the expense are disadvantages.⁴

Non-surgical (intraluminal or transcatheter) closure of PDA is becoming more common, as it is a less invasive intervention compared with surgery and may be done with local anaesthetic and sedation. The process was first described by Porstmann *et al.*⁵ The PDA is closed via the placement of an occlusion device introduced through the femoral vein or artery. There has been an improvement in the devices over the past ten years, with devices now being delivered through catheters as small as 4 French (4F).

The anatomy of PDA varies considerably in size and configuration. Where a diameter is described, it arbitrarily refers to its narrowest segment, which is smaller than 4 mm in 78% of cases.⁶ PDAs have been classified into five types, the most common being Type A where the ductus is funnel shaped with a narrowing at the pulmonary artery junction. Type B is the next common, and is funnel shaped with an aortic ampulla (neck). Type C is tubular, Type D is oval shaped with aortic and pulmonary ampullae and Type E refers to other rare forms. Some forms of occlusion device are more ideal than others for the various types and sizes of PDA.

Several devices have been described for the occlusion of PDA, including the Rashkind umbrella device developed in the 1980s⁷, the Sideris buttoned device first described by Rao *et al.*⁸ delivered by a size 7F catheter^{9,4} and the Botallooccluder.¹⁰ The most common devices used at present are Cook coils and the Amplatzer Duct Occluder.

Coils

The use of coil embolisation was first described by Cambier *et al.*¹¹ Coils can be delivered through catheters as small as 1.3 mm in diameter (4F).¹² This allows the procedure to be performed on smaller patients. Gianturco coils were the first coil system to be used. Use was successful but there was a difficulty in adjustment or retrieval of the coils, increasing the chance of embolisation (loss of coil into bloodstream). Controlled release coils (Flipper™ detachable embolisation coil; Cook®, Bloomington, IN, USA) have improved the process of occluding PDAs. The Cook coils (see Figure 1) allow adjustment and positioning of the coil before release, avoiding protrusion of the coil into the vascular lumen that may otherwise result in turbulent flow of blood or obstruction. As the risk of embolisation is lower smaller coils can be used.¹³



Figure 1. The Flipper™ Detachable Embolisation Coil
(Courtesy of Cook®)

Amplatzer duct occluder

The Amplatzer device was originally trialed in dogs in 1996.¹⁴ The Amplatzer Duct Occluder (AGA Medical Corporation, Golden Valley, MN, USA) may be re-positioned. The device is mushroom-shaped (Figure 2) and a flange (like the cap of a mushroom) is deployed first and pulled against the opening of the ductus. The skirt (similar to the stalk of a mushroom) is deployed which has a stenting action, making contact with the duct walls. The polyester filling of the device promotes thrombosity (clotting) and eventually, the natural tissue lining of the blood vessel grows and covers the device.



Figure 2. The Amplatzer Duct Occluder
(Courtesy of AGA Medical Corporation)

According to the manufacturer's advice, the use of the Amplatzer Duct Occluder is not recommended for use in infants weighing less than 5 kg. This is substantiated by failures in implantation and reversion to surgery, reported by several authors.¹⁵⁻¹⁷ An infant "normally"

reaches 5 kg by about two months of age, but an infant with PDA may grow slower, and will be older before use of ADO is recommended. This device is not suitable for premature babies.

Comparisons between devices

A study by Jaeggi *et al.*¹⁸ compared the Cook detachable coil with a preceding series of Rashkind umbrella series. Long-term shunt persistence after single coil deployment in moderate sized ducts was as frequent as compared to the Rashkind device, and use of multiple coils was advocated. Residual leaks are high with the Rashkind device¹⁹ and there is high risk of embolisation with multiple coils.²⁰ Bulbul *et al.*²¹ demonstrated that closure of PDA was more complete using coils compared with the Rashkind device.^{21,22}

Galal *et al.*²³ evaluated the safety of Cook detachable coils versus Gianturco coils, with respect to embolisation. The embolisation rate was smaller with Cook detachable coils.

Patient group

Patients greater than 1 year old

The type of device for closure of PDAs in patients greater than one year of age is mostly dependent on the size and type of PDA and the preference of the cardiologist. Generally coils will be used, with the Amplatzer Duct Occluder being used for larger PDAs.

Patients less than 1 year old (infants)

Fischer *et al.*²⁴ found that that the placement of the Amplatzer Duct Occluder (ADO) was carried out with no difficulty in patients older than one year, but technical problems were often encountered during the placement of the ADO in 12 patients with an age range of 1-11 months (body weight ranged from 2.6 kg to 8.7 kg). In this group, kinking of the long sheath tended to occur (at the angle of the right ventricular outflow tract and the pulmonary artery). This problem was overcome by snaring the sheath from the systemic arterial side, and using the snare to “pull” the sheath, containing the delivery cable and device, into position. If the snaring failed, the long sheath (size 5F) was exchanged for a larger 6, 7 or 8F sheath which advanced with greater smoothness owing to their larger diameter. These technical problems were seen in 75% (9 of 12 cases) of the patients under the age of one, compared to 20% (5 of 25 cases) in older patients. In two of the twelve patients (weighing 2.6 kg and 4.4 kg) the procedure had to be abandoned because of excessive procedural and fluoroscopy time, and the PDAs were surgically closed. This study supported the manufacturer’s recommendation that the device should not be used in patients below 5 kg body weight.²⁴

Hijazi *et al.*²⁰ closed PDAs in 20 patients aged one year or less. The weights ranged from 2.3 kg to 8 kg. There were three failures of closure due to coil embolisation, but none of these was in a patient weighing less than 5 kg.

The Rashkind device, the Sideris buttoned device and the Botallooccluder require substantially larger introduction catheters compared to coils, which limits their application in small infants.²⁰

Premature infants

Surgical ligation is still the gold standard for the closure of PDA in premature infants who do not respond to drug treatment.

Risks with devices

Embolisation of the device, residual shunts, stenosis and reversion to surgery are potential risks associated with closure of PDAs with devices. There is an embolisation risk of up to 16%, especially from the closure of ducts greater than 4 mm using coils.²⁰ Due to the risk of residual shunts it is recommended that infective endocarditis prophylaxis be taken until the shunts are closed. Residual shunts can also cause mechanically induced haemolysis (damage to red blood cells). If this is the case, it is usually necessary to implant another occluder.²⁵ Stenosis of the left pulmonary artery is a known complication of coil usage. Incidences of between 10% and 18% have been reported.^{20,22} Loss of femoral artery pulse may occur and is usually treated with heparin.

Cost and Availability in Australia**Availability**

Both the Cook coils and the Amplatzer Duct Occluder are available in Australia. Cook coils have been used since 1995 and the Amplatzer Duct Occluder since 1998.

Cost

The Cook coils cost up to \$AUD500 and the Amplatzer device costs several thousand dollars. Although expensive, the Amplatzer Duct Occluder is useful for the closure of large PDAs.

Summary

Intraluminal (or transcatheter) closure of PDA in infants, using Cook coils or the Amplatzer Duct Occluder, is a technique that has evolved from its use in older children. The success of intraluminal closure of PDA in infants depends greatly on the patient's weight, the size of the PDA, and the type of occlusion device used. The Amplatzer Duct Occluder may be successful in treating larger babies and larger PDAs, but the manufacturers do not recommend its use to close PDAs in infants less than 5 kg in body weight. This recommendation is supported by other studies. Coil closure may still be a treatment option in infants weighing less than 5 kg, but surgical ligation of PDA may still be appropriate, and remains the gold standard treatment for premature babies who do not respond to drug treatment.

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