Transcatheter Closure of Patent Ductus Arteriosus

Medical Policy

Section: Surgery

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Description

The ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. A patent ductus arteriosus (PDA) is the persistent opening of the channel beyond its expected time of closure during the first few days of life. Catheter-based techniques have been developed to close PDAs to eliminate the need for general anesthesia, a thoracotomy, and an extended hospital stay and convalescence associated with open surgical PDA closure.

The ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. A patent ductus arteriosus (PDA) is the persistent opening of the channel beyond its expected time of closure during the first few days of life. Symptoms are related to the size of the ductus; a large non-restrictive ductus with a left to right shunt can cause cardiac failure, while small restrictive PDAs are associated with an increased risk of infective endarteritis. Because of the twin threats of heart failure or endarteritis, it is recommended that all PDAs that persist after the age of 2 years be surgically closed with ligation or division of the PDA.

Open surgical treatment of the PDA is a low-risk procedure, if performed electively. However, over the past several decades there has been interest in developing a catheter-based technique to close PDAs, thus eliminating the need for general anesthesia, a thoracotomy, and an extended hospital stay and convalescence. A number of devices have been developed for this purpose.

The Gianturco coil, also referred to as the Cook embolization coil, is an arterial and venous occlusive device that was marketed prior to 1976, when the U.S. Food and Drug Administration (FDA) formally acquired regulatory authority over devices. (The Gianturco coil is entirely different than the Gianturco stent, which is used in coronary arteries.) Therefore, the Gianturco device has never undergone formal FDA approval but is available for clinical use. Transcatheter insertion of the coil is typically an outpatient procedure performed in the catheterization lab. General anesthesia may only be required in those very young patients who cannot reliably hold
still during the procedure. General anesthesia in a child younger than 1-year-old may require overnight hospitalization.

**Regulatory Status**

In 2003, the Amplatzer Duct Occluder received FDA approval, with the specific indication for non-surgical closure of patent ductus arteriosus. This device is a self-expandable device made from a Nitinol wire mesh and polyester fabric. As the occluder is implanted, it expands outward, and the wires push against the wall of the ductus. The polyester fabric induces thrombosis, which closes the communication.

**Policy**

Transcatheter closure of a patent ductus arteriosus using an FDA-approved device may be considered **medically necessary**.

Transcatheter closure of a patent ductus arteriosus using other non-FDA-approved devices is considered **investigational**.

**Policy Guidelines**

According to the labeled indications of the Amplatzer Duct Occluder, the following are contraindications for the use of this device:

- Patients weighing less than 6 kg
- Patients less than 6 months of age
- Presence of thrombus at the intended site of implant, or documented evidence of venous thrombus in the vessels through which access to the defect is gained
- Active endocarditis or other infections producing bacteremia
- Patients whose vasculature, through which access to the defect is gained, is inadequate to accommodate the appropriate sheath size.
- Patients with pulmonary hypertension with pulmonary vascular resistance of >8 Woods units or Rp/Rs of >0.4.

**Rationale**

This policy was created in February 2003 and next updated in December 2010, followed by periodic updates with literature review. The most recent update with literature review covers the period between 2011 and August 2012. A number of different devices have been used to close patent ductus arteriosus (PDAs), including coils and occlusion devices. The evidence on the efficacy of percutaneous closure devices for PDA primarily consists of clinical series and a small number of non-randomized comparative studies. A representative sample of some of the larger studies is discussed below.

**Efficacy of closure devices for PDA**
The Gianturco coil has been successfully adapted for use in closure of PDAs. Studies suggest a success rate of more than 90% in abolishing a clinically detectable shunt. (1, 2) Postoperative angiography and/or Doppler echocardiography frequently detect the persistence of a subclinical or trace shunt. The clinical significance of this finding is thought to be minimal. For example, Latson points out that using the Rashkind device, there have been no late cases of infection in more than 1,800 patient years of follow-up in postimplantation patients who have had no clinical evidence of a residual shunt. (3)

One nonrandomized comparative trial compared percutaneous closure to open surgery. In this study from China, Chen et al. (4) compared 72 patients treated with percutaneous closure with 183 patients treated with open surgery. The choice of procedure was made at the discretion of the patient and/or treating physician. There were more procedure-related events in the open surgery group compared to the percutaneous group (13.7% vs.1.4%, p=0.004), and recovery time was longer for the open surgery group (8.7 days vs. 1.3 days, p<0.001). Freedom from persistent residual shunt was higher in the percutaneous group (98.6% vs. 91.3%, p=0.04). Other clinical outcomes such as pulmonary arterial hypertension and left ventricular size were similar between groups.

Other evidence on the efficacy of closure devices consists of case series. A large case series of 1,291 attempted PDA coil occlusions was reported from the European Paediatric Cardiology Registry. (5) Immediate occlusion was demonstrated in 59% of patients, and this increased to 95% 1 year after the procedure. A suboptimal outcome occurred in 10% of patients, defined as failure to implant, coil embolization, residual leak, hemolysis, duct recanalization and flow impairment to adjacent structures. Increasing size of the PDA greater than 2 mm and PDAs that were tubular in shape were associated with an increased likelihood of unfavorable outcome.

In 2003, the Amplatzer Duct Ocluder device received FDA approval for closure of PDA. (6) The clinical data submitted to the FDA as part of the FDA approval process consisted of results from a multi-center non-randomized pivotal study that enrolled 441 patients. The primary efficacy measure was complete closure and was achieved in greater than 98.6% of patients at 12 months. A total of 1.3% of patients was reported to have serious or major adverse events, and 4.8% were reported to have a minor adverse event.

The Multicenter USA Amplatzer patent ductus arteriosus device trial (7) reported periprocedural and 1-year outcomes in 484 patients from 25 U.S. centers. Of the 484 patients enrolled, the Amplatzer device implantation was not attempted in 45; due to the size of the PDA or the morphology of the PDA was more suited for treatment with a coil. Of the 439 patients in whom implantation was attempted, the device was successfully implanted in 435 patients (99%). Immediate postprocedure occlusion was reported in 76% of patients, which increased to 89% on postprocedure day 1 and to 99% at 1 year. At last evaluation, PDA occlusion was documented in 98% of patients. At 1-year follow-up 359/360 (99.7%) evaluable patients have no evidence of a left to right shunt on echocardiography. Complications were uncommon, with one periprocedural death and major events reported in 2.3% (10/439) of patients. Examples of major events included device embolization (n=2), partial obstruction of the pulmonary artery (n=2), and bleeding requiring transfusion (n=2). Minor events occurred in 7.1% (31/439) of patients.

Other case series of both the Amplatzer device and the Gianturco coils report similar outcomes. (8-13) These series vary in terms of patient selection, types of device, and outcomes reported. However, the case series are consistent in reporting a high rate of procedural success, a high rate of successful closure of the PDA, and a low rate of serious complications.
Comparative efficacy of different devices and/or different techniques

Wang et al. (14) compared outcomes among 214 patients undergoing percutaneous closure with coils and 134 patients undergoing closure by an occluder device. Patients were selected for either group by the size of the PDA, with coils utilized for small to moderate PDAs and the occluder device utilized for larger PDAs. The procedural success rate was high for both the coils (96.7%) and the occluder (98.5%), with no significant difference between groups. There were higher complication rates reported for the coil group. Distal embolization occurred in 8.9% (19/214) of patients in the coil group compared with 1.5% (2/136) patients in the occluder group (p<0.01). Pulmonary artery stenosis occurred in 4.2% (9/214) patients in the coil group compared with zero in the occluder group (p<0.05).

In a non-randomized study, Chen et al. compared PDA occlusion using the transcatheter Amplatzer occluder in 98 patients to video-assisted thoracoscopic surgery in 196 patients. (15) No deaths or late recanalizations occurred in either group. However, residual shunt and left ventricular overload occurred in 4 (4.3%) patients in the transcatheter occluder group compared to zero patients in the thoracoscopic group. Acute complications related to the procedures occurred in 10.2% of the transcatheter occluder group compared to 1.5% of the video-assisted thoracoscopic surgery group (p<0.05). After follow-up of 3.1 to 8 years (mean, 5.4 ± 1.2 years) in the transcatheter occluder group and 3-8 years (mean, 5.6 ± 2.8 years) in the thoracoscopic surgery group, heart structures in both groups returned to normal. While fewer complications occurred in the thoracoscopic group, the non-randomized nature of the study limits interpretation of the results.

Hongxin and colleagues reported on a parasternal, perpulmonary approach for PDA device closure in a cohort study of 79 patients. (16) Complete PDA occlusion occurred in 61 (78%) patients immediately after device placement while 7 (9%) patients required device redeployment. Complete PDA closure was found by echocardiogram in 76 (97%) patients during the follow-up period of 3 months to 2 years. While this minimally invasive approach is theoretically designed to avoid or reduce the disadvantages of other PDA occlusion procedures and devices, such as the trauma of thoracotomy and risk of transcatheter device embolization, these devices are not available in the United States, and this approach still requires general anesthesia.

Ongoing Clinical Trials

A search of online site ClinicalTrials.gov identified 2 ongoing non-randomized studies of PDA occluders. In a Phase I study, the safety and PDA closure outcomes of a new PDA occluder by Occlutech is being evaluated in 50 patients (NCT01479218). This trial is expected to be completed in December 2012 and is still recruiting patients. In the Amplatzer Duct Occluder II (ADOII) study, the safety and PDA closure outcomes of the Amplatzer Duct Occluder II will be evaluated in 192 patients (NCT00713700).

This study is ongoing but is no longer recruiting patients and is expected to be completed in July 2016.

Summary

The ductus arteriosus is the vascular remnant of the left sixth aortic arch, connecting the main pulmonary artery to the aorta. A patent ductus arteriosus (PDA) is the persistent opening of the channel beyond its expected time of closure during the first few days of life. Catheter-based
techniques have been developed to close PDAs to eliminate the need for general anesthesia, a thoracotomy, and an extended hospital stay and convalescence associated with open surgical PDA closure.

The use of percutaneous closure devices has become the procedure of choice for closure of patent ductus arteriosus in suitable patients. The evidence base for percutaneous closure of PDAs consists of a large number of case series that report high success rates with low rates of adverse events. A few non-randomized comparative trials compare outcomes of different devices and techniques, and one such study reports better outcomes with a thoracoscopic approach compared to a percutaneous approach. However, these non-randomized studies are not adequately rigorous to form conclusions because there is a high likelihood of selection bias, resulting in populations that are not comparable. Based on the evidence that percutaneous closure achieves high success rates and avoids the morbidity of open surgery, this technique may be considered medically necessary.

Practice Guidelines and Position Statements

In 2008 the American College of Cardiology/American Hospital Association (ACC/AHA) published guidelines on the management of adults with congenital heart disease. (17) Class I indications for closure of a PDA were listed as:

- Left atrial enlargement, left ventricular enlargement, pulmonary arterial hypertension, or left-to-right shunt (Level of evidence C)
- Prior endarteritis (Level of evidence C)

Class IIa indications for closure of a PDA were:

- It is reasonable to close an asymptomatic small PDA by catheter device (Level of evidence C)
- PDA closure is reasonable for patients with pulmonary arterial hypertension with a net left-to-right shunt (Level of evidence C)

Medicare National Coverage

There is no national coverage determination.

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