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Transcatheter Closure of Patent Ductus Arteriosus

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Abstract

Patent ductus arteriosus (PDA) constitutes 6 to 11% of all congenital heart defects. While surgical ligation and video-assisted, thoracoscopic interruption of PDA are still available, transcatheter occlusion of PDAs has recently assumed a major role in closure of PDA. A large number of devices have been designed and tested both in animal models and human subjects, but only few devices (free and detachable Gianturco coils, GGVOD and Amplatzer duct occluder) are approved by the FDA for general clinical use. A few other devices are in clinical trials and are available only at institutions participating in clinical trials within or outside the US. At the present time, Gianturco coils for closure of very small and small PDAs and Amplatzer duct occluder for occlusion of small, moderate and large PDAs appear to be feasible, safe and effective in the majority of patients.

Keywords: Patent ductus arteriosus; Transcatheter occlusion; Gianturco coils; Amplatzer duct occlude; Indications; Silent ductus

Introduction

Case Report

Ductus arteriosus develops from the distal portion of the left sixth aortic arch and connects the main pulmonary artery with descending aorta. After birth, the ductus closes by contraction of the medial smooth muscle leading to constriction, shortening and functional closure, followed by permanent sealing of the lumen to form ligamentum arteriosus. Failure of constriction of ductus leads to patency of ductus. The incidence of isolated patent ductus arteriosus (PDA) in terms of infants is 1 in 2,000 live births [1]. The PDA constitutes 6 to 11% of all congenital heart defects. In preterm infants, the incidence is higher, at about 8 per 1,000. The shape of the PDA varies, but most often the aortic end is wide and narrows towards the pulmonary end. Earlier descriptions such as conical, tubular, short, and long, have largely been replaced by a classification described by Krichencko et al. [2] Type A. Ductus with narrowest segment is at the pulmonary end, Type B. Ductus is short and narrow segment is at the aortic end, Type C. Tubular ductus without narrowing, Type D. Ductus with multiple constrictions and Type E. Bizarre configuration with elongated, conical ductus with narrowing is remote from the anterior border of trachea. Types A and B are further divided in to three subgroups based on the relation of the pulmonary end to the trachea. In this paper we will review the methods of PDA closure, indications for closure, devices available for percutaneous closure, selection of devices for closure and methods of device implantation along with results and future directions.

Methods of PDA Closure

First successful ligation of PDA was performed by Gross and Hubbard [3]. Since then, surgery has been the treatment of choice for PDA until transcatheter approaches were developed. First transcatheter method was developed by Porstman et al. [4] in late 1960s, followed by Rashkind et al. [5] in late 1970s and these paved the way for the development of a number of other PDA closure devices, reviewed elsewhere [6,7]. Historical aspects of PDA closure devices are reviewed elsewhere in this issue [8] and will not be discussed here. Video-assisted, thoracoscopic technique for interruption of PDA was developed in early 1990s [9] and is used in a limited number of institutions.

Indications for Percutaneous Closure

The procedure is indicated only in patients with continuous murmur suggestive of PDA with Echo-Doppler confirmation. We do not recommend [10] closure of the so-called "silent ductus" detected incidentally without typical auscultatory features. Very small and small PDAs are candidates for closure even though they are not hemodynamiclly significant, mostly to eliminate the risk of subacute bacterial endocarditis. Medium- and large-sized ducts should be closed to prevent further volume overloading of the left ventricle, to treat congestive heart failure and to prevent pulmonary vascular obstructive disease along with eliminating the risk of endocarditis. Closure is contraindicated in patients with ductal-dependent congenital cardiac anomalies and those associated with pulmonary vascular obstructive disease.

Approved PDA Occlusion Devices

A number of devices were used in human subjects and underwent clinical trials, but only a few devices are approved by FDA in the US for transcatheter closure of PDA; these include, Gianturco coil, Gianturco-Grifka vascular occlusion device and Amplatzer duct occluder.

Gianturco coils

These are comprised of stainless-steel wire with thrombogenic Dacron fibers incorporated into them. These coils were originally described in 1975 [11] and were used to occlude renal arteries and have undergone a number of changes over the years. They are commercially available at the present time for clinical use in a variety of wire diameters, loop diameters and lengths. They were initially used on an off-label basis; subsequently received FDA approval. Since the initial description by Cambier et al. [12] of occlusion of PDA, a number of refinements and modifications of the procedure or of the coil have occurred; these include antegrade and multiple coil techniques, [13] snare-assisted coil delivery, [14] bioptome-assisted coil delivery, [15]temporary balloon occlusion of the ductus on the aortic [16]or pulmonary artery [17] end, five loop coil design, [18,19] coil delivery via catheters with tapered tip, [20,21] increasing the wire diameter to 0.052″, [22,23] coil implantation without the use of heparin [24] and detachable design [25,26]. Some

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of these techniques may have advantage over the conventional retrograde free coil delivery, while others may marginally improve upon the technique. Many of these changes increase the complexity of the procedure, prolong the fluoroscopy and procedure time and add to the cost. These considerations should be taken into account when embarking on the use of modified techniques. Our own view is that conventional retrograde delivery of free 0.038" Gianturco coils for very small PDAs is adequate [27] (Figure 1 A).

Detachable coils

Gianturco coils have been successfully used in the occlusion of PDA; however, lack of controlled delivery and inability to retrieve and reposition the coil are thought to be potential problems. Consequently, detachable coils have been developed. Two different designs have been undertaken: the first type (Cook detachable coil) has a mechanism in which the notch of the stretched coil winding interlocks with the bead at the end of the core wire in the delivery catheter [25]. Once the coil is positioned appropriately, the coil can be released by the handle at the proximal (outside the patient) end of the delivery catheter. The second design is also a Gianturco coil, but with an added short threaded extension at its proximal end. This is attached to the distal end of the delivery wire, which provides controlled delivery and retrieval when required. Following implantation at the desired location, the delivery wire is unscrewed from the coil, thus releasing the coil [26]. This is named "Flipper" detachable coil (Figure 1 B).

Gianturco-Grifka vascular occlusion device (GGVOD)

The GGVOD, consists of a nylon sac and a long occluding wire [28,29] and is presumed to be a modification of Megal's conical nylon sack filled with segments of modified guide wire (which was experimented in the late 1980s [30]). The GGVOD is manufactured in several sizes (3, 5, 7, and 9 mm) and can be implanted via 8 French sheaths. It is approved by the FDA for general clinical use. In the limited published studies [28,29] residual shunts were present in 9% patients immediately after device deployment but, all of them closed spontaneously during follow-up. Because of requirement of a large delivery sheath for device delivery and difficulty in retrieval of dislodged devices, it is not commonly used in clinical practice (Figure 1 C).

Amplatzer ductal occluder (ADO)

The ADO is made up of 0.004" Nitinol wire mesh designed as a mushroom -shaped implant and is self-expandable [31,32]. The device length is 7 mm except for the 5/4 device (which is 6 mm long). The aortic end is 2 mm larger than the pulmonary end, gradually tapers from the aortic to pulmonary end. A thin retention disc is placed at the aortic end and is 4 mm larger than the aortic end of the device. A recessed screw is assembled into the pulmonary end and is connected to the delivery wire during deployment. Polyester fibers are sewn into the device to encourage thrombosis after implantation. The devices can be implanted via 6 to 8 French sheaths. Multiple sizes are manufactured. At the present time, ADO is the most commonly used device worldwide in the closure of moderate-to-large PDAs (Figure 1 D).

Which Device to Select

Based on our experience with a number of devices and methods of closure, it appears that it is best to individualize decision based on the size (minimal ductal diameter) of PDA (Table 1) and probably the shape of the ductus [33].

Minimal ductal diameter

Very small PDAs measuring less than 1.5 mm (Table 1) can be

successfully closed using free 0.038" Gianturco coils. The method is fairly straightforward and economical. Small PDA *i.e.*, between 1.5 to 3 mm, can also be closed with 0.038" Gianturco coils, but residual shunts are expected and many may require multiple coils. We no longer use multiple coils or 0.052" coils; instead, we employ the ADO for these ducts. Moderate-to-large PDAs (>3 mm; Table 1) require devices and we now regularly employ the ADO; a device size one to two mm larger than minimal ductal diameter is typically selected. Indeed, conventional surgical closure [34] and video-assisted thoracoscopic clipping of PDA [9,35]are also other available options.

Ductal shape

If the ductus is very small or small, the shape may not play an independent role in determining the feasibility or effectiveness of transcatheter duct occlusion. Nonetheless, if the ductus is moderate to large in size, the shape may have a particular role in the feasibility and effectiveness of device occlusion. In the majority, ADO is likely to address the shapes. However, in long, tubular PDA, the Amplatzer vascular plug [36,37] may be a superior choice. If the ductus is very short, similar to aorto-pulmonary window, atrial septal devices may be used. In very small or small PDAs with good sized ductal ampulla (Figure 2A), ADO (instead of coils) may be used to ensure complete closure (Figure 2B) without residual shunt.

Methods of Device Implantation

The methods of implantation of the two most commonly used devices, namely free Gianturco coils and Amplatzer duct occluder will be described.



Figure 1: Photographs of transcatheter delivered patent ductus arteriosus occlusion devices: A. Gianturco coil, B. Cook detachable coil, C: Gianturco-Grifka vascular occlusion device and D. Amplatzer Duct Occluder.

Туре	Description
Silent PDA	Less than 1.5 mm and no murmur
Very small PDA	≤ 1.5 mm with audible murmur
Small PDA	1.5-3 mm and murmur
Moderate PDA	3-5 mm and murmur
Large PDA	>5 mm and murmur

Size is determined by minimal ductal diameter on lateral cineangiographic view; PDA, Patent ductus arteriosus

Table 1: Classification of PDA based on size. Adopted from Rao³³ with permission.

Gianturco coils

Implantation of free coils was initially described by Cambier et al. [12] and the method that we use [10,18,19,27] is similar to that detailed by Cambier. Cardiac catheterization is performed percutaneously via the femoral vein and artery to confirm the clinical and echocardiographic diagnosis. Heparin (50 to 75 units/kg) is administered intravenously following insertion of the arterial sheath. Aortic arch angiography in 30° right anterior oblique (RAO) and straight lateral views is performed by injecting 1 ml/kg of contrast material via a 4- or 5-French marker pigtail catheter introduced through the femoral arterial sheath (Figure 3). Measurement of narrowest ductal diameter (usually at the pulmonary end), size of ampulla (at the aortic end) and length of ductus are measured (Figures 4) in both views and averaged. Sometimes foreshortening may give spurious values, which may be ignored. These measurements serve as a guide for selection of the diameter of the coil used for occlusion. We almost exclusively use 0.038" Gianturco coils because of better occlusion when compared 0.035" coils.

A 4-French right coronary artery catheter (Cordis, Miami, FL) or a 4-French Glidecath catheter (Meditech, Watertown, MA) is introduced from the descending aorta into the main pulmonary artery via the PDA. If the catheter cannot be advanced easily into the ductus, the soft end of a 0.035" straight Benston (Cordis, Miami, FL), straight Teflon-coated Amplatz (Cook, Bloomington, IL), or angled floppy (Meditech, Watertown, MA) guide wire is used to cross the ductus. Our first preference is straight Benston guide wire. The catheter is advanced across the ductus over the guide wire. Position of the tip of the catheter in the main pulmonary artery is ensured by pressure measurements and if necessary, test injection of contrast material. Aortic arch angiographic frames, obtained in the RAO and straight lateral views (Figure 3), are used as a reference/guide throughout the



Figure 2: Selected cine frame from aortic arch angiogram in lateral view demonstrating a small patent ductus arteriosus (PDA) (arrow) in A. But, the ductal ampulla (AMP) was large and therefore, an Amplatzer duct occluder (ADO) was used to close the ductus resulting in complete occlusion of the ductus (B). Catheter with markers is seen in both A & B. DAo, descending aorta.



Figure 3: Selected cine frames from aortic arch angiogram in right anterior oblique (A) and lateral (B) views demonstrating a small patent ductus arteriosus (PDA). Catheter with markers is seen in both A & B. DAo, descending aorta.





procedure. The relationship of the minimal ductal diameter with the anterior tracheal shadow is noted and should be used to position the coil in the ductal structure.

A coil with a loop 2 to 3 times the narrowest ductal diameter is selected for implantation. The coil is loaded into the catheter with the stiff end of a 0.038-in Teflon-coated guide wire but is advanced with its floppy end. Under fluoroscopic guidance (lateral view) one to one and one-half loops of the coil are delivered into the main pulmonary artery. The delivery guide wire is partially withdrawn and the entire system (the coil and catheter) is pulled back so that the delivered coil loops are drawn into the pulmonary end of the ductus. Then, the delivery catheter is pulled back gently into the aortic end of the ductal ampulla. The delivery guide wire is re-advanced until it touches the coil in the catheter. The guide wire is fixed in position and the catheter is slowly withdrawn over the wire into the descending aorta, thus extruding the remaining coil into the aortic end of the ductal ampulla. Thus, the delivered coil straddles the narrowest diameter of the ductus. Fifteen minutes after coil delivery, repeat aortic arch angiography (Figure 5), careful pressure pullback from the aortic arch to descending aorta, and measurement of oxygen saturations from the right ventricle, main pulmonary artery and ascending aorta are performed. One dose of Ancef (25 mg/kg/dose) is administered intravenously in the catheterization laboratory and two additional doses are given 6 and 12 hours after the first dose. The heparin is not continued nor its effect reversed. Clinical evaluation, chest roentgenogram and echo-Doppler studies are obtained on the day following the procedure and at 1, 6, 12, 36 and 60 months after coil implantation.

Amplatzer ductal occlude

Musura and his associates [32] were the first to report use of the Amplatzer duct occluder in human subjects and the method that we use is similar to that described by Musura. The procedure is similar to that described in the coil implantation section above up to the measurement of ductal size (Figure 6). A 4 or 5-French multipurpose catheter is introduced into femoral vein, positioned in the main pulmonary artery and advanced into the descending aorta via the ductus. If the catheter cannot be advanced across the ductus by itself, we use 0.035" straight Benston guide wire, with a long floppy tip to cross the ductus. A 0.035" extra-stiff exchange-length J-tipped Amplatzer guide wire is positioned in the descending aorta and the multipurpose catheter removed. In rare occasions when antegrade entry into the PDA is not feasible, a guide wire (exchange length) is advanced into the pulmonary artery via a catheter and introduced into the ductus from the descending aorta. The guide wire is further manipulated into the right ventricle, right atrium and superior vena cava. The wire is snared from the superior vena cava



Figure 5: Selected cine frames from aortic arch angiogram in lateral view demonstrating the position of the coil (arrow) in the patent ductus arteriosus (A) and complete occlusion of the ductus (B). Catheter with markers is seen in both A & B. DAo, descending aorta.



Figure 6: Selected cine frames from aortic arch angiogram in lateral views demonstrating measurements in a patient with moderate to large patent ductus arteriosus (PDA). Measurements of minimal ductal diameter and ductal ampulla in A and minimal ductal diameter and length of the ductus in B are shown. DAo, descending aorta; MPA, main pulmonary artery.

(or pulmonary artery) and exteriorized via the femoral venous sheath. Then, an appropriate-sized Amplatzer PDA device delivery sheath is advanced over the wire, across the right heart and ductus and its tip positioned in the descending aorta.

An ADO device whose pulmonary end is 1 to 2 mm larger than the size of the narrowest diameter of the PDA is selected for implantation. The selected Amplatzer duct occluder is deaerated and screwed onto the delivery cable. After completely screwing the device, the device is unscrewed by one to one and one-half turns to facilitate unscrewing and release after it is positioned in the ductus. The device is withdrawn under saline into the loader sheath and the device is deposited into the delivery sheath already in place while flushing the device loader to avoid air entry into the system. The device is advanced within the sheath under fluoroscopic guidance. When the tip of the device arrives at the tip of the sheath, the entire system is withdrawn until the tip of the sheath is in the descending aorta just distal to the aortic ampulla of the ductus. Then, holding the device in place, the sheath is retracted so as to uncover and deploy the aortic disc of the device. The entire system is slowly pulled back into the ductal ampulla and if possible into the mid-ductus. An aortogram is performed to evaluate the position of the aortic disc of the device (Figure 7A). If satisfactory, the sheath is further withdrawn, while holding the device in place, to uncover the remaining part of the device, across the narrow pulmonary end of the ductus. An aortogram (Figure 7B) is repeated to verify the position of the aortic disk within the ductus without protruding into the descending aorta and the position of the pulmonary end of the device across the narrowest part of the ductus and that there is no residual shunt around (and parallel to) the device. Having been assured of good position of the device, the delivery cable is rotated counterclockwise until the device is released thus implanting the device. The delivery cable and sheath are withdrawn into the inferior vena cava and the delivery cable is then taken out of the patient and the delivery sheath flushed. The long sheath is exchanged with a short sheath. Ten minutes following device implantation, aortic arch cineangiography is performed in 30° RAO and straight lateral (Figure 8) projections. Measurement of the pressures on pullback across the descending aorta and right ventricular, pulmonary arterial and aortic oxygen saturations are obtained. Antibiotic administration and follow-up are similar to those described for the coil occlusion section.

Results

The feasibility, safety and effectiveness of the described techniques are demonstrated [6,38] and will be reviewed briefly.

Gianturco coils

The results of Gianturco coil occlusion of PDA were reviewed and tabulated elsewhere; [6,38] residual shunts were present in 18% patients 24 hours after the procedure which decreased to 9% at follow-up.

Detachable coils

The results of detachable coils were also reviewed; [6,7] residual shunts were present in 7% to 28% immediately after the procedure which decreased at follow-up to 3% to 12%.

The prevalence of coil dislodgement and residual shunts are similar with free Gianturco coils and detachable coils. [6,33,38] Consequently we prefer cheaper, simpler, conventional retrograde delivery of free 0.038" Gianturco coils for very small ducts.



Figure 7: Selected cine frame from aortic arch angiogram in lateral view demonstrating the position of the aortic disc of the Amplatzer duct occluder (ADO) (arrow) in the patent ductus arteriosus (A). Similar cine frame after opening the pulmonary end of the ADO (B). Both illustrate good position of the device components. In B, note small residual shunt thru' the device and none parallel to it. This would indicate that the size of the device implanted is appropriate to the size of the ductus. Catheter with markers is seen in both A & B. DAo, descending aorta.



Figure 8: Selected cine frames from aortic arch angiogram in lateral view demonstrating patent ductus arteriosus (PDA) in A. Following implantation and release of the Amplatzer duct occluder (ADO) (arrow), the device position looks good the small residual shunt thru' the device (Figure 7B) is no longer seen (B). Catheter with markers is seen in both A & B. DAo, descending aorta.

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Gianturco-Grifka vascular occlusion device

In the limited published studies [28,29] residual shunts were present in 9% patients immediately after device deployment but, all of them closed spontaneously during follow-up. Because of requirement of a large delivery sheath and difficulty in retrieval of the dislodged device, the device in not frequently used in most centers.

Amplatzer ductal occlude

Review of the results of ADO occlusion in several initially published studies [6,7] demonstrated residual shunts in 5% to 34% at implantation, which decreased to 0 to 3% at follow-up. In the multicenter US trial;

[38] successful implantation of ADO was accomplished in 435 (99%) of 439 patients. Complete angiographic occlusion was shown in 384 (76%) immediately after implantation, which increased further to 89% on the following day by Echo-Doppler studies. Complete closure was demonstrated in 359 (99.7%) of 360 patients at one year follow-up. Of the more than 100 consecutive Amplatzer ductal occlusions performed at our institution during a seven-year period ending December 2009, small to trivial shunts were present in 17% by angiography immediately after implantation which decreased to 11% echocardiography the following day. At one month follow-up 1% had trivial residual shunts and none at 6 month follow-up. At two to five-year follow-up, no residual shunts were seen.

Year of First Report	Name of the Device (Investigators)
1967	Ivalon foam plug (Porstmann et al)
1976	Dumbbell-shaped plug (Mills and King)
1979	Polyurethane foam covered single umbrella with miniature hooks (Rashkind & Cuaso)
1983	Two opposing polyurethane covered umbrellas (Rashkind PDA Occluder System)
1984, 1988	Botallo-occluder (Saveliev et al)
1986	Detachable silicone double-balloon (Warnecke et al)
1989	Conical nylon sack filled with segments of modified guide wire with a 1.5 cm long flexible wire cross bar attached to the distal end of the sack (Magal et al)
1990	Two polyurethane foam discs attached to each other with elastic thread (Sideris et al)
1990	Temperature-shape changeable, shape-memory polymer (polynorbornene) (Echigo et al)
1991	Adjustable Buttoned Device (Rao et al)
1991	Clamshell ASD device (Bridges et al)
1992	Gianturco Coil (Cambier et al)
1993	Butterfly vascular stent plug (Nazarian et al)
1993, 1996	Thermal shape-memory nickel-titanium coil (Liu et al)
1993	Duct-occlude pfm (Le et al)
1993	Cook Detachable Coil (Cambier et al)
1994	Silicone-coated balloon expandable stent (Moss et al)
1995	Conical-shaped stainless steel wire mesh (Pozza et al)
1996	Flipper Detachable Coil (Uzun et al)
1996	Gianturco-Grifka Sac (Grifka et al)
1996	Infant Buttoned Device (Sideris et al)
1996	Miniaturized duct-occluder pfm (Grabitz et al)
1997	Polyvinyl Alcohol Foam Plug mounted on titanium core pin (Grabitz et al)
1998	Amplatzer Duct-occluder (Masura et al)
1999	Folding Plug Buttoned Device (Rao et al)
2001	Wireless PDA Devices (Sideris et al)
2001	Reinforced Duct-occlude pfm (Le et al)
2001	Angulated Nitinol plug – Amplatzer (Kong et al)
2002	Swivel disk and plug occluders – Amplatzer (Thanopoulos et al)
2005	Amplatzer Vascular Plug (Hoyer)
2005	Nit-Occlud coils (Celiker et al)
2005	Inoue single-branched stent graft (Saito et al)
2008	Amplatzer duct occluder II - ADO II (Thanopoulos et al)
2008	Non-ferromagnetic Inconel MReye embolization coils (Grifka et al)
2008	Amplatzer Vascular Plug with prefilled embolization coils (Glatz et al)
2009	Self-expanding platinum-coated Nitinol device (Lertsapcharoen et al)
2009	Chinese self-expandable occluder, similar to the Amplatzer occlude (Yu et al)
2009	Amplatzer Vascular Plug II (Cho et al)
2009	Valved stent (Zhou et al)
2010	Cardio-O-Fix occluder** (Białkowski et al)
2011	Nit-Occlud PDA-R (reverse) device (Heath)

* Amplatzer muscular VSD devices and various ASD occluding devices, including, Rashkind, clamshell, buttoned, CardioSEAL, STARFlex, Amplatzer and Lifetech atrial septal occluder devices and aortic stents (covered) have been used for closure of large PDAs and are not separately tabulated. **a self-expandable Nitinol wire-mesh device very similar to the Amplatzer device. ASD, atrial septal defect; PDA, patent ductus arteriosus; VSD, ventricular septal defect. Reproduced from Rao (2012)⁴⁴

Table 2: Devices Used to Occlude Patent Ductus Arteriosus*.

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Complications

Complications associated with Gianturco coil, GGVOD and Amplatzer device occlusion of PDA are negligible. Coil/device embolization may occur (Coils, both free and detachable - 1.5 to 9%; GGVOD - 3%; ADO - 0 to 4%), requiring snare-assisted transcatheter, or occasionally surgical retrieval [6,7,33] Careful evaluation of the size and morphology of the ductus during selection of type and size of the device may help prevent or reduce the embolization rates. Residual shunts were present in 18% patients 24 hours following implantation of free Gianturco coils; these decreased to 9% at follow-up [6,7]. Similarly residual shunts were present in 7% to 28% immediately after implantation of detachable coils which decreased at follow-up to 3% to 12% [6,7]. With GGVOD immediate residual shunts were seen 9% patients which completely closed during follow-up [28,29]. Residual shunts were present in 5 to 34% immediately after ADO implantation which decreased to 0 to 3% at follow-up [6,37]. Intravascular hemolysis may be seen in patients with residual shunts; [39-42] transcatheter or surgical closure of the residual shunts usually resolves this problem. Device/coil encroachment and obstructions either in the left pulmonary artery or descending aorta can occur particularly in small infants with large PDAs. Monitoring for these complications during follow-up is mandatory.

PDA in patients with right aortic arch

The vast majority of patients with PDA have a normal left sided aortic arch, and interventional cardiologist is familiar with the anatomy of the PDA in such cases. In patients with right aortic arch, the ductal location is different from that seen with left aortic arch and is variable within the right aortic arch group [43,44]. The anatomy of the right aortic arch and ductus should initially be defined [45]. If there is no evidence for symptomatic vascular ring, occlusion of the PDA may be performed; the device used should be determined based on minimal ductal diameter and ductal shape as discussed above. If vascular ring with obstruction is present, surgical relief of vascular ring is recommended.

Other PDA occluding devices

Since the initial description of PDA closure devices by Porstmann [4], Rashkind [5] and their associates, a number of PDA occluding devices have been designed and investigated and were reviewed elsewhere [6,7,33,37,46]. Most of these PDA devices were tested initially in animal models followed later by clinical trials in human subjects. The devices that have been tested in human subjects are listed in Table 2 [46]. Only a few devices received FDA approval as discussed above. Some of the other devices are undergoing clinical trials both within and outside the US and will not be discussed in this review.

Future Directions

New devices

Availability of multiple approved devices, either new or modified (to improve performance) versions of old devices (Table 2) to the interventionalist helps in the selection of a device most suitable for a particular patient. They also may pave the way to prospective randomized trials, which we would recommend although the likelihood of such trials in the current circumstances is low.

Devices to close PDAs in the premature and very young infant

PDA closure devices useful in premature infants should be developed. Some initial strides [47-51] for such methods/devices have occurred and may continue to evolve.

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Hypertensive PDAs

PDAs with high pulmonary artery pressure may require special devices such as muscular VSD occluder, although the major considerations are issues related to pulmonary vascular reactivity.

Long-term follow-up

Since the devices that we currently use are relatively new, long-term (10 to 20 years) follow-up studies are necessary to document long-term effectiveness and to demonstrate absence of adverse events during late follow-up such as those seen with ASD devices.

Aortic obstruction

Aortic coarctation may develop following implantation of ADO in infants and young children [52,53]. To prevent aortic obstruction, the device was modified [54] such that the retention disc was made thinner and concave and was build at a 32 degree angulation with the cylindrical long axis of the device so that the device conforms to the descending thoracic aorta. A platinum marker is placed in the downstream rim of the retention disc. Experimental evaluation [54] suggested that the objective of preventing aortic obstruction is achieved. Further modifications using finer wire mesh and without polyester disc were undertaken and successfully used in a single case [55]. Additional experience with this and other modified (swivel disc or disc-less) devices appears to address the aortic obstruction in infants associated with the use of the conventional Amplatzer duct occluder [55-57]. Larger experience with longer duration of follow-up is indicated. While modifications of ADO to address aortic obstruction were made, none of these are currently available for routine clinical use.

Summary and Conclusion

A large number of devices have been designed and tested; however, only a few devices (free and detachable Gianturco coils, GGVOD and Amplatzer duct occluder) are approved by FDA for general clinical use. Several other devices are undergoing clinical trials and are available only at institutions that participate in clinical trials. At the present time ADO appears to be the most commonly used device worldwide in the closure of moderate to large PDAs. Transcatheter occlusion of PDAs is feasible, safe and effective in the majority of patients.

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