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## **The Amplatzer duct occluder for PDA closure: indications, technique of implantation and clinical outcome**

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### **Abstract**

Following its introduction into clinical practice, the Amplatzer duct occluder (ADO) has achieved a definite place in the armamentarium of the interventional cardiologist for the closure of moderate to large sized PDAs. The device combines ease of use, including retrievability and repositioning when required, and a high occlusion rate (>99% complete occlusion of PDA within 6 months of implant, with the majority of occlusions occurring within 24 hours of implant). Possible complications, such as device embolization, protrusion of the retention disc of the device into the aorta producing aortic obstruction, or obstruction of a branch pulmonary artery by the device are also uncommon and can be avoided by choosing the appropriate sized device (with the pulmonary end of the device being 2mm larger in diameter than the minimum measured ductal diameter), and paying scrupulous attention to technique of deployment. The device can be safely deployed in infants >3.5 kg, and can currently close PDAs of upto 11 to 12mm in minimum diameter. A brief description of the device, the technique of implantation, and the clinical results to date are provided.

**MeSH:** patent arterial duct, transcatheter closure, Amplatzer duct occluder

### **Introduction**

A number of devices are currently available for percutaneous closure of the patent ductus arteriosus (PDA). For the smaller ducts, the Gianturco coil and its modifications, including the detachable release coil, have proven to be efficacious, utilising delivery systems of 4F or 5F diameter, and allowing implantation from either the arterial or venous approach.<sup>1</sup> For ducts with minimum diameters exceeding 3mm however, coil implantation is associated with higher procedural complexity such as the use of multiple coils usually via a combined arterial and venous approach to allow simultaneous deployment with intertwining of coils, and a higher rate of embolization and residual shunting. The Amplatzer duct occluder (ADO) has proven to be an elegant device that allows moderate and larger sized ducts (upto 11 mm in minimum diameter) to be successfully occluded by the percutaneous approach. It combines ease of implantation with a high occlusion rate and a low rate of procedure – related

complications.<sup>2–6</sup> The procedure can be safely carried out in infants >3.5 kg in weight with symptomatic PDA.

### Device description

The Amplatzer Duct Occluder (AGA Medical Corporation, Golden Valley, MN) is a self-expanding and self-centering device, made from 0.0004 to 0.0005 inch Nitinol wire mesh. It is mushroom-shaped with a low profile and consists of a flat retention disk and a cylindrical main body, into which polyester fibers are sewn. Platinum marker bands are laserwelded to each end and a steel sleeve with a female thread is welded into the marker band (figure 1). The retention disk is 4 mm larger than the main body, which itself has a conical structure. The delivery system consists of a delivery cable, a Mullins-type sheath, loader and a pin vise. The device comes in different sizes, requiring sheath sizes from 5 to 7 F for delivery. These details are available from the accompanying graphic charts supplied by the manufacturer. The size of device chosen is generally such that the diameter of the pulmonary end of the device is at least 2 mm larger than the narrowest diameter of the duct. Device sizes are categorised according to the diameters of the aortic and pulmonary ends of the device. The standard device sizes are 6/4, 8/6, 10/8, 12/10, 14/12 and 16/14 mm respectively, where the first number refers to diameter of the the aortic end and the second number to the pulmonary end of the conical shaped device. The devices are all 7mm long. The device can be delivered through sheath sizes ranging from 5F (for devices upto 8/6) to 7F (for all larger devices).

Figure 1 Left - the Amplatzer duct occluder as seen when removed from its packaging. The device has a tapering conical shape, with the pulmonary end at the bottom of the picture. The female end of the screw-system for attachment of the device to the delivery cable is also seen at this end. At the top of the picture (at the aortic end of the device), the flared aortic retention disc is seen. Centre - the ADO viewed side-on, as held between the operator's fingers. Right - the pulmonary end of the device is shown, with the screw welded screw-system for device attachment to the delivery cable.



### Implantation technique

The procedure can be performed under conscious sedation in older patients, or using general anesthesia. A single dose of intravenous antibiotic is administered (usually a cephalosporin), as is standard practice for all interventional implantation procedures. The femoral vein and artery are cannulated percutaneously. The size and configuration of the duct are determined by descending aortic angiography, using a 4F or 5F pigtail catheter (figure 2).

The arterial catheter is then withdrawn to the femoral artery to avoid interference with ADO deployment. The minimum diameter, the diameter of the aortic ampulla and the length of the duct are measured. An endhole catheter (usually 5F) is passed through

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the duct from the pulmonary side into the descending aorta, if necessary with the help of an 0.035" guidewire (figure 3).

Figure 2 Descending aortogram demonstrating the shape, length and course of the duct (arrow). AO=aorta; PA=pulmonary trunk.

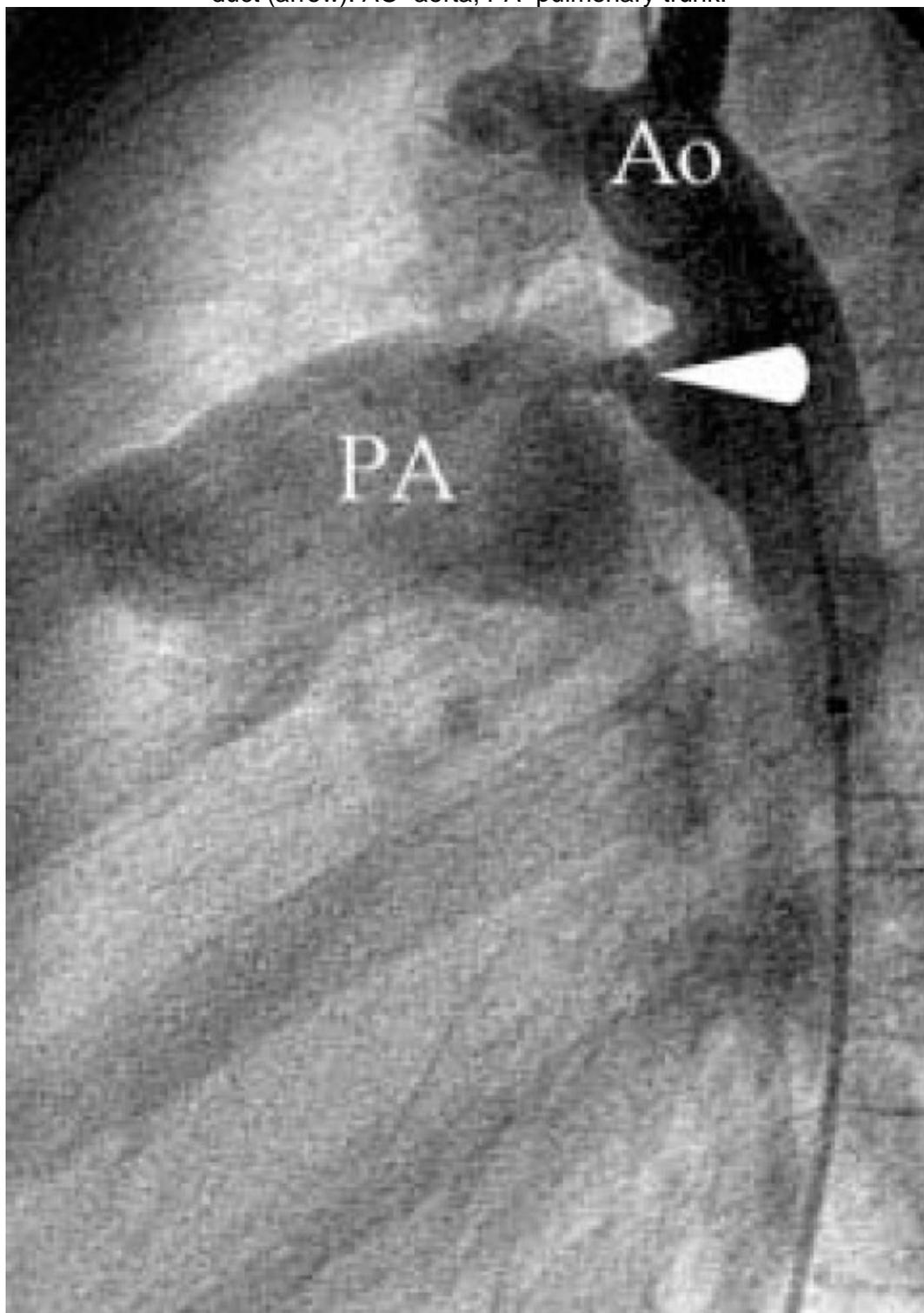
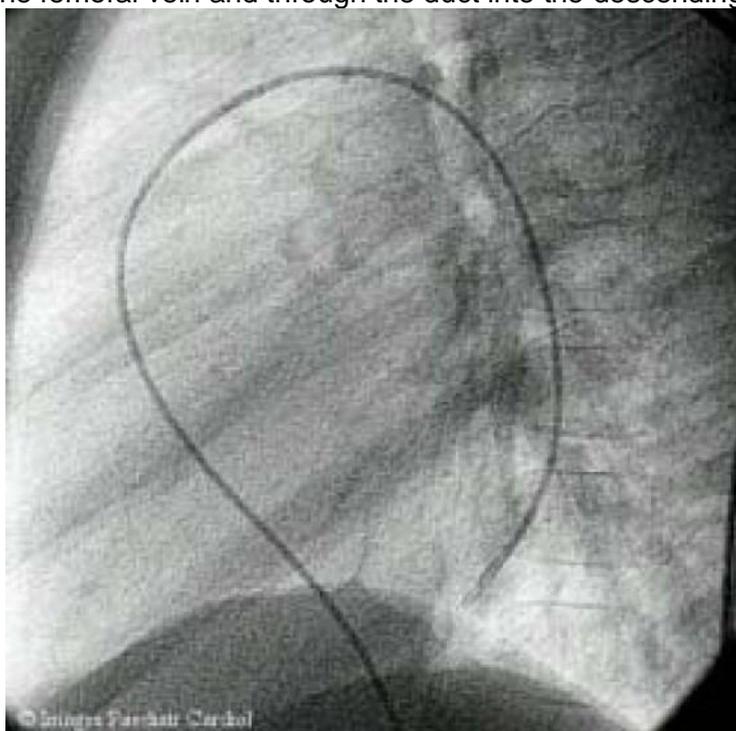
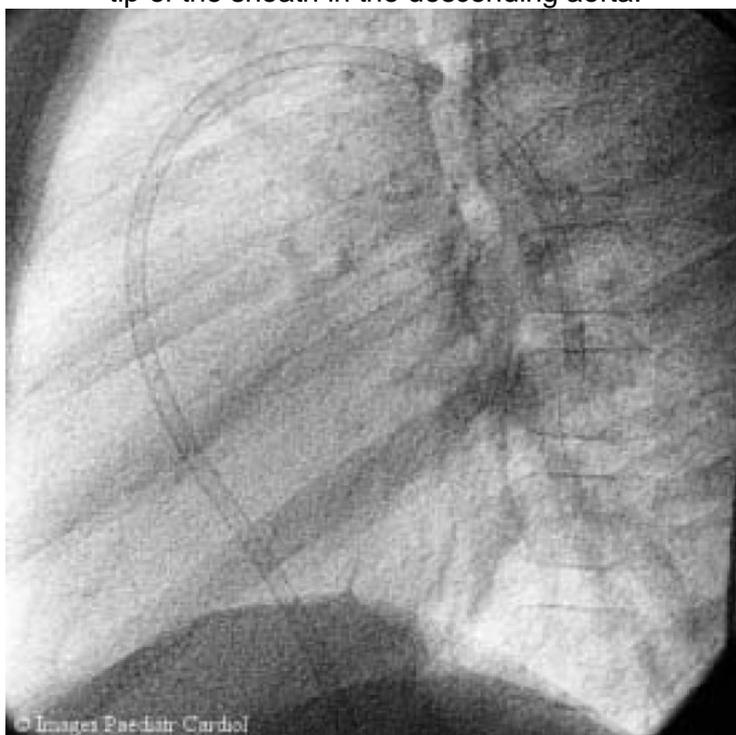


Figure 3 An end-hole 5F multipurpose catheter has been advanced antegradely from the femoral vein and through the duct into the descending aorta.



The endhole catheter is then exchanged for a delivery sheath, over an 0.035" exchange length (260 cm long for older patients) guidewire (figure 4).

Figure 4 The endhole catheter has been exchanged for a 6F delivery sheath, with the tip of the sheath in the descending aorta.



The appropriate ADO device is chosen, such that the diameter of the pulmonary end is at least 2 mm larger than the narrowest diameter of the duct, and immersed into saline solution. The delivery cable is passed through the loader and the device is screwed on clockwise to the tip (figure 5).

Figure 5 Top panel - the delivery cable for the ADO has been passed through the loading sheath. Second panel - after attachment of the ADO to the delivery cable, the cable is gently withdrawn to allow the device to pass into the loading sheath. Third panel - the delivery cable is shown within the loading sheath, with the ADO attached to its distal end. Bottom panel - The delivery cable has been pulled back so that the ADO is at the tip of the loading device. Further pullback compresses the device and allows it to enter the loading sheath.

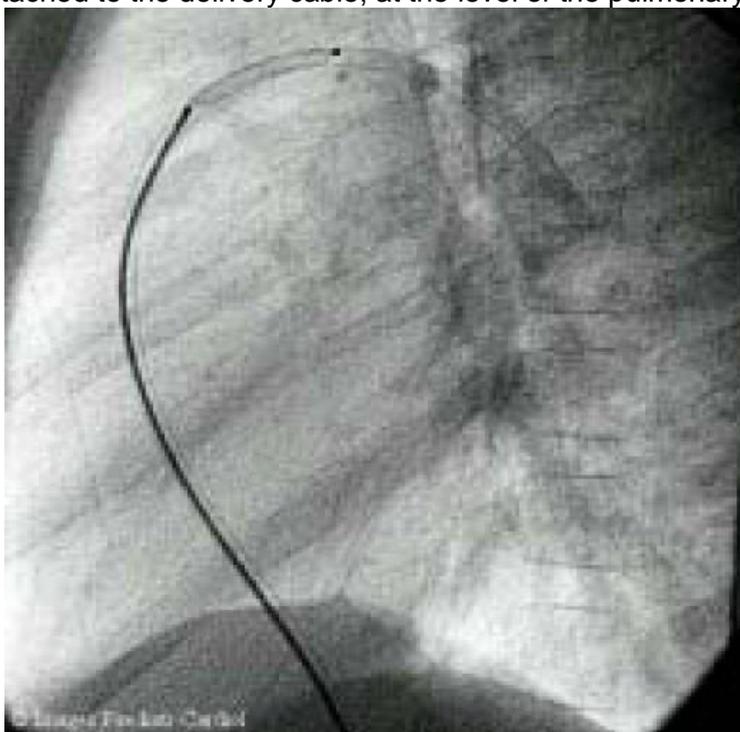


Thereafter, the whole system is immersed into saline again (figure 6). The device is now pulled into the loader and the loader is introduced into the delivery sheath. The device is advanced through the delivery sheath into the descending aorta (figure 7).

Figure 6 Top - the ADO is completely within the loading sheath, and the entire system is flushed with saline to remove any air bubbles. Bottom - the hub of the loading sheath (with the device contained within it) has been advanced through the haemostatic valve at the proximal end of the delivery catheter. The ADO can now be advanced into the delivery sheath by pushing the delivery cable distally.



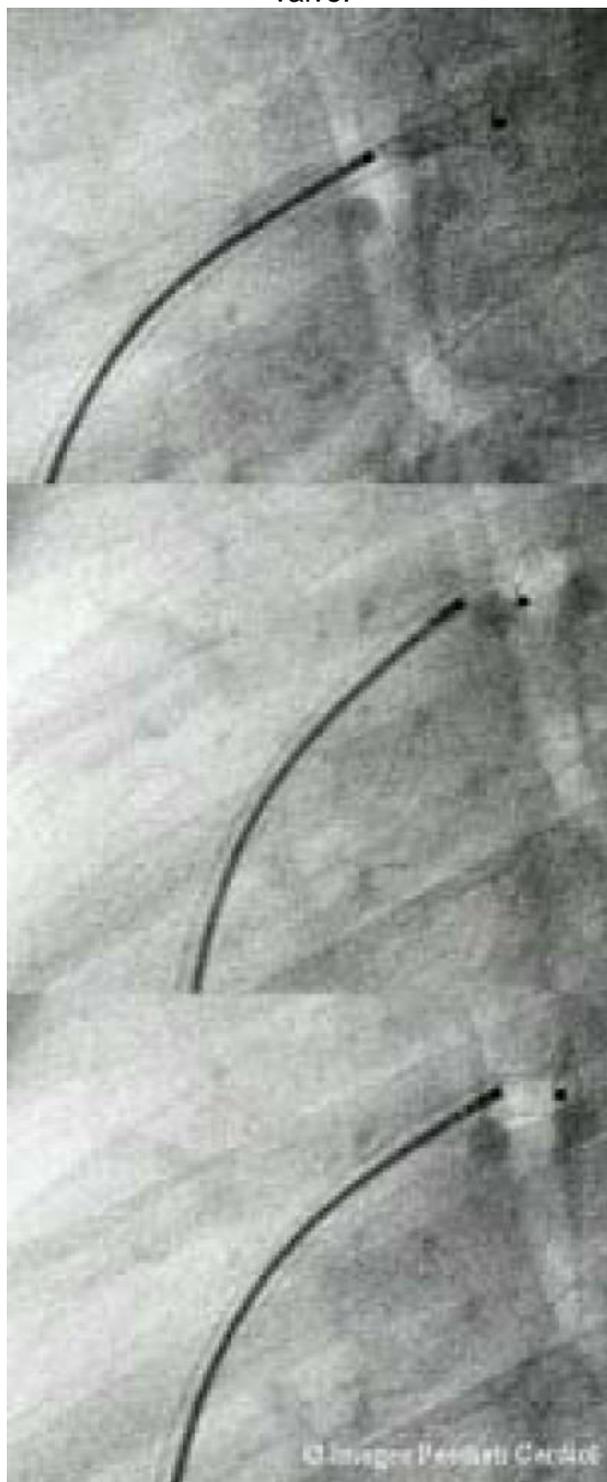
Figure 7 The fluoroscopic image demonstrates the ADO within the delivery sheath, still attached to the delivery cable, at the level of the pulmonary trunk.



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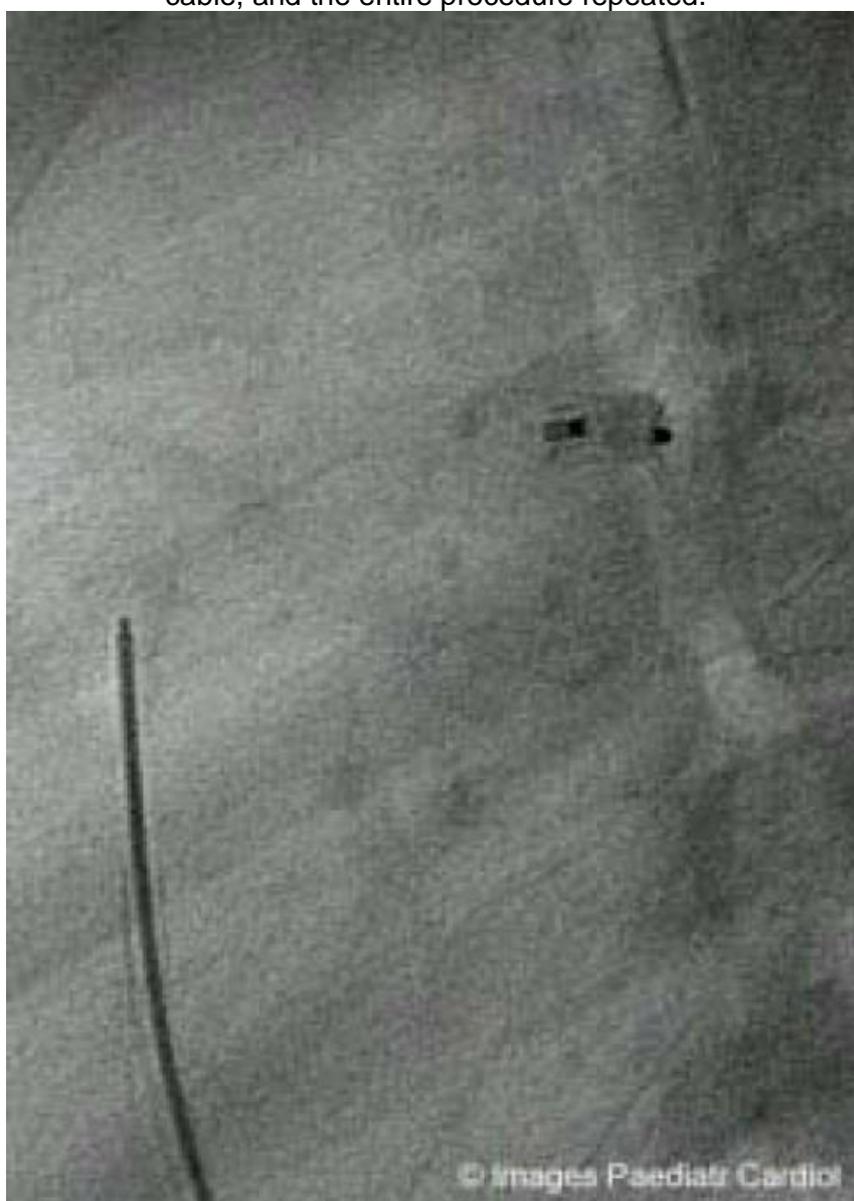
The retention disk is deployed in the descending aorta, by gently withdrawing the delivery sheath (figure 8). The sheath and the retention disk are pulled back as a single unit, firmly into the ampulla of the duct. The rest of the device is then uncovered within the duct, by holding the delivery cable of the ADO stationary while pulling back the delivery sheath.

Figure 8 Real-time fluroscopy showing release of the device. The device is released, and the delivery cable is within the delivery sheath, at the level of the pulmonary valve.



An aortogram is performed to confirm correct device position, taking care in particular to ensure that the retention disc is sitting entirely on the rim of the ductal ampulla, is not obstructing the descending aorta, and has not partially prolapsed into the body of the duct (figure 5). If the device needs to be repositioned or retrieved, it can be pulled back into the sheath, and the entire procedure repeated, either with the same device or using a different sized device as deemed appropriate. If the position is correct, the device is released by rotating the delivery cable in an anticlockwise direction (as indicated by the arrow on the vise) with the pin vise (figure 9).

Figure 9 Top - the retention disc of the device has been extruded beyond the distal end of the delivery sheath, in the descending aorta. Middle - the sheath and delivery cable are pulled back as one unit, to allow the retention disc to engage the ampulla of the duct. Bottom - further pullback of the delivery sheath allows the entire occluder to be uncovered within the duct. At this point, descending aortography may be performed to confirm that the device is appropriately positioned. If such is not the case, the device may be withdrawn into the delivery sheath by pulling on the delivery cable, and the entire procedure repeated.



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Following successful detachment of the device the delivery system is removed. A repeat aortogram may be done 5 to 15 minutes after the release, to reconfirm device position (figure 10).

The arterial and venous catheters and sheaths may thereafter be removed, and hemostasis achieved by manual compression of the groin. At 24 hours post-procedure, an echocardiogram (cross sectional, spectral and colour flow Doppler studies are performed to demonstrate the orientation of the device, its relation to the descending aorta and the branch pulmonary arteries, and to document the presence and degree of residual shunting) and a chest x ray in the posteroanterior and lateral projections are obtained, prior to discharging the patient from hospital. Further clinical follow-up and echocardiography are undertaken at 6 weeks, 3 months, 6 months and 12 months post-ADO implantation.

Figure 10 Post-release aortogram confirming ideal device position. The retention disc is appropriately configured to the ductal ampulla.



## Discussion

Follow-up studies following ADO deployment have confirmed occlusion rates of >99% within 6 months of device deployment, with minimal complication rates.<sup>2–6</sup> The majority of occlusions can be confirmed within 24 hours, prior to discharge from hospital. Protrusion of the retention disc into the descending aorta, producing aortic obstruction is a rare complication, and may necessitate removal of the device.<sup>7</sup> To avoid this potential complication, aortography is always recommended after device deployment, prior to release, and following release of the device. Even after the device has been released, it can be retrieved if necessary by transcatheter techniques, and the duct occluded using a new device. A modification of the ADO has been described to avoid this complication, in which the aortic retention disc is angulated at approximately 32° to the body of the device and is concave towards the aorta, and may be indicated in special instances.<sup>8</sup> Device protrusion into the left pulmonary artery is also infrequently seen when compared with the Rashkind device or following the use of multiple coils,<sup>9,10</sup> as the device has a low profile on the pulmonary side. Late device embolization into the pulmonary arteries, occurring at upto 24 hours following implant, was reported in the early series, and was probably due to the use of a smaller than optimal device.<sup>4</sup> This may be avoided by confirming that no part of the retention disc has prolapsed into the body of the duct, prior to release.

There has to date been a single procedure-related death with use of the ADO.<sup>11</sup> In that patient the device, which was probably too small for the duct in question, embolized into the descending aorta and was not retrieved until 4 hours later, resulting in mesenteric vascular complications and sepsis. Device embolization into the aorta would constitute a medical emergency, necessitating immediate transcatheter or surgical retrieval of the embolized device.

In conclusion, the implantation and clinical follow-up data available to date confirm that moderate to large PDAs can be safely occluded using the ADO in patients from 3.5 kg in weight upwards, with excellent occlusion rates and minimal complications.

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