The Amplatzer Duct Occluder: Experience in 209 Patients
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OBJECTIVES
The aim of the study was to assess the safety and efficacy of the Amplatzer ductal occluder (ADO) in transcatheter occlusion of patent ductus arteriosus (PDA).

BACKGROUND
Transcatheter closure of small to moderate sized PDAs is an established procedure. The ADO is a self-expandable device with a number of salutary features, notably its retrievability, ease of delivery via small 5F to 7F catheters and a range of sizes suitable even for the larger PDAs.

METHODS
Between November 1997 and August 1999, the ADO was successfully implanted in 205 of 209 patients with PDA. The inclusion criteria for this device occlusion method were patients with clinical and echocardiographic features of moderate to large PDA, weighing ≥3.5 kg as well as asymptomatic adolescents and adults with PDA measuring ≥5.0 mm on two-dimensional (2D) echocardiogram. Occlusion was achieved via the antegrade venous approach. Follow-up evaluations were performed with 2D echocardiogram, color-flow mapping and Doppler measurement of the descending aorta and left pulmonary artery velocity at 24 h and 1, 3, 6 and 12 months after implantation.

RESULTS
Two hundred and five patients had successful PDA occlusion using this device. The patients were between two months and 50 years (median 1.9) and weighed between 3.4 kg and 63.2 (median 8.4). Infants made up 26% of the total patients. The PDA measured from 1.8 to 12.5 mm (mean 4.9) at the narrowest diameter. Forty-four percent of patients achieved immediate complete occlusion. On color Doppler the closure rates at 24 h and 1 month after implant were 66% and 97%, respectively. At 6 and 12 months all except one patient attained complete occlusion. Device embolization occurred in three patients; in two this was spontaneous, and in the other it was due to catheter manipulation during postimplant hemodynamic measurement. Mild aortic narrowing was seen in an infant.

CONCLUSIONS
Patent ductus arteriosus occlusion using ADO is safe and efficacious. It is particularly useful in symptomatic infants and small children with relatively large PDA. Embolization can be minimized by selection of appropriate sized devices, and caution should be exercised in infants <5 kg. (J Am Coll Cardiol 2001;37:258–61) © 2001 by the American College of Cardiology

Over the last decade, clinical experience with transcatheter device occlusion of patent ductus arteriosus (PDA) has been reported extensively (1–6). While the small to moderate size ductus can be readily closed with various devices such as Gianturco coils (7,8), Cook’s detachable coils (9) and DuctOcclud (PFM, Inc., Germany) (10), transcatheter closure of the larger ones is still rather limited. Recently Masura et al. (11) reported the use of a new self-expandable device (Amplatzer duct occluder [ADO]) to occlude moderate to large sized PDA. An account our experience using this new device for transcatheter occlusion follows.

METHODS
From November 1997 to August 1999, 209 patients underwent attempted transcatheter occlusion of PDA using this new device. Informed consent was obtained from all patients or their guardians. All patients had clinical and echocardiographic findings of a PDA. Two patients had concomitant pulmonary stenosis, and another had a small ventricular septal defect (VSD); the fourth patient had previous surgical correction for pulmonary atresia with VSD. The patients who were selected for this device occlusion were those with clinical and echocardiographic features of moderate to large PDA and weighed ≥3.5 kg. These patients had one or more of the following: symptoms and signs of cardiac failure requiring medications, failure to thrive, bounding pulses, cardiomegaly on chest radiography and at least moderate dilation of the left atrium and ventricle on two-dimensional (2D) echocardiography. There were a small number of adolescents and adults who were asymptomatic but had PDA measuring ≥5.0 mm on 2D echocardiography and were included for this method of occlusion. Those with clinical presentation and echocardiographic confirmation of small PDAs were occluded using the coil embolization technique.

The transcatheter occlusion was performed under general anesthesia in all infants and small children or under sedation and local anesthesia in the older patients. The method for ADO device implantation has previously been described (12). Follow-up evaluation was performed with 2D echocardiogram, color-flow mapping and Doppler measurement...


**RESULTS**

Two hundred and five of 209 patients had successful PDA occlusion using this device. The median age was 1.9 years (range 0.2 to 50). Infants made up 26% of the total patients. The median weight was 8.4 kg (range 3.4 to 63.2). Twenty-seven percent of all patients weighed ≤5 kg. Seventy-two patients (35%) had associated pulmonary hypertension with the systemic pulmonary artery (PA) to aortic pressure ratio of more than 0.5. One hundred and nine patients (54%) were symptomatic, presenting as either congestive heart failure (29%) or failure to thrive (23%). One hundred and eighty-three (90%) patients had various degrees of cardiomegaly. Marked cardiomegaly was present in 31% of them. According to the classification adopted by Krichenko et al. (13), 84% had type A PDA; 24% had type C, and 5% were type E. The median PDA size was 4.5 mm (range 1.8 to 12.5) on angiographic measurement, and the mean pulmonary to systemic flow ratio was 4.4 (range 1.7 to 11.6). The occlusion was achieved anterogradely through the venous side. In three patients the PDA was deemed too large and not suitable for occlusion on aortography. They underwent surgical ligation. This occurred during the initial phase of this study when the larger devices were not available. In one patient, an infant weighing 3.9 kg with a large duct, we encountered a problem placing the delivery sheath into the PDA. It kinked persistently at the ductus, and this impeded the device delivery. The PDA was occluded using multiple Gianturco coils with great difficulty. On the other hand, five patients who were initially treated with the coil occlusion technique subsequently received the ADO device due to large PDA size, resulting in embolizations. The coils were retrieved, and the ADO devices were implanted successfully.

The mean systolic PA pressure was 45 mm Hg (range 17 to 124), and the mean systolic PA: aortic pressure ratio was 0.47 (range 0.18 to 0.95). The mean fluoroscopy time was 15.3 min (range 3.1 to 160). Forty-four percent of patients achieved immediate complete occlusion. On color Doppler interrogation, the closure rate at 24 h and one month after implant were 66% and 97%, respectively. At six months all except one patient achieved complete occlusion. The residual shunt disappeared spontaneously at 15 months after the procedure. All patients completed one-month follow-up, and 99% attended the three-month follow-up clinic. Two patients were lost to follow up, and one patient died due to sepsis of unrelated cause. Ninety-three percent of patients completed six months follow-up, and 43% were seen at one-year after implantation.

Two infants had significant blood loss requiring transfusion due to difficult cannulation. One patient acquired mild aortic narrowing with a pressure gradient of 15 mm Hg. This was attributed to a large size device deployed (size 10/8 mm) in a 5 kg infant due to a large size ductus (6.2 mm).

In three patients the device embolized to the PA after being released. In one patient this was due to catheter manipulation during postimplant hemodynamic measurement. In two patients, the embolization was spontaneous, at the end of the procedure in one and at 24 h in the other, despite complete occlusion on angiography. In all three cases the device was removed at the time of surgical ligation.

**DISCUSSION**

Transcatheter PDA closure is now a well-established procedure, that is, performed frequently (1–6), with conventional surgery generally reserved for patients with a large duct or symptomatic preterm infants. A number of devices and techniques have been in clinical use with varying degree of popularity and success since Porstmann et al. (12) introduced the Ivalon plug nearly three decades ago. The extensively investigated Rashkind PDA occluder was once widely accepted, but its high cost, the need for a relatively large transvenous sheath, a late incidence of residual shunt of up to 15% to 20% and the risk of stenosis at the origin of the LPA with the use of the 17 mm device led to the search for alternatives (13). Ironically, the Gianturco coils, though not purpose-designed for closure of PDA, are currently among the most widely used techniques due to its low cost, ease of delivery using small 4F and 5F conventional catheters and, more importantly, its high closure rate, approaching 98% to 100% at the three to six month follow-up in the later series (14,15). The use of multiple coils has enabled moderate sized ductus to be readily closed by this technique (15), and, in another report, this technique has been successfully applied to close PDAs larger than 4-mm (16). Inadvertent embolization remains a risk, albeit small, and this has led to its modification; the detachable Cook’s PDA coils (9).

Notwithstanding its remarkable efficacy and safety profile, there remains a significant number of patients in whom surgical ligation is easier, safer and, indeed, preferable, excluding the symptomatic preterm infants. These are infants and small children with relatively large PDAs (>4 mm) with manifest cardiac failure and pulmonary hypertension where coil occlusion can be technically difficult if not impossible without the risk of inadvertent embolization. This includes too a small number of adult patients who

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**Abbreviations and Acronyms**

- ADO = Amplatzer duct occluder
- LPA = left pulmonary artery
- PA = pulmonary artery
- PDA = patent ductus arteriosus
- VSD = ventricular septal defect
- 2D = two-dimensional
may not be symptomatic but, nevertheless, whose PDA are too large to be occluded comfortably with coils.

The newly introduced ADO, apart from having a range of sizes to close larger PDAs, has a number of salutary features, namely retrievability up to the point of deployment and ease of delivery using small 5 to 7F long sheaths. The great majority of patients in the present series were those who would otherwise have been considered unsuitable for closure with Gianturco coils, which is the treatment of choice in our institution. Twenty-six percent of these patients were infants, and 27% weighed <5 kg. All the infants were symptomatic and were receiving medications. Thirty-five percent of the patients had significantly elevated PA pressure (mean PA/aorta >0.5). In these patients, the use of the ADO achieved a closure rate of 66% at 24 h, 97% at one month and 99% at 12 months after implantation. It is worthwhile to note that the residual shunts were only detectable by color Doppler except in one patient who had an audible systolic murmur, but even this eventually closed at 15 months. Encroachment on the origin of the LPA leading to increased flow velocity of >1.5 m/s was not seen. This may be ascribed to the fact that the ADO has a low profile at its pulmonary side in contrast with the Rashkind umbrella. In our experience, the major complication with the ADO was inadvertent embolization to the PAs, which was seen in three patients (1.5%) with no adverse clinical or hemodynamic effects. Though in one case this was due to catheter manipulation after implantation; in the other two this occurred spontaneously, one of which had complete occlusion on angiography. We feel the error lies in the choice of too small a device size, which in all cases led to the top part of the retention disc to slant forward midway in the ductus instead of sitting entirely on the rim of the ampula. The appearance of an indentation forming a bump on the superior wall of the ductus caused by the retention disc slanting forward towards the PA should be taken as an ominous sign of the likelihood of embolization (Fig. 1). A device size of at least 2 mm larger that the smallest PDA diameter has, thus, been recommended by the manufacturer. A large margin should perhaps be considered for tubular ductus.

Although it is eminently feasible to implant the ADO in a symptomatic infant with a large PDA without much difficulty, the retention disc may significantly encroach on the aortic lumen as demonstrated in one patient. Though this problem may lose its significance with subsequent somatic growth, one needs to exercise caution when using this device in infants less than 5 kg. At any rate, the device can be easily removed before final deployment if this problem arises.

Conclusions. Our data suggest that transcatheter closure of the PDA of virtually any size with the ADO is safe and efficacious. It is particularly useful in symptomatic infants and small children with relatively large PDAs where the role of other transcatheter techniques is limited. However, its use in infants below 5 kg is not advisable due to the risk of aortic narrowing by the device. Inadvertent embolization to the PAs can be minimized by the use of an appropriate sized device. Larger numbers of treated patients and longer follow-up will be necessary to precisely define the efficacy, safety and appropriate indications of this device.

REFERENCES
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