

Transcatheter Closure of Patent Ductus Arteriosus Using the Amplatzer Duct Occluder in Infants Under 1 Year of Age

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Introduction and objectives. Percutaneous closure of patent ductus arteriosus (PDA) is a well-established technique. We evaluated the usefulness of the Amplatzer duct occluder for the percutaneous closure of patent ductus arteriosus in 29 children under 1 year of age.

Methods. The patients' mean age was 8.9 [2.8] months and their mean weight was 6.4 [1.5] kg. In addition, 24.1% of patients were aged 6 months or less and 17.2% weighed 5 kg or less. All completed follow-up (0.5-36 months).

Results. The minimum PDA diameter was 3.16[1.24] mm. The device was implanted successfully in 26 patients (89.6%). Failures were due to either the device migrating to the descending aorta, persistent moderate leakage, or to difficulty in the advancement of the device. No deaths were associated with the procedure. Three major complications occurred in two patients (10.3%). Aortography showed initial total occlusion in 65.5% of patients. At 3-month follow-up, total occlusion was observed in 96.1% of patients. Ultimately, closure was achieved successfully in 25 of the 29 patients (86.2%). During follow-up, 4 patients exhibited mild left pulmonary artery stenosis and 1 exhibited mild stenosis of the descending aorta.

Conclusions. In children under 1 year of age, percutaneous closure of patent ductus arteriosus using an Amplatzer occluder was a safe and effective procedure. It is possible that improvements in the design of the occluder could decrease the complication rate.

Key words: Patent ductus arteriosus. Transcatheter closure. Amplatzer duct occluder.

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Cierre transcatóter del conducto arterioso persistente con dispositivo de Amplatzer en niños menores de un año

Introducción y objetivos. El cierre percutáneo del conducto arterioso persistente (CAP) es una técnica bien establecida. Evaluamos la utilidad del ocluidor de Amplatzer (ADO), en el cierre percutáneo del CAP en 29 niños menores de 1 año.

Métodos. La edad de los pacientes fue de 8,9 ± 2,8 meses y el peso, 6,4 ± 1,5 kg. El 24,1% de los pacientes con edad ≤ 6 meses y el 17,2%, con peso ≤ 5 kg. Se realizó seguimiento en todos (0,5-36 meses).

Resultados. El diámetro mínimo del conducto fue 3,16 ± 1,24 mm. El dispositivo se implantó con éxito en 26 (89,6%) pacientes. Las causas del fracaso se debieron a migración del dispositivo a la aorta descendente, persistencia de la fuga en forma moderada y dificultad en progresar el dispositivo. La mortalidad fue nula con el procedimiento. Ocurrieron 3 complicaciones mayores en 2 (10,3%) pacientes. Un aortograma mostró oclusión completa inicial en el 65,5% de los pacientes. La oclusión completa del conducto se demostró en el 96,1% de los pacientes al tercer mes de seguimiento. El éxito final del cierre del CAP se logró en 25/29 (86,2%) pacientes. En el seguimiento, 4 pacientes mostraron estenosis leve en la rama pulmonar izquierda, y 1, estenosis leve en la aorta descendente.

Conclusiones. En niños menores de 1 año, el cierre percutáneo del CAP con el ocluidor de Amplatzer es un procedimiento efectivo y seguro. Las mejoras en el diseño del ocluidor posiblemente disminuirán la frecuencia de complicaciones.

Palabras clave: Conducto arterioso persistente. Cierre percutáneo. Amplatzer.

INTRODUCTION

Percutaneous closure of patent ductus arteriosus (PDA) is a well-established procedure for the

ABBREVIATIONS

ADO: Amplatzer duct occluder
 PDA: patent ductus arteriosus
 TTE: transthoracic echocardiogram

vast majority of pediatric patients. Since the first percutaneous closure of PDA by Porstmann,^{1,2} various researchers have described several techniques and occluders for non-surgical closure.³⁻⁷ Since 1996, detachable coil systems have been widely used.⁵⁻⁸ Although satisfactory results have been obtained in the closure of small ducts (<2 mm) using detachable coils,⁸ there is a greater incidence of residual shunt, hemolysis, and embolization in larger ducts.⁹ In 1998, Masura et al¹⁰ published the first series of cases of percutaneous closure of the arterial duct using the new Amplatzer device, which was especially designed for medium to large ducts. The Amplatzer duct occluder (ADO) has been widely used in different pediatric cardiology hospitals, with less incidence of residual leak, embolization, and left pulmonary artery stenosis.^{11,12} An important advantage is that it has a small-caliber detachment system, and so can be used in young children. Few studies have investigated their usefulness in children under 1 year of age.

Aims

In our hospital, the percutaneous closure of PDA began in 2000. The aim of this study was to evaluate the safety and efficacy of the ADO in a cohort of children under 1 year of age, with special attention to the problems and complications encountered during its use.

METHODS

Patients

Between August 2005 and August 2008, we analyzed the medical records of 29 patients under 1 year of age undergoing percutaneous closure of PDA. Of the patients, 21 (71.4%) were girls and 8 (28.6%) were boys. The patients were aged between 4 months and 12 months (8.9 [2.8] months), and weighed between 3.8 kg and 10 kg (6.4 [1.5] kg); 7 (24.1%) patients were less than 6 months old and 5 (17.2%) weighed 5 kg or less. All patients underwent chest x-ray, electrocardiogram, and transthoracic echocardiogram (TTE) before the procedure, and informed consent was obtained from their parents

or guardians. The selection criteria were as follows: age ≤ 1 year, weight > 3.5 kg, and clinical and echocardiographic findings of PDA with a minimum diameter of ≥ 2 mm. The clinical indications for PDA closure were as follows: heart failure in 15 (51.7%) patients; heart failure and retarded growth in 11 (37.9%); 3 (10.3%) were asymptomatic; 17 (58.6%) had dilatation of the left cavity as evaluated by 2-dimensional echocardiogram. Retarded growth was defined in line with Ramos-Galván et al.¹³

Patent ductus arteriosus presented as an isolated lesion in 19 (65.5%) patients. Nonsevere PDA-associated heart lesions were as follows: two cases of interatrial communication, 2 cases of interventricular communication, 1 case of pulmonary stenosis, and 1 case of aortic stenosis and vascular ring. Five patients had Down syndrome. No patient had undergone previous intervention of the arterial duct. The form of the arterial duct was determined according to the classification of Krichenko.¹⁴

Device

The ADO and release system (AGA Medical, Golden Valley, Minnesota, USA) has been widely described.^{10,15-17}

Device Selection and Implantation Protocol

The ADO implantation protocol has been described in previous communications.^{10,15-17} The procedure was conducted under sedation, the femoral artery and vein were catheterized and 100 U/kg sodium heparin was administered. After recording pulmonary and systemic pressures, an aortogram was conducted in lateral and right anterior oblique projections to define duct morphology and size (Figure 1A). Anterograde catheterization was performed in all cases. Devices at least 1-2 mm larger than the minimum diameter of the PDA were selected. The device, which was attached to the tip of the release cable, was introduced through the sheath to the descending aorta. Once in place, the retention disk was opened and positioned in the aortic ampulla of the duct. Subsequently, the rest of the sheath was withdrawn toward the pulmonary trunk, positioning the tubular part of the Amplatzer device within the duct. With the device still anchored to the release cable, an aortogram (Figure 1B) was performed and when good placement was verified, the device was detached; 10 min after ADO implantation angiography of the descending aorta was conducted to detect any residual shunt (Figure 1C).

The following types of leakage were arbitrarily defined as follows: trivial, observed within the occluder; mild, observed up to the pulmonary trunk without visualizing the pulmonary valve; and

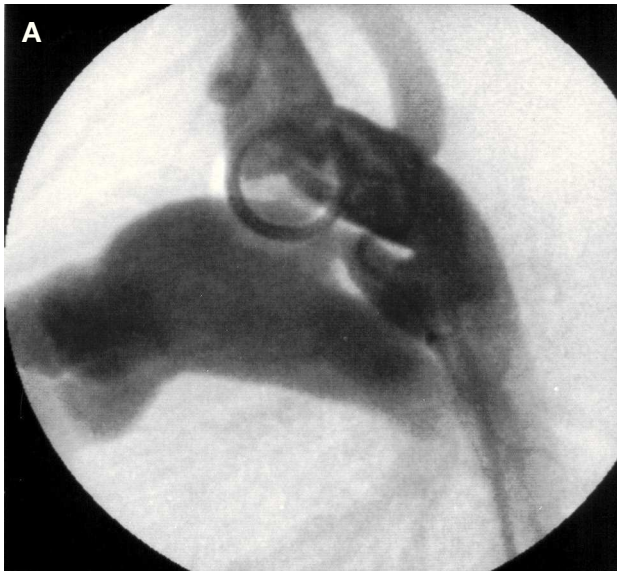
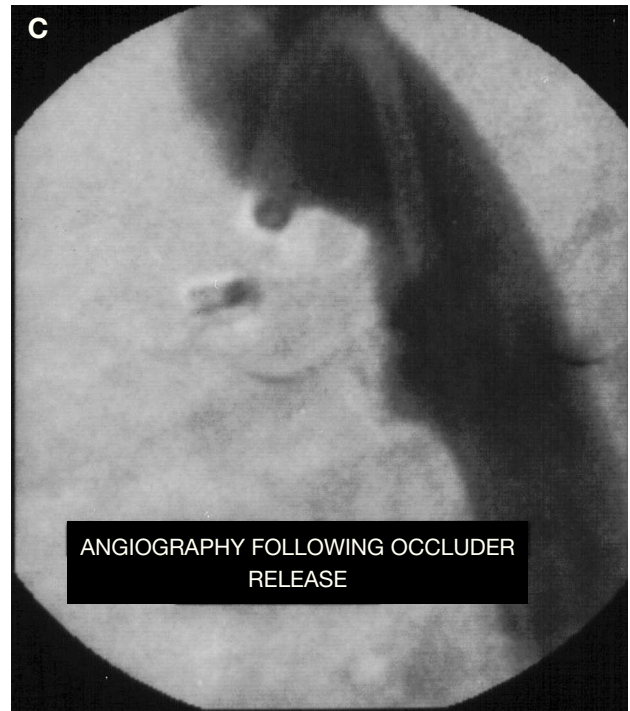


Figure 1. A: lateral aortogram showing the PDA (3.3-mm diameter) in a girl aged 7 months weighing 6.8 kg, with QP:QS ratio >2 and pulmonary hypertension. B: Amplatzer duct occluder retention disk positioned in the aortic ampulla. C: final angiography following occluder release. Complete occlusion of the duct can be seen.



moderate, observed up to the level of the pulmonary valve. We recorded the withdrawal pressure in the descending aorta and left pulmonary branch to rule out obstruction. The following were considered procedure-related technical problems: *a)* inability to position the device within the aortic ampulla due to underestimating the size of the PDA; *b)* any difficulty related to advancing, implanting, and withdrawing the device; and *c)* inadequate functioning of the device itself or any component of the release system.

Follow-up Protocol

Chest x-ray and TTE were conducted at 24 h to evaluate the shape and position of the device. Color-Doppler ultrasound was used to detect and quantify any residual shunt. The following were arbitrarily defined: the severity of leakage as assessed by color-Doppler was arbitrarily defined as follows: trivial, <1 mm diameter; mild, 1-2 mm diameter; moderate, >2 mm diameter at the site of leak onset. Pulsed and continuous wave Doppler ultrasound were used to determine flow and velocity patterns in the descending aorta and pulmonary artery to rule out obstruction. Follow-up with TTE was conducted at 1 month, 3 months, 6 months, and 12 months after implantation. Major and minor complications

related to device implantation were analyzed and described at each assessment. Major complications included: procedure-associated mortality; femoral artery lesion; blood loss $\geq 5\%$ of the estimated blood volume; migration of the device to the lumen of the pulmonary branch or descending aorta. Minor complications included: protrusion of the device

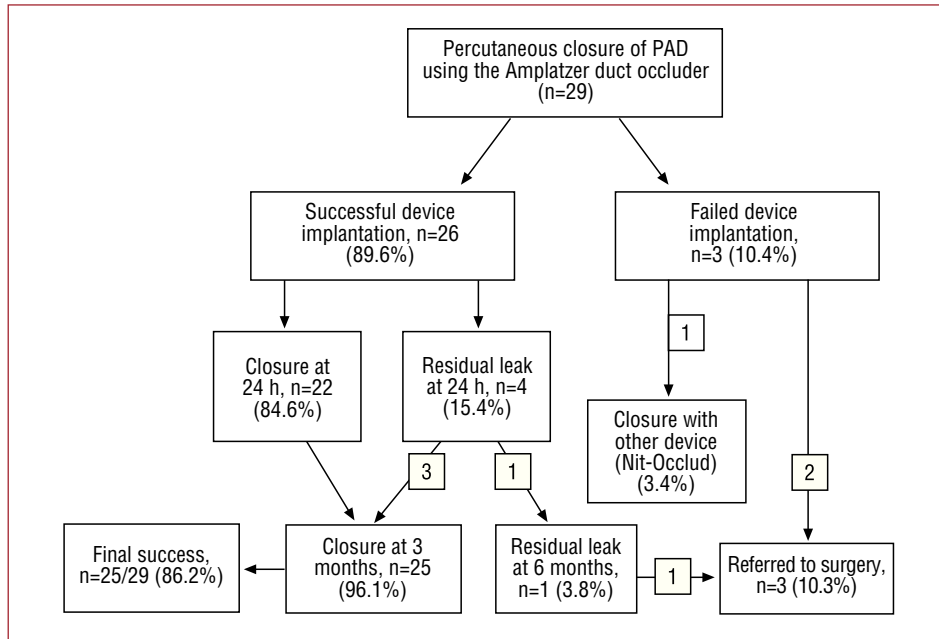


Figure 2. Outcomes of percutaneous occlusion of arterial duct using the Amplatzer device. PDA indicates patent ductus arteriosus.

into the bed of the pulmonary branch or descending aorta leading to accelerated blood flow (maximum Doppler velocity <2-2.5 m/s); and spasticity of the femoral artery at the vascular access point. Aspirin (5 mg/kg) and prophylaxis for bacterial endocarditis were indicated and administered for 6 months following the procedure.¹⁶

Statistical Analysis

Continuous variables are expressed as mean (standard deviation) or as median and intervals; discrete variables are expressed as absolute value and percentage. The Student *t* test was used to compare continuous variables, and the Fisher exact test for the discrete variables. A *P* value less than .05 was considered significant.

RESULTS

Between August 2005 and August 2008, 29 patients aged less than 1 year underwent percutaneous closure of PDA of ≥2-mm diameter (Figure 2). The minimum arterial duct diameter, as measured by echocardiography, was 4.4 (1.3) mm (range, 2-7.5 mm). Table shows the demographic, hemodynamic, and angiographic characteristics of the patients. The maximum and minimum diameters of the arterial duct, measured angiographically, were 3.2 (1.2) mm (range, 2-7.3 mm) and 8 (2.1) mm (range, 4-13.2 mm), respectively. Device implantation was effective in 26

TABLE 1. Demographic, Hemodynamic, and Angiographic Characteristics of Patients (n=29) Undergoing Percutaneous Closure of Patent Ductus Arteriosus Using the Amplatzer Duct Occluder

Age, mo	8.9 (2.8) (4-12)
Boys	8 (28.6%)
Girls	21 (71.4%)
Weight, kg	6.36 (1.53) (3.85-10)
Height, cm	66.8 (6.64) (50-77)
Pulmonary artery systolic pressure, mm Hg	45.6 (18.3) (16-81)
PSP/PSS ratio	0.55 (0.22) (0.2-1)
QP:QS ratio	2.4 (1.3) (0.7-6.7)
Minimum arterial duct diameter, mm	3.16 (1.24) (2-7.3)
Maximum arterial duct diameter, mm	8 (2.1) (4-13.2)
Fluoroscopy time, min	13.3 (6.6) (4-32)
Procedure time (n=21), min	66.2 (24) (40-134)

(89.6%) of the 29 patients. The morphology of the duct, according to the Krichenko classification¹⁴ was as follows: type A in 20 patients (69%); type B in 1 patient (3.4%); type C in 6 patients (20.7%); and type E in 2 patients (6.9%). Pulmonary hypertension was observed in 17 patients (58.6%), with a pulmonary/systemic arterial pressure ratio of 0.54 (0.23) (range, 0.18-1), and that improved after PDA closure (0.33 [0.08]). Fluoroscopy time was 13.3 (6.6) min (range, 4-32 min) and procedure time, 66.2 (24) min (range, 40-134 min). There were no procedure-associated

deaths. The sizes of the implanted devices were as follows: 5/4 in 3 patients; 6/4 in 14 patients; 8/6 in 9 patients; 10/8 in 2 patients; and 12/10 in 1 patient. Immediate occlusion, confirmed by angiography, was achieved in 19 (73.1%) of 26 patients; 7 (26.9%) patients presented postprocedural residual leak which was trivial in 4 of them. After device implantation, no patient presented a pressure gradient between the ascending and descending aorta, or between the left pulmonary artery and pulmonary trunk.

Technical problems associated with the procedure were observed in 4 (13.8%) patients. Their ages ranged from 5 months to 11 months (weight, 3.9-7.4 kg), with duct diameters of 2.7-4.1 mm and pulmonary hypertension in 3. In 1 patient, the procedure failed due to the inability to correctly position the device in a duct with an abnormal origin, shape, and orientation. The device was removed on one occasion, before release, in order to implant a larger one (8/6 by 6/4). This procedure was successful. In 1 patient, a kink developed in the sleeve of the release system, making it difficult to advance the device in a complex type-C duct. In 1 patient, the device had to be withdrawn due to underestimating the diameter of a type-B duct; another type of device or a larger one was not available.

Major complications were observed on 3 (10.3%) occasions. In 1 patient aged 10 months (weight, 7.4 kg) with a type-A duct of 2.7 mm diameter, the device migrated toward the bed of the descending aorta, but was subsequently removed successfully using a double lasso catheter. The duct was finally occluded using another type of occluder (Nit-Occlud 9×6 mm). This patient also developed femoral artery thrombosis that required thrombectomy and subsequent management with heparin (72 h) and oral anticoagulation therapy for 3 months. Pulse was completely restored without sequelae. One patient presented blood loss >5% of the estimated blood volume and that required blood transfusion. Procedure-associated mortality was nil. Minor complications were observed in 5 (17.2%) patients. Doppler ultrasound study at 24 h detected an increase in maximum flow velocity in the descending aorta (1.8 m/s) in 1 patient aged 9 months, weighing 3.95 kg and with type-A PDA. Four patients, all less than 7 months of age and weighing 3.9-6.7 kg (type-A and type-E PDA in 2 patients), presented mild stenosis in the left pulmonary branch (Doppler gradient of 16-22 mm Hg). The temporary loss of the arterial pulse was not detected in any of the patients.

Follow-up time was 17.3 (10.6) (range, 0.5-36) months. All the patients were asymptomatic. Subsequent TTE at 24 h showed total occlusion rates of 84.6% (22/26) and at 3 months of 96.1% (25/26). Completely successful PDA closure was achieved in 25 (86.2%) of the 29 patients.

Of the 4 remaining patients, 3 (10.3%) were referred to surgery and another type of occluder was implanted in the other patient (Figure 2). During 3-year follow-up, no late complications were observed, such as PDA recatheterization, hemolysis, endocarditis, or device migration.

DISCUSSION

This study presents the results of using the Amplatzer duct occluder for the percutaneous closure of PDA in children under 1 of age. An occlusion rate of 96% was obtained at 3-month follow-up.^{10-12,15-18} There are few studies on their use in children under 1 year of age or weighing ≤10 kg.^{11,16,19-21} Despite recent progress in the percutaneous closure of PDA, the closure of medium to large ducts, closure in nursing infants and in those of low weight continues to be a problematic. Detachable coils have shown their effectiveness⁸ in ducts ≤2-mm diameter. In contrast, a greater incidence of complications (residual shunt, need for 2 or more occluders, embolization, etc) has been observed in ducts of greater diameter.^{22,23} The improvements made to the Amplatzer occluder—taking into account the small size of the release systems (5-7 Fr) and the conic shape of the prosthesis—facilitate their use in relatively large ducts in low-weight, premature babies under 1 year of age.^{19-21,24,25} Previous studies have recommended that the ADO should not be used in patients weighing <5 kg, due to observed technical difficulties.^{11,17,20} However, these technical difficulties are still being observed in infants weighing ≥5 kg.²⁰ In the present study, 5 (17.2%) patients weighed <5 kg (3.8-4.1 kg). Several authors^{16,19-21} have concluded that, in experienced hands, the percutaneous closure of PDA in symptomatic infants under 1 year of age, or weighing ≤10 kg, is a very safe and effective procedure. Despite this, it is difficult to recommend this device as the treatment of choice for this age group.

The failure of the procedure has been well documented.^{10,11} Fischer et al²⁰ mention technical difficulties in 9 out of 12 patients. In our experience, we observed procedure-associated technical problems in 4 (13.8%) patients. In one of our patients, the duct had an abnormal origin, orientation and shape. Despite obtaining aortograms in different projections, we could not effectively determine the PDA dimensions and, finally, using the best image, we decided to use a 10/8 ADO, taking into account its smallest diameter (5.4 mm). The ADO implantation procedure was difficult and the follow-up aortogram indicated significant residual shunt, thus, we decided against device implantation and the patient was referred to surgery. A critical point in the procedure, and one that is encountered more frequently in

children under 1 year of age,²⁰ occurs when the device—connected to the release cable—is advanced from the bend of the right ventricular outflow tract toward the pulmonary artery. Together, these form a more or less right angle, and can lead to kinks in the introducer sheath, which makes device advancement difficult. This difficulty can be overcome by using a larger sheath or the lasso technique. This occurred in a patient with a complex duct, and despite changing the release sheath for a larger one, we could not advance the device, and finally the patient was referred to surgery. In an attempt to eliminate these technical problems, the manufacturer has recently improved the release cable, which is now thinner and more flexible. In one patient, the first ADO had to be removed in order to implant a larger one. In another patient, we underestimated the size of the PDA, and the device was removed. Since another type of device or larger one was not available, the patient was referred to surgery.

Death is an exceptional complication.¹² Complications arising from the percutaneous closure of PDA using the ADO are rare, and only immediate complications have been reported.^{11,12,21,26,27} Procedure-associated complications have been described in the different age groups, and these are relatively major in patients under 1 year of age or weighing <10 kg.¹⁹⁻²¹ Faella et al¹² report an 8.2% incidence of complications in children aged 1 year or less, compared to an incidence of 3.8% among older children. Butera et al,²¹ observed minor complications in 3 patients under 1 year of age in a series of 18 symptomatic children under 3 years of age, all of whom had undergone successful closure of PDA. The incidence of complications observed in our study (27.5%) may be considered high, but most of these were minor (17.2%). In our study, mortality was nil and the incidence of major complications was relatively greater (10.3%) than that reported in the literature, although the age of the patients should be taken into account. Embolization or poor positioning of the device are rare.^{11,19,21,28} High velocity residual leaks are also rare, which means that mechanical hemolysis is infrequent.²⁶ Thrombus formation or the development of infectious endocarditis have not been reported, although the administration of aspirin (5 mg/kg) and antibiotic prophylaxis is recommended for 6 months.¹⁶

Minor procedure-associated complications are more frequent in children aged less than 1 year.^{11,19-21} Aortic obstruction due to protrusion of the aortic retention disk and left pulmonary artery obstruction has been detected with greater frequency in this group of patients.^{19,20,27} In most patients, aortic obstruction is clinically nonsignificant and is only detected by echocardiographic study.^{5,11,27-29} In our group, at 24 h postprocedure, Doppler

echocardiogram demonstrated mild stenosis in the descending aorta (Doppler gradient, 13 mm Hg) in 1 patient who weighed <4 kg. A relatively low patient weight is considered to contribute to the aortic retention disk protruding into the angle formed by the descending aorta and the arterial duct.^{16,19,20,29} Left pulmonary branch obstruction is also rare.^{16,21} Four patients, all of whom were less than 7 months of age (weight, 3.9-6.7 kg) and with PDA \geq 4 mm, developed mild stenosis of the left pulmonary artery. To date, several modifications have been made to the Amplatzer device^{30,31} to avoid the risk of the device protruding toward the descending aorta or left pulmonary artery which lead to significant hemodynamic alterations. When comparing the advantages of the new ADO II with other Amplatzer occluders, Thanopoulos et al,³¹ reported that its most important feature were the low-profile retention disks that can adapt to the different PDA insertion angles within the aorta and left pulmonary artery, thereby minimizing the risk of device-associated obstruction. In a group of 25 patients,³¹ they report 2 patients (both 2 months of age and weighing 3.5 kg and 4 kg, respectively) with mild left pulmonary artery stenosis associated with the device. In line with other authors, we consider that, as the patient gradually grows, flow velocities can decrease in both sites.³² The use of the Amplatzer device in very young children (weighing <5 kg) with large ducts (\geq 4 mm) involves the risk of protrusion, and that leads to obstruction in the left pulmonary branch or descending aorta.

The effectiveness of the percutaneous closure of PDA using the ADO has been demonstrated, both immediately and during follow-up.^{11,12,15-21,24} In the current study, ADO implantation was effective in 89.6% of the patients. Residual leaks are frequent after ADO implantation; however, residual shunt can persist during 24 h of follow-up but with a high rate of closure, which reaches approximately 99% during 1-year follow-up.^{11,12,15,18,21} The results of our series show an occlusion rate of 84.6% at 24 h and of 96.1% at 3-month follow-up. Completely successful closure of PDA with the ADO was achieved in 86.2% of the patients. This confirms the safety of percutaneous closure of PDA using the ADO, both in the immediate follow-up period and in the long-term in children aged less than 1 year.¹⁹⁻²¹ Our results could be improved given a more experienced cardiac catheterization specialist. Reopening following effective ADO implantation has not been reported to date.

We agree with other authors¹⁸⁻²⁰ who suggest that ADO implantation can be an alternative to using coils^{11,12,15-21,24} in small PDA (\leq 2 mm), if the anatomy of the PDA is favorable and if its minimum diameter allows advancing a 5 Fr sheath.

In our study, minor complications, such as obstruction of the descending aorta and left pulmonary artery stenosis, were possibly related to the small size of the vessel. Special attention should be paid to these types of patients during ADO implantation and follow-up. Finally, studies with long-term follow-up are needed to establish any potential limitation related to its use in children under 1 year of age.^{19-21,31} We have the impression that procedure-related difficulties can lead to more severe complications.

CONCLUSIONS

Since the beginning of its clinical use, the ADO has demonstrated its effectiveness and safety in the percutaneous closure of PDA. The low incidence of complications and residual shunt means that this device is suitable for the closure of medium or large PDA and for elective use in small ducts. Recent studies¹⁹⁻²¹ have demonstrated the safety of this device in patients under 1 year of age. Improvements in the design of the standard Amplatzer device^{29,30} will possibly decrease the frequency of complications. Larger series of patients under 1 year of age are needed to document its safety, efficacy and long-term outcomes and to be able to establish it as the treatment of choice in the percutaneous closure of PDA in this age group.

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