

Transcatheter Closure of Patent Ductus Arteriosus Using the Amplatzer Duct Occluder: Initial Results and Mid-Term Follow-Up

Aurora Fernández Ruiz, M.^a Jesús del Cerro Marín, Dolores Rubio Vidal, M.^a Carmen Castro Gussoni and Felipe Moreno Granados

Servicio de Cardiología Pediátrica. Hospital Infantil La Paz. Madrid. España.

Introduction and objectives. Transcatheter closure of patent ductus arteriosus is a well-established procedure. The aim of this study was to assess the initial and mid-term results of the treatment of PDA with the Amplatzer duct occluder.

Patients and methods. From October 1999 to December 2001, 30 children underwent transcatheter closure of persistent ductus arteriosus at a mean \pm SD age of 5 ± 4.02 years (range: 3 months to 14 years) and weight of 20.3 ± 10.3 kg (range: 4.5-45 kg). Infants under 10 kg weight made up 46% of total patients. A lateral view aortogram was made to determine the morphology of the ductus and select the size of the device. Occlusion was achieved using the anterograde venous approach. Follow-up evaluations were made with chest X-ray and echocardiogram at 24 hours and 1, 4 and 12 months after implantation.

Results. Twenty-eight patients (93.3%) immediately achieved complete occlusion, and on color Doppler examination the closure rate was 100% within 24 hours of implantation. There was no device embolization. In the follow-up, a 19-month-old patient developed a 20 mmHg gradient across the aortic arch.

Conclusions. Patent ductus arteriosus can be easily occluded with the Amplatzer Duct Occluder, which is effective and particularly useful in infants and children with relatively large PDA. Further experience and long-term follow-up are still needed to assess the safety of this device in smaller children.

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

Full English text available at: www.revespcardiol.org

Cierre percutáneo del ductus arterioso persistente con dispositivo de Amplatz: resultado inmediato y seguimiento a medio plazo

Introducción y objetivos. El cierre percutáneo del ductus arterioso es una técnica establecida. Nuestro objetivo fue evaluar los resultados obtenidos a corto y medio plazo en el tratamiento del ductus con el dispositivo ocluidor de Amplatz.

Pacientes y métodos. Desde octubre de 1999 a diciembre de 2001, 30 niños con edad media de $5 \pm 4,02$ años (rango: 3 meses-14 años) y peso medio de $20,3 \pm 10,3$ kg (rango: 4,5-45 kg) fueron sometidos al cierre percutáneo del ductus. El 46% eran lactantes de peso < 10 kg. Mediante aortografía en proyección lateral se determinó la morfología del ductus, y se seleccionó el tamaño del dispositivo, que se implantó por vía venosa anterógrada. Se realizaron controles radiológicos y ecocardiográficos a las 24 h, y a los meses 1, 4 y 12 postimplante.

Resultados. Se consiguió la oclusión de forma inmediata en 28 de los 30 pacientes (93,3%), y en la ecografía realizada a las 24 h la tasa de oclusión completa fue del 100%. No hubo ningún caso de migración del dispositivo. Un paciente de 19 meses desarrolló en el seguimiento un gradiente de 20 mmHg en el istmo aórtico.

Conclusiones. El cierre percutáneo del ductus con el dispositivo ocluidor de Amplatz es un método seguro y efectivo, especialmente útil en el tratamiento de ductus moderados o grandes. Estudios más amplios y a más largo plazo son necesarios para determinar su seguridad en los pacientes pediátricos de menor peso.

Palabras clave: Ductus arterioso persistente. Cierre percutáneo. Amplatz.

Correspondence: Dra. A. Fernández Ruiz.
Servicio de Cardiología Pediátrica.
Hospital Infantil La Paz.
Paseo de la Castellana, 261. 28046 Madrid. España.
E-mail: afernandez@hulp.insalud.es

Received 11 March 2002.
Accepted for publication 28 May 2002.

INTRODUCTION

Percutaneous closure of a patent ductus arteriosus (PDA) was first described by Porstmann in 1966.^{1,2} Since that time, different types of coils and occluder devices have been used,³⁻⁶ with varying results. Although the use of Cook[®] detachable coils^{7,8} has pro-

ABBREVIATIONS

PDA: patent ductus arteriosus

duced satisfactory results in closure of small PDAs (<2 mm), an increased incidence of residual shunt, hemolysis, and embolization have been reported in closure of larger PDAs.^{9,10} In 1998, Masura et al¹¹ published the first series of cases of percutaneous closure of PDA using the Amplatzer occluder device, which is self-expanding, can be repositioned, and is specially designed for moderate and large PDAs. In recent years, this device has been widely used (more than 1400 published cases as of the publication of this article),¹²⁻¹⁴ decreasing the incidence of residual short-circuit, embolization and hemolysis, especially in the closure of larger PDAs.

The aim of this study was to evaluate the efficacy and safety of the Amplatzer duct occluder device over the short- and medium-term for the closure of PDAs in children.

PATIENTS AND METHODS

Patients

From October, 1999, to December, 2001, 30 children (9 boys and 21 girls) with a diagnosis of PDA underwent percutaneous closure. An ECG, chest X-ray, and echocardiogram were performed on all patients prior to the procedure, and informed consent was obtained from the children's parents or guardians. Study inclusion criteria were: body weight of more than 4 kg, pulmonary vascular resistance <8 Wood units/m², and a PDA size ≥1.8 mm. Patient age varied from 4 months to 14 years (mean, 5±4.02 years), with body weight that varied between 4.5 and 45 kg (mean 20±10.3 kg); 46% of the children in the study having a weight of less than 10 kg.

Associated anomalies seen included: right anomalous subclavian artery (1 patient), moderate to severe aortic insufficiency (1 patient), small muscular interventricular communication (1 patient), and permeable foramen ovale (2 patients). One patient had human immunodeficiency virus (HIV). One of the patients had a residual PDA following surgical ligation.

Device

The Amplatzer (AGA®) duct occluder (Figure 1A) is a self-expanding nitinol stent that is made up of a flat retention flange that is placed on the aortic wall and a

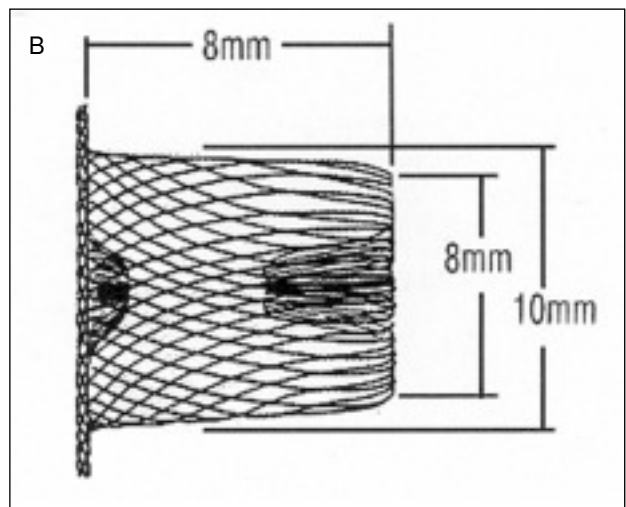
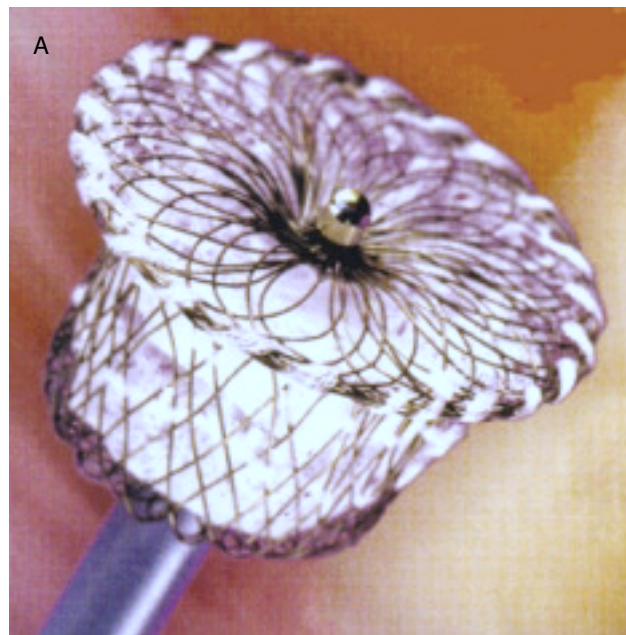


Fig. 1. A. Amplatzer duct occluder device for PDA. B. Drawing of the dimensions of a 10/8 Amplatzer duct occluder device.

tube (which is placed in the PDA itself) that contains thrombogenic material (a polyester patch sewn to the nitinol stent). The diameter of the retention flange is 4 mm larger than the tube sheath, which is in the form of a cone; the pulmonary end of the cone is 2 mm smaller than the end that is attached to the retention flange. The different Amplatzer duct occluder models refer to the size in millimeters of the two ends of the tube: 6/4, 8/6, 10/8, 12/10, 14/12, and 16/14. The total length of the device is 7 mm in the 6/4 and 8/6 models, and 8 mm in the remaining models (Figure 1B). The implantation system consists of a detachable cable that screws into the device, and a large delivery sheath of 5 Fr to 7 Fr (in accordance with the size of the device). Once the device is implanted, it is possible

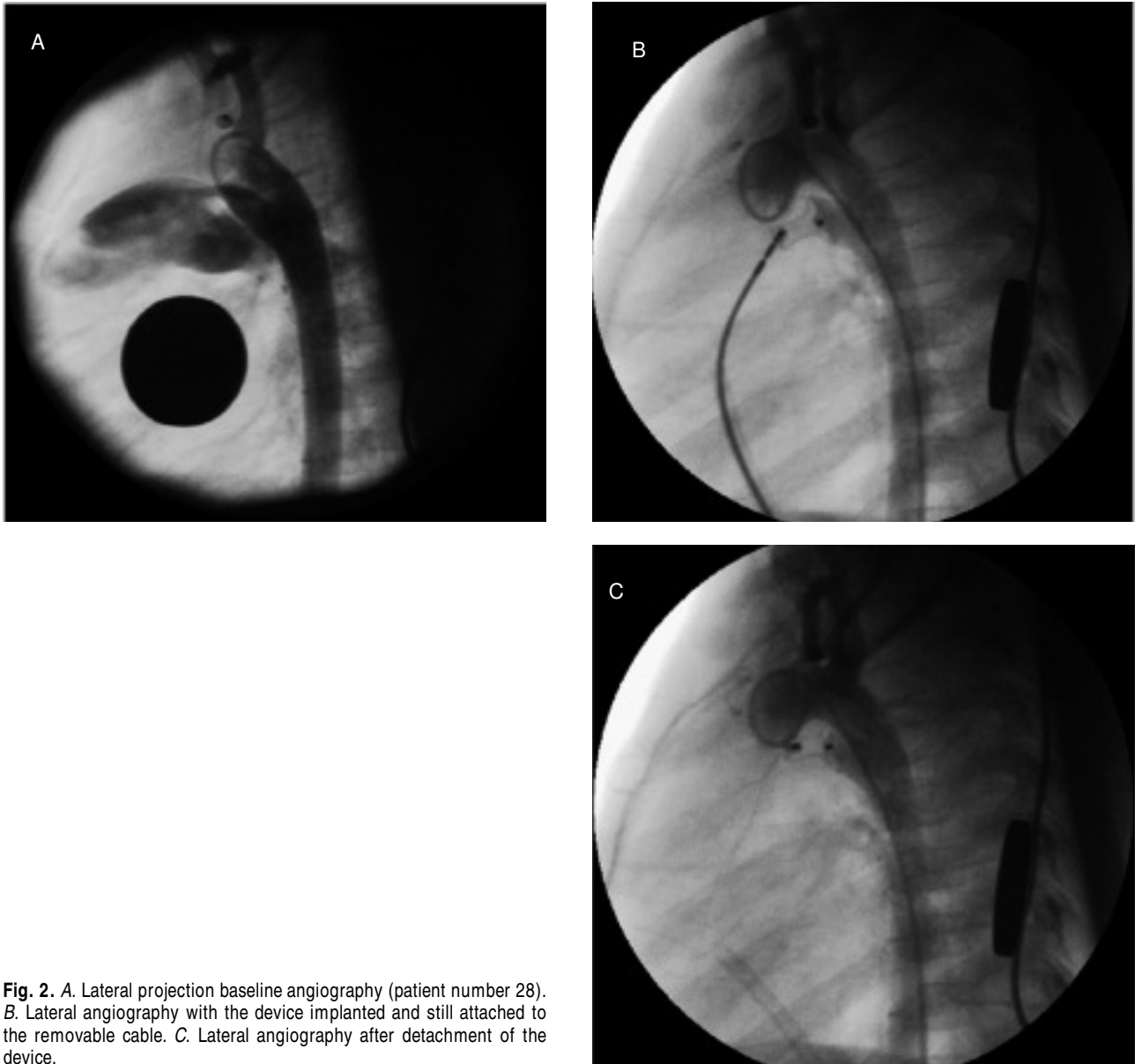


Fig. 2. A. Lateral projection baseline angiography (patient number 28). B. Lateral angiography with the device implanted and still attached to the removable cable. C. Lateral angiography after detachment of the device.

to remove it while it remains screwed in the removable cable.

Catheterization

The procedure were performed under sedation. The femoral artery and vein were catheterized in all patients, 30 mg/kg of cephazoline was administered at the start of the catheterization, and 100 UI/kg of sodium heparin was administered after catheterizing the artery. After recording pulmonary and systemic pressures, a lateral projection aortogram was performed to define the morphology and size of the PDA (Figure 2A). The PDA was catheterized in an antegrade manner in 28 patients, and a multipurpose catheter

was substituted for the 35-inch guided exchange introductory sheath in 2 patients in whom the PDA could not be catheterized from the pulmonary trunk. In these cases, the PDA was catheterized in a retrograde manner from the aortic side, using an arteriovenous opening to then introduce the sheath in an antegrade manner. A device was selected than was at least 1 to 2 mm larger than the smallest part of the PDA, and the device was introduced screwed onto the end of the removable cable via the sheath, up to the descending aorta. Once this site was reached, the sheath was removed in order to open the retention flange, which was positioned at the aortic end of the ductal ampulla and, while maintaining tension on the cable, the remainder of the sheath was pulled back toward the pul-

TABLE 1. Patient characteristics, hemodynamic data, morphology of the PDA, and size of the device implanted.

Patient No.	Age	Weight (kg)	PAP/SP	PDA type	Minimum Ø	Maximum Ø	Amplatzer Ø
1	17 m.	9.5	30%	A	3	7	6/4
2	9 y.	28	18%	A	3.6	21	8/6
3	12 m.	8.2	83%	A	3	8.6	8/6
4	9 m.	11.5	27%	B	3.9	5.2	6/4
5	27 m.	12	40%	A	1.9	11	6/4
6	12 m.	9	40%	A	4	10	8/6
7	13 m.	9	25%	A	2.5	10	6/4
8	5 y.	17	25%	A	3	8	6/4
9	8 m.	8.5	26%	A	2.7	6	6/4
10	7 m.	5.6	35%	A	4	9	6/4
11	6 m.	4.5	28%	A	3	7	6/4
12	6 y.	20	29%	A	4.9	7.6	8/6
13	8 m.	13.6	28%	E	3.5	6	8/6
14	14 y.	45	15%	A	2.6	7.8	8/6
15	8 m.	6.2	64%	A	7	10	10/8
16	19 m.	7.1	26%	A	3.1	8.3	6/4
17	4 m.	5.3	42%	A	3.5	6	6/4
18	4 y.	21	40%	A	2.8	12	8/6
19	3 m.	4.7	41%	E	3.4	7	6/4
20	8 m.	8.4	31%	A	2.3	10	6/4
21	5 y.	23	42%	A	1.8	6.1	6/4
22	8 y.	30	27%	D	1.9	3	6/4
23	24 m.	11	30%	A	2.5	7.9	6/4
24	3 y.	20	19%	A	1.9	5	6/4
25	7 y.	27	21%	E	1.8	2.4	6/4
26	6 y.	20	27%	A	2.5	4.5	6/4
27	7 y.	12	29%	A	5	10.3	10/8
28	8 m.	6.8	32%	E	2.5	11.2	6/4
29	5 y.	11.5	53%	E	8	15	10/8
30	14 m.	11.5	30%	B	2.7	5	8/6

PAP/SP indicates ratio of pulmonary:to systemic pressures at catheterization; Maximum Ø, PDA diameter at its largest point (mm); Minimum Ø, diameter of the PDA at its smallest point (mm); m, months; y, years.

monary trunk, positioning the tubular portion of the Amplatzer device within the PDA. With the device still attached to the removable cable, an aortogram was performed (Figure 2B) and, once it was determined that the Amplatzer was in a good position, this was detached by turning the cable counterclockwise. Ten minutes after the detachment angiography of the aorta was performed to determine whether or not a residual short-circuit was present (Figure 2C), and pulmonary and systemic pressures were taken again.

During the 24 hours following catheterization, the patients received 3 doses of cephazoline, a chest radiograph, and color echo-Doppler. The device was checked using chest radiograph and echo-Doppler at 1, 4, and 12 months postimplant.

RESULTS

The device was successfully implanted in all patients. Patient clinical data is shown in Table 1. The smallest PDA diameter ranged from 1.8 to 8.0 mm (mean, 4.4 ± 1.8 mm), and the largest diameter from

21.0 to 5.2 mm (mean, 8.8 ± 4.1 mm). According to the classification of Krichenko et al,¹⁵ there were 22 type A PDAs, 2 type B PDAs, 1 type D PDA, and 5 type E PDAs. Ten of the 30 patients (33.3%) had pulmonary hypertension, with a pulmonary:systemic pressure $>35\%$, which decreased or normalized following PDA closure. The size of the implanted device was 6/4 in 19 patients, 8/6 in 8 patients, and 10/8 in 3 patients (Table 1). In 2 patients, the first implanted device had to be removed (before it was detached from the cable) in order to implant another that was larger. Immediate complete occlusion of the PDA was achieved in 28 of the 30 cases (93.3%) (Figure 3), and in 100% of cases upon check by echography performed 24 hours postimplant. None of the patients had a gradient through the aortic arch on post-implant hemodynamic evaluation.

There were no cases of embolization of the device or hemolysis. One 8-month-old patient required a blood transfusion because of anemia in the hours following the catheterization, and another required 20 hours of heparin perfusion because of a decrease in the

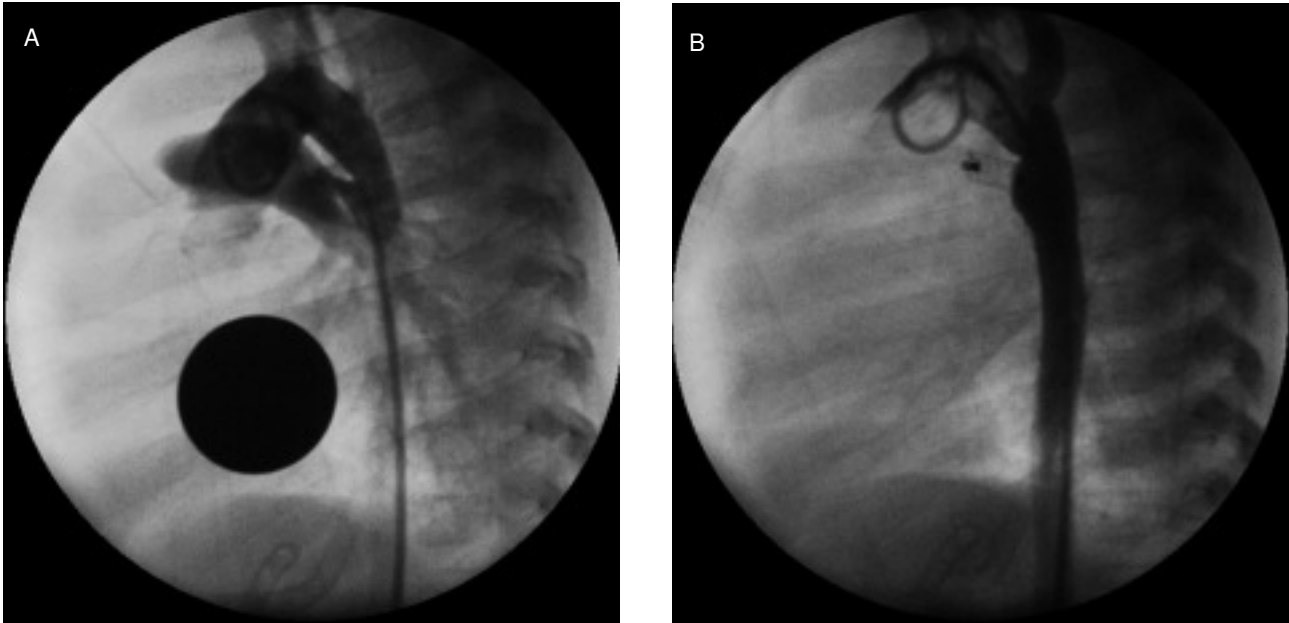


Fig. 3. Lateral projection angiography corresponding to patient number 17 in the series. A. Baseline angiography. B. Post-implant aortogram and detachment of the device.

pedal pulse. All patients were discharged 24 hours after the procedure.

Twenty-eight of the 30 patients (93.3%) came in for clinical follow-up, and also underwent ECG, chest radiograph, and echo-Doppler. Follow-up periods ranged from 1 month to 25 months (mean 13 ± 7.6 months). All patients were asymptomatic and none of them showed breakage or later displacement of the device. There was no flow acceleration in the left pulmonary artery noted that was more than 1.5 m/second. One 19-month, 7 kg girl, who had undergone PDA closure with a 6/4 Amplatzer device and who had no evidence of postimplant aortic occlusion on hemodynamic evaluation, progressively during the 5 months post PDA closure developed a gradient at the level of the aortic isthmus both clinically (decrease of femoral pulses) and on echographic evaluation (acceleration of flow velocity in the descending aorta up to 3.7 m/second with diastolic flow prolongation). At the 5th month postimplant, the patient was catheterized again, and a baseline peak systolic gradient of 20 mm Hg and 34 mm Hg postangiography was confirmed at the level of the isthmus, with a significant reduction in aortic size at this level, but without evidence of displacement of the Amplatzer device. Percutaneous balloon angioplasty was performed, producing a reduction of the postangiographic gradient to 24 mm Hg and the disappearance of the diastolic flow prolongation on postangioplasty echography.

DISCUSSION

The percutaneous closure of a PDA is a well-established technique that has a low incidence of compli-

cations. Nevertheless, and in spite of the different devices that have been used up until this point^{16,17} (such as double umbrella, controlled removable coils, etc), the closure of medium or large PDAs and treatment of PDA in lower-weight infants presented some difficulties since this type of patient has a greater incidence of complications (residual short-circuit, embolization of the device) and the need to implant a device more often, which lengthens scope times and increases the risk of embolization — surgery is frequently the only therapeutic option in low-weight patients with large PDAs.

The Amplatzer duct occluder provides several improvements over the devices used until recently. Closure of the PDA is achieved by a mechanical barrier that the prosthesis creates that, in addition to the thrombogenic effect of the polyester patches inside it, decreases the incidence of residual short-circuit and allows repositioning and removal of the device while it remains attached to the removable cable, diminishing the risk of embolization. The implantation is performed using low profile (5 Fr to 7 Fr) sheaths, which facilitates their use in low-weight infants.

The results of our study of percutaneous PDA closure with the Amplatzer duct occluder, with an occlusion rate of 100% at 24 hours, concurs with results reported in other studies,^{12,18} thus confirming the increased efficacy of the Amplatzer device in the closure of medium and large PDAs. Similarly and in accordance with other authors,¹⁹ the results were equally efficacious for smaller PDAs (<2.5 mm), in which, if the PDA anatomy is favorable and a smaller diameter device is used that allows for passage of a 5 Fr sheath,

Amplatzer device implantation which may be an alternative to using coils.

On followup we did not observe any significant stenosis of the left pulmonary artery, possibly due to the low profile of the pulmonary end of the prosthesis. The only significant complication encountered in our series was the development of an aortic occlusion in 1 of our patients. This is one of the principal problems this device can cause in lower-weight children and, although it is not a frequent complication, it has also been described by other authors.^{12,20} The low patient weight (smaller aortic lumen size in the isthmus area), the larger device size at its aortic end (retention flange), and the anatomy of the PDA (size, length, and angle between the PDA and the aortic arch) are some of the factors that may influence the development of this complication. It is possible that the Amplatzer duct occluder, still in experimental testing,²¹ in which the retention flange forms a 32° angle with the cylindrical body of the device (to adapt to the curvature of the thoracic aorta), may eliminate protrusion of the retention flange into the descending aorta. In any case, and although successful closure with the Amplatzer device has been reported in children weighing <4 kg,^{14,22} greater difficulty with the implantation²² and an increased risk of complications frequently occur.

CONCLUSIONS

Percutaneous PDA closure with the Amplatzer duct occluder device is an effective method for the treatment of PDA.

The low incidence of complications and of residual shunts makes this device ideal for the percutaneous closure of medium or large PDAs, and its elective use for small PDAs.

Studies of larger patient populations and with longer follow-up periods are necessary to determine the safety of this device for lower-weight children.

REFERENCES

1. Porstmann W, Wierny L, Warnke H. Der Verschluss des Ductus Arteriosus in persistens ohne Thorakotomie 81, Miiffeilung. *Thoraxchirurgie* 1967;15:109-203.
2. Porstmann W, Wierny L, Warnke H, Gerstberger G, Romaniuk PA. Catheter closure of patent ductus arteriosus: Sixty-two cases treated without thoracotomy. *Radiol Clin North Am* 1971;9:203-18.
3. Rashkind WJ, Mullins CE, Helenbrand WE, Tait MA. Non-surgical closure of patent ductus arteriosus: clinical application of the Rashkind PDA occluder system. *Circulation* 1987;75:583-92.
4. Hosking MCK, Benson LN, Musewe N, Dyck JD, Freedom RM. Transcatheter occlusion of the persistently patent ductus arteriosus: forty-month follow-up and prevalence of residual shunting. *Circulation* 1991;84:2313-7.
5. Hijazi ZM, Geggel RL. Transcatheter closure of patent ductus arteriosus using single or multiple gianturco coils: immediate and mid-term results. *J Am Coll Cardiol* 1994;74:925-9.
6. Podnar T, Masura J. Percutaneous closure of patent arterial ductus using special screwing detachable coil. *Cath Cardiovasc Diagn* 1997;41:386-91.
7. Tometzki AJP, Arnold R, Peart I, Sreeram N, Abdulahmed JM, Godman MJ, et al. Transcatheter occlusion of the patent ductus arteriosus with Cook detachable coils. *Heart* 1996;76:531-5.
8. Rosenthal E, Quereshi SA, Reidy J, Baker EJ, Tynan M. Evolving use of embolization coils for occlusion of the arterial duct. *Heart* 1996;76:525-30.
9. Ing FF, Sommer RJ. The snare-assisted technique for transcatheter coil occlusion of moderate to large patent ductus arteriosus: immediate and intermediate results. *J Am Coll Cardiol* 1999;33:1710-8.
10. Uzun O, Veldtman GR, Dickinson DF, Parson JM, Blackburn ME, Gibbs JL. Haemolysis following implantation of duct occlusion coils. *Heart* 1999;81:160-1.
11. Masura J, Walsh KP, Thanapoulos B, Chan Ch, Bass J, Goussous Y, et al. Catheter closure of moderate-to-large-sized patent ductus arteriosus using the new Amplatzer Duct Occluder: Immediate and short term results. *J Am Coll Cardiol* 1998;31:878-82.
12. Podnar T, Masura J. Percutaneous closure of patent arterial ductus using special screwing detachable coil. *Cath Cardiovasc Diagn* 1997;41:386-91.
13. Bilkis AA, Alwi M, Hasri S, Haifa AL, Geetha K, Rehman MA, et al. The Amplatzer duct occluder: experience in 209 patient. *J Am Coll Cardiol* 2001;37:258-61.
14. Faella HJ, Hijazi ZM. Closure of the patent ductus arteriosus with amplatzer PDA device: immediate results of the international clinical trial. *Cath Cardiovasc Interv* 2000;51(1):50-4.
15. Krichenko A, Benson LN, Burrows P, Möes CAF, Mc Laughlin P, Freedom RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. *Am J Cardiol* 1989;63:877-80.
16. Acerete A, Bermúdez Cañete R, Herraiz JI. Cateterismo intervencionista: cierre percutáneo del ductus arterioso persistente. *Rev Esp Cardiol* 1993;46(Supl 2):55-61.
17. Novo García E, Bermúdez R, Herraiz I, Salgado A, Balaguer J, Moya JL, et al. Cierre de ductus en adultos mediante dispositivo de Rashkind: resultados comparativos. *Rev Esp Cardiol* 1999;52:172-80.
18. Thanapoulos D, Hakim FA, Hiari A, Goussos Y, Basta E, Zarayelyan AA, et al. Further experience with transcatheter closure of the patent ductus arteriosus using the amplatzer duct occluder. *J Am Coll Cardiol* 2000;35:1016-21.
19. Sandhu SK, King TD, Troutman WB, Hixon RL, Kiel EA, Bourgeois KV. Transcatheter closure of patent ductus arteriosus with the amplatzer duct occluder: short-term follow-up. *J Invas Cardiol* 2001;13:298-302.
20. Duke C, Chan KC. Aortic obstruction caused by device occlusion of patent arterial duct. *Heart* 1999;82:109-11.
21. Kong H, Gu X, Bass JL, Titus J, Urness M, Kim TH, et al. Experimental evaluation of a modified amplatzer duct occluder. *Catheter Cardiovasc Interv* 2001;53:571-6.
22. Fisher G, Stieh J, Uebing A, Grabitz R, Kramer HH. Transcatheter closure of persistent ductus arteriosus in infants using the amplatzer duct occluder. *Heart* 2001;86:444-7.