Cardiol Young 2003; 13: 413–419

ISSN 1047-9511

Original Article

Transcatheter occlusion of moderate to large patent arterial ducts, having a diameter above 2.5 mm, with the Amplatzer Duct Occluder. Comparisons with the Rashkind, buttoned devices, and coils in 116 consecutive patients

François Godart,[1] Christian Rey,[1] Patrick Devos,[2] Georges-Marie Brevière,[1] Charles Francart[1]

[1]*Department of Paediatric Cardiology, Cardiac Hospital;* [2]*Department of Biostatistics, University of Lille, Lille, France*

Abstract *Aim:* To report results of transcatheter occlusion of moderate to large patent arterial ducts, having a minimum diameter above 2.5 mm, with the Amplatzer duct occluder, and to compare these with results achieved using Rashkind or Sideris devices and Cook detachable coils. *Design and setting:* Retrospective study conducted on intention-to-treat data from a tertiary referral centre. *Patients:* Since 1989, 116 consecutive patients, 77 females and 39 males, underwent percutaneous closure with several devices. We used the Rashkind double umbrella in 23 patients, the Sideris buttoned device in 39 patients, coils in 17 patients, and the Amplatzer duct occluder in 37 patients. The median age of the patients was 37 months, and the median weight 13 kg. The mean minimum diameter of the duct was 3.8 ± 1.22 mm, with a median of 3.5 mm, and range from 2.5 to 10 mm. *Results:* Implantation succeeded in all but 9 of the children (92%). The time of fluoroscopy was shorter, and full occlusion was better as judged on angiography, in patients closed using the Amplatzer device, despite closure of larger ducts, than in patients closed using other devices ($p < 0.0001$, $p = 0.0003$, and $p = 0.0015$ for the Rashkind, Sideris, and coils, respectively). Complications included embolisation in 2 patients, and haemolysis in 3 patients. In 12 patients, a second device was inserted because of residual shunting noted during follow-up. Complete occlusion was achieved earlier after implantation ($p = 0.0002$), and the rate of complete occlusion was better in patients receiving an Amplatzer device (97%, $p = 0.024$) than in patients undergoing closure with other devices. *Conclusion:* Transcatheter closure of moderate to large patent arterial ducts using the Amplatzer duct occluder is an effective and safe procedure, providing better results than those achieved using other occluders.

Keywords: Ductus arteriosus; catheter intervention; mechanical devices

Transcatheter occlusion of the patent arterial duct is a well-established alternative procedure to surgery. As early as 1967, Porstmann and colleagues[1] showed that interventional closure was effective, achieving complete occlusion in nine-tenths of patients, but the minimum diameter of the introducer, at 13 French, was a limiting factor. After this initial experience, several techniques and devices were developed in the late '80s and '90s.[2–8] Closure of moderate to large patent arterial ducts, nonetheless, remained a real challenge for the interventionist, and none of these devices achieved a wide acceptance. A few years ago, the Amplatzer duct occluder was introduced as an alternative to surgery for closure of moderate to large ducts.[9,10] The purpose of our retrospective study from one tertiary referral centre was to analyse the results of transcatheter occlusion of such moderate to large patent arterial ducts, having a minimum diameter above

Correspondence to: Dr François Godart, Service des Maladies Cardiovasculaires Infantiles et Congénitales, Hôpital Cardiologique, Bd. Pr. J. Leclercq, 59037 Lille cedex, France. Tel: 33 (0) 3 20 44 50 62; Fax: 33 (0) 3 20 44 54 56; E-mail: f-godart@chru-lille.fr

Accepted for publication 30 April 2003

2.5 mm, with the Amplatzer duct occcluder, comparing the findings with those achieved previously using the Rashkind double-disc umbrella, the Sideris buttoned device, and Cook detachable coils.

Methods

Patients

From January 1989 to October 2001, elective non-surgical closure of patent arterial duct was undertaken in 230 patients using several devices. In the present study, we focus on the 116 consecutive patients, 77 females and 39 males, having moderate to large patent arterial ducts, with a minimum diameter above 2.5 mm as measured on lateral aortography. The indication for occlusion was the presence of a significant left-to-right shunt documented on echocardiography by left atrial and left ventricular volume overload, and to reduce the risk of endarteritis, and possibly heart failure, in later life. Most patients were asymptomatic, except 27 who had failure to thrive in presence of elevated pulmonary arterial pressures. The median age at the procedure was 37 months, with a range from 0.8 month to 76 years, and the median weight was 13 kg, with a range from 3.9 to 82 kg. Only five had associated cardiac defects, namely small ventricular septal defects in 3 patients, and atrial septal defects in two. A few patients also had associated non-cardiac malformations. Thus, there were two patients with Down's syndrome, one with congenital rubella syndrome, one with Rubinstein-Taybi's syndrome, one with Pierre-Robin's sequence, one with hydronephrosis, and one with craniostenosis. Transcatheter closure was achieved using a Rashkind double-disc umbrella in 23 patients, specifically 19 females and 4 males, with a Sideris buttoned device in 39 patients, 23 females and 16 males, with Cook detachable coils in 17 patients, 11 females and 6 males, and with Amplatzer duct occluder in the remaining 37 patients, of whom 24 were females and 13 males. The characteristics of the devices are presented in Table 1. The mean minimum diameter of the duct as assessed on angiography was 3.8 $\pm$ 1.22 mm, with a median of 3.5 mm, and a range from 2.5 to 10 mm.

Implantation

Informed consent was obtained from all patients or their guardians. All Rashkind and Sideris devices were implanted under general anaesthesia, as were 5 of the coils, but local anaesthesia was used for the remainder. The shape of the duct was classified according to Krichenko et al.[11] Devices were implanted according to their availability at successive periods of time.[2–5,9,12] Patients were discharged within 2 days of the procedure after a repeat chest X-ray and electrocardiogram. Follow-up was similar for all groups, including routine clinical examination, electrocardiogram, chest radiograph, and regular colour flow Doppler echocardiography scheduled at one month, 3 to 6 months, one year after implantation, and yearly thereafter. Prophylaxis against endocarditis was discontinued at the third to the sixth month follow-up visit when the duct was completely occluded.

Statistical analysis

Data were collected on an intention-to-treat basis from 1989 to 2001. A standard data collection sheet was recorded, analysing several criterions. Results were analysed retrospectively, and expressed as mean value and standard deviation, median and range. With respect to complete occlusion as assessed by Doppler, patients with residual shunt were considered as "censored" at the time of latest follow-up, or at the time of a repeated occlusion. Comparison of frequency was performed with the chi-squared or Fischer's exact tests. Comparison of means was achieved using a non-parametric analysis of variance. Pairwise comparisons were performed using Bonferroni's correction. A p-value of less than 0.05 was regarded as statistically significant. This analysis was performed using SAS V 8 statistical software.

Table 1. Characteristics of devices.

	Rashkind	Sideris	Coil	Amplatzer
Description	Double-discs of polyurethane 3 or 4 arms	Squared foam of polyurethane + wire skeleton; wire + foam	Spiral shaped device + dacron fibres	Mushroom-shaped nitinol wire mesh − polyester patches
Size	12 mm, 17 mm	15–40 mm (5-mm increments)	Diameter: 3–8 mm 3–5 loops	4–14 mm (2-mm increments)
Sheath	8 and 11 F	7 and 8 F	4 or 5.5 F	5–7 F
Repositionable	No	No	Yes	Yes

Repositionable: The device can be retracted within the delivery sheath and redeployed several times
Abbreviation: F: French

https://doi.org/10.1017/S104795110300088X Published online by Cambridge University Press

Results

Procedure success

Results of implantation are expressed in Table 2.

Failure of the procedure

In 3 patients receiving a Rashkind umbrella, implantation failed due to the size of the duct, the diameters being 3.45, 3, and 10 mm, respectively. In the first patient, a stable position could not be achieved and the device was pulled back into the sheath. In the second, the device was judged to be protruding too much in pulmonary artery after release, and it was then retrieved with a lasso. In the third patient, the device embolised in the pulmonary arteries, and could not be removed by catheter techniques. All three were subsequently corrected by surgery, with retrieval of the embolised device in the third patient. Attempted implantation of a Sideris device failed in 2 patients with ducts of diameters 3.5 and 5 mm, respectively. The devices in both instances were retrieved during cardiac catheterisation. One patient subsequently underwent surgical ligation of the duct. For the other, a second procedure was performed 12 months later to implant, with success, a folding plug buttoned device. A third procedure involving implantation of a coil was also required to achieve complete occlusion because of a persistent leak. Of the patients undergoing attempted closure using detachable coils, the procedures failed in 3 patients having ducts with diameters of 5, 4, and 2.6 mm, respectively. The coils were retrieved during cardiac catheterisation in 2 patients and left in place in the other. All of them subsequently underwent closure of the duct with an Amplatzer device. In only one patient early in our experience did we fail to close the duct using an Amplatzer device. In this patient, the duct was large, having a diameter of 5 mm, and the device slipped into the pulmonary artery. It was pulled back into the sheath, and no further attempt was made at closure because larger devices were not then available. This patient underwent subsequent surgical ligation of the duct.

Table 2. Procedure success.

	Implant success	Device
Rashkind	20 out of 23 (87%)	17-mm device in 18 patients 12-mm device in 5 patients
Sideris	37 out of 39 (95%)	15-mm device in 18 patients 20-mm device in 21 patients (18 modified folding plugs)
Coil	14 out of 17 (82%)	1 coil in 13 patients 2 coils in 4 patients
Amplatzer	36 out of 37 (97%)	6/4-mm device in 10 patients 8/6-mm device in 17 patients 10/8-mm device in 10 patients

Complications

Embolisation

Embolisation to the left pulmonary artery occurred in 2 patients, one with a Rashkind umbrella and another one with a coil. The Rashkind device was retrieved by surgery coupled with ligation of the duct. This repair was complicated by a chylothorax. Retrieval of the embolised coil was unsuccessful, and it was left in place.

Haemolysis

Haemolysis occurred in 3 patients, 2 with a coil and 1 with an Amplatzer. None of them required blood transfusion. In the patients with coils, a second cardiac catheterisation was performed respectively 1 and 7 days after implantation to place other coils. Residual shunting decreased and the haemolysis resolved completely. In the sole patient with an Amplatzer occluder, a second cardiac catheterisation was performed 4 days later, but implantation of a second device was not possible. Temporary balloon occlusion of the ductal ampulla was performed with a balloon catheter for 10 min to reduce the residual shunt. On the following day, there was no haemolysis, and Doppler-echocardiography showed a small residual shunt that disappeared 3 weeks later.[13]

Immediate angiographic closure

On control angiography, complete occlusion was noted in 4 of 20 patients (20%) undergoing closure with the Rashkind umbrella, in 8 of 37 patients (22%) with the Sideris device, in 4 of 13 patients (31%) with coils, and in 23 of 36 patients (64%) with the Amplatzer duct occluder.

Late follow-up occlusion

Complete occlusion on control colour Doppler echocardiography is presented in Table 3.

Table 3. Late follow-up occlusion on colour Doppler evaluation.

	Occlusion number (%)	Time after implantation (months)
Rashkind	14 (70)	0–57
Sideris	27 (73)	0–52
Coil	11 (79)	0–22
Amplatzer	35 (97)	0–24

https://doi.org/10.1017/S104795110300088X Published online by Cambridge University Press

Further procedures

Of the 6 patients with residual shunting after insertion of a Rashkind umbrella, 5 had a second cardiac catheterisation to close the persistent leak from 22 to 86 months after the initial implantation. A second 17-mm Rashkind device was implanted in 3 of them, and a coil in the 2 remaining patients. All had no residual shunt at the latest follow-up.

Of the 10 patients with residual shunting after attempted closure using the Sideris device, 6 had a second cardiac catheterisation to close the duct from 14 to 24 months after the initial implantation. A second 15-mm buttoned device was implanted in one, coils in 4 patients, and an Amplatzer device in the remaining patient. All but one had no residual shunt at the latest follow-up.

From the 3 patients with residual shunting after insertion of coils, one had a second cardiac catheterisation 5 months later to implant another coil with success and no residual shunt. Two others had tiny residual shunts up to 39 months after implantation.

Comparative study (Table 4)

The clinical and haemodynamic data and the outcomes are shown in Table 4. The minimum diameter of the duct was larger in patients in whom closure had been attempted with an Amplatzer occluder as compared to patients closed with other devices ($p = 0.0015$). Cardiac catheterisation required shorter fluoroscopy times in the patients undergoing closure with the Amplatzer occluder as compared to patients receiving the Sideris device ($p < 0.0001$), and with lesser radiation dose as compared to patients in whom closure had been attempted using the Sideris occluder or coils ($p < 0.0001$). No comparison was attempted against patients closed with the Rashkind umbrella concerning the time of fluoroscopy and dose of radiation because these factors were not recorded in the early '90s. On immediate control angiography, the rate of occlusion was better in patients closed with an Amplatzer occluder than in the others ($p = 0.0003$). During follow-up, complete occlusion on control colour-flow Doppler occurred earlier after implantation for patients with an Amplatzer occluder as compared to those with the Rashkind and Sideris devices ($p = 0.0002$). The rate of complete occlusion on Doppler was clearly better in patients receiving the Amplatzer duct occluder than in the others (94%; $p = 0.024$).

Discussion

Our study reflects our experience in occluding moderate to large patent arterial ducts over the last 10 years. Transcatheter closure of the patent arterial duct beyond the neonatal period has now become established practice in most paediatric cardiologic centres. Surgery carries major limitations, including an overall mortality from 0% to 2%, a rate of adverse events from 4% to 15%, and a significant incidence

Table 4. Comparative data.

	Rashkind n = 23	Sideris n = 39	Coil n = 17	Amplatzer n = 37	p
Duct shape (n)	A(17); B(1); C(2); E(3)	A(30); B(5); C(1); E(3)	A(10); C(4); E(3)	A(29); C(8)	NS
Age (months)	52 (47)	63 (82)	104 (87)	87 (202)	p = 0.0067 Amp √ coil
Weight (kg)	17 (12)	18 (16)	29 (17)	16 (15)	p = 0.0006 Amp √ coil Sid √ coil
PAs (mmHg)	40 (14)	40 (16)	34 (11)	43 (14)	p = 0.1018
Diameter (mm)	3.72 (1.52)	3.73 (1.18)	3.12 (0.67)	4.23 (1.11)	p = 0.0015 Amp √ coil
XR dose (Gy/cm^2)	–	36.08 (84.91)	9.34 (9.82)	4.61 (12.62)	p < 0.0001 Amp √ Sid Amp √ coil
Fluoros. time (min)	–	14.8 (7.1)	12.3 (9.2)	8.0 (4.0)	p < 0.0001 Amp √ Sid
Angiographic shunt	80%	78%	71%	36%	p = 0.0003
Occlusion (Doppler)	70%	73%	79%	97%	p = 0.024
Date of occlusion (months)	24.5 (28)	11 (14)	7 (12)	2.6 (6)	p = 0.0002 Amp √ Rash Amp √ Sid

Results expressed in mean value and (standard deviation). Ductal shape classification by Krichenko. Pairwise comparisons were performed using a Bonferroni's correction (√). Abbreviations: Amp: Amplatzer; F: female; Fluoros: fluoroscopic; M: male; PAs: systolic pulmonary artery pressure; Rash: Rashkind; Sid: Sideris; XR: X-ray dose of radiation

https://doi.org/10.1017/S104795110300088X Published online by Cambridge University Press

of residual shunting revealed by Doppler of about 6%.[14–17] Surgery nowadays, therefore, is mainly reserved for the closure of large ducts in symptomatic infants. In this setting, many of the available devices carry their own advantages and drawbacks, and closure of large ducts remains technically challenging for the interventionist.

The Amplatzer duct occluder was initially developed to close the large duct. Its mechanism of occlusion is original and different from the other devices, which use double umbrellas, patching, or coils. The Amplatzer device stretches and stents the duct, and the conal shape of the plug is very similar to the initial concept of the Ivalon plug developed by Portsmann in 1967,[1] but without the need of large introducer sheaths. This design also seems appropriate for closing most of moderate to large patent arterial ducts, avoiding the need for multiple devices and the possible risk of embolisation.[8–10,18–20]

The Amplatzer duct occluder has several advantages. First, the occlusion of large ducts is achievable and really effective, as demonstrated by our study in which larger ducts were closed with better results than those achieved using all the other devices. Second, the rate of complete occlusion is higher on both control angiography and Doppler evaluation. This is clearly of major interest for the patient.[9,10,18,19] Third, implantation is easier than that for the Rashkind or Sideris devices, and this is confirmed by much lower periods of fluoroscopy, and subsequent lower dose of radiation, achieved after closure with the Amplatzer.[8,18] This reduction is a great advantage for both the patient and the interventionist. Fourth, the Amplatzer device is delivered from the venous side using a small 5 to 7 French sheath. Release of the device, therefore, can be controlled either from the arterial side, without the need for a large sheath, or by transthoracic echocardiography as was achieved in our 4 infants. The Amplatzer device, therefore, could probably be used in symptomatic infants weighing around 4 to 5 kg with a well-developed ampulla.[19,20] Lastly, the Amplatzer device can be repositioned. It can be easily retracted into the sheath, and redeployed several times if the position is not appropriate. This can also be achieved with the detachable coils, but is not feasible with the Rashkind or Sideris devices.[18]

Despite a widespread experience, the use of the Rashkind device was abandoned for different reasons. These included the rate of residual shunting up to 20%, but also the cost, the need of large introducing sheaths, the availability of only 2 sizes, the risk of embolisation, the possibility of producing stenosis of the left pulmonary artery with the larger device, and the lack of approval from the Food and Drug Administration in the United States of America. We had similar experience and results, and stopped its use at the end of 1993. In the same way, the Sideris device did not achieve wide acceptance, mainly because of the complex nature of its system for delivery, and the incidence of residual shunting. We abandoned this device at the beginning of 1998.

Nowadays, the use of Cook detachable coils is probably the major alternative to the Amplatzer duct occluder for transcatheter occlusion of large patent arterial ducts.[5,6,8,12,21–24] Usually several coils are necessary to close these ducts, and different techniques have been described with antegrade and multiple coil approaches, snare-assisted delivery of the coils, temporary balloon occlusion, shaped diabolo configuration, with increased wire diameter and number of loops.[5,6] Our rate of occlusion using coils, nonetheless, was not as good as when we used the Amplatzer occluder. Implantation of more coils, as many as 3 or 4, would have probably decreased the rate of shunting or haemolysis. On the other hand, such an approach would probably increase the risk of embolisation, protrusion of the devices, and the period of fluoroscopy.[6,24] As have others, we think it is difficult to judge which residual shunts may close spontaneously, and on occasion avoid further coil implantation even on control angiography performed 10 min after release.[5] We cannot draw here any conclusion about the use of other types of coils.[6,12,21,22] The European Registry, nonetheless, assessing 1291 attempted occlusions using coils, has revealed an unfavourable outcome to be positively associated with increasing ductal size and the presence of a tubular arterial duct.[12] Taking these results into account, we support the proposal of Podnar et al.[8] that the Amplatzer duct occluder be used in association with coils for transcatheter occlusion of the patent arterial duct, using the Amplatzer device when the diameter of the duct is over 2.5 mm, and coils for the smaller ones.

The Amplatzer duct occluder also has some drawbacks. Concerns have been expressed regarding persistent shunting and haemolysis. Enzymic evaluation was not routinely performed in our experience, and major haemolysis is infrequent. Both phenomenons, moreover, have been reported with all the occluders. In the presence of residual shunting, we propose to wait 1 or 2 years before planning a second procedure, based on our past experience and the notion of endothelisation of the device. The shunting may also result from possible disconnection of polyester patch within the device, or use of an undersized device. This last event was probably the cause of failure in our sole case of persistent shunting. Implantation of the 2-mm oversized device is clearly mandatory to avoid such an event. For both persistent shunting and haemolysis, it is usual to attempt complete occlusion by placing

a second occluder.[13] Such an approach was problematic for us because it was not possible to cross the arterial duct after release of the Amplatzer device. We thus carried out balloon occlusion of ductal ampulla, as suggested initially to decrease the incidence of shunting after implantation of the Rashkind double disc umbrella.[3] Recently intradevice coil deployment has also been reported to cope with such complications.[25] The major overall limiting factor may be the high cost of the Amplatzer device, but its different advantages should probably outweigh its price.

Our study has some limitations. First, it is retrospective, so experience has gained with time and choice of the device was mainly due to availability at particular time. The study does provide a basis for comparison between 4 different occluders, three of these still being available. The technique of implantation was similar in all patients except for coils, with routine right and left heart catheterisation. In our experience, coils were released from a sole femoral artery approach. Both the time of fluoroscopy and dose of radiation were less after use of the Amplatzer compared to coils. To the best of our knowledge, no prospective randomised clinical trials have been undertaken in the closure of moderate to large arterial ducts between closure by devices, conventional surgery, and videothoracoscopic interruption. Second, no short ducts lacking an ampulla were encountered amongst the patients closed with an Amplatzer occluder. Although some occlusions have been reported in such ducts,[18] it seems that the Amplatzer duct occluder is not really appropriate in this situation because of possible aortic or left pulmonary arterial obstruction.[8] A double disk might be more suitable in this setting.[12] Third, nitinol is a nickel-titanium alloy, and some have reported corrosive behaviour of the alloy in biological environments after implantation.[26] Fourth, concerning the dose of radiation, the calculation at the exit of the tube does not reflect the true irradiation given to the skin. Fifth, we cannot draw any conclusion about the maximal ductal diameter amenable to transcatheter occlusion. The largest arterial duct of which we attempted occlusion with an Amplatzer was 6 mm, but closure of duct up to 12.5 mm has already been reported.[19]

In conclusion, the Amplatzer duct occluder is a safe and effective device for closure of moderate to large patent arterial ducts. It provides better results in terms of complete occlusion and dose of radiation than do the Rashkind or buttoned devices or Cook detachable coils. Currently, our approach is to use detachable coils and the Amplatzer duct occluder in a complementary manner. We recommend use of the Amplatzer duct occluder in the closure of arterial ducts with a diameter above 2.5 mm. Further studies, and long-term follow-up, are mandatory to support these recommendations.

References

1. Portsmann W, Wierny L, Warneke H. Closure of the persistent ductus arteriosus without thoracotomy. Ger Med Mon 1967; 12: 259–261.
2. Rashkind WJ, Mullins CE, Hellenbrand WE, Tait MA. Nonsurgical closure of patent ductus arteriosus: clinical application of the Rashkind PDA occluder system. Circulation 1987; 75: 583–592.
3. Wessel DL, Keane JF, Parness I, Lock JE. Outpatient closure of the patent ductus arteriosus. Circulation 1988; 77: 1068–1071.
4. Rao PS, Sideris EB, Haddad J, et al. Transcatheter occlusion of patent ductus arteriosus with adjustable buttoned device. Initial clinical experience. Circulation 1993; 88: 1119–1126.
5. Uzun O, Hancock S, Parsons JM, Dickinson DF, Gibbs JL. Transcatheter occlusion of the arterial duct with Cook detachable coils: early experience. Heart 1996; 76: 269–273.
6. Hijazi ZM, Geggel RL. Transcatheter closure of large patent ductus arteriosus (⩾4 mm) with Gianturco coils: immediate and mid-term results. Heart 1996; 76: 536–540.
7. Rao PS, Kim SH, Choi JY, et al. Follow-up results of transvenous occlusion of patent ductus arteriosus with the buttoned device. J Am Coll Cardiol 1999; 33: 820–826.
8. Podnar T, Gavora P, Masura J. Percutaneous closure of patent ductus arteriosus: complementary use of detachable Cook patent ductus arteriosus and Amplatzer duct occluders. Eur J Pediatr 2000; 159: 293–296.
9. Masura J, Walsh KP, Thanopoulous BV, 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: 878–882.
10. Marwah A, Radhakrishnan S, Shrivastava S. Immediate and early results of closure of moderate to large patent arterial ducts using the new Amplatzer™ device. Cardiol Young 2000; 10: 208–211.
11. Krichenko A, Benson LN, Burrows P, Möes CAF, McLaughlin P, Freedom RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. Am J Cardiol 1989; 63: 877–880.
12. Magee AG, Huggon IC, Seed PT, Qureshi SA, Tynan M, Association for European Cardiology. Transcatheter coil occlusion of the arterial duct. Results of European Registry. Eur Heart J 2001; 22: 1817–1821.
13. Godart F, Rodes J, Rey C. Severe haemolysis after transcatheter closure of patent arterial duct with the new Amplatzer™ duct occluder. Cardiol Young 2000; 10: 265–267.
14. Sorensen KE, Kristensen BO, Hansen OK. Frequency of occurrence of residual ductal flow after surgical ligation by color-flow mapping. Am J Cardiol 1991; 67: 653–654.
15. Zucker N, Qureshi SA, Baker EJ, Deverall PB, Tynan M. Residual patency of the arterial duct subsequent to surgical ligation. Cardiol Young 1993; 3: 216–219.
16. Galal O, Nehgme R, Al-Fadley F, et al. The role of surgical ligation of patent ductus arteriosus in the era of the Rashkind device. Ann Thorac Surg 1997; 63: 434–437.
17. Anonymous. Proposed standards for clinical evaluation of patent ductus arteriosus occlusion devices. Multiorganization advisory panel to FDA for pediatric cardiovascular devices. Cathet Cardiovasc Interv 2000; 51: 293–296.
18. Thanopoulos BD, Hakim FA, Hiari A, et al. Further experience with transcatheter closure of the patent ductus arteriosus using the Amplatzer Duct Occluder. J Am Coll Cardiol 2000; 35: 1016–1021.

19. Bilkis AA, Alwi M, Hasri S, et al. The Amplatzer Duct Occluder: experience in 209 patients. J Am Coll Cardiol 2001; 37: 258–261.
20. 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: 444–447.
21. Tometzki A, Chan K, De Giovanni J, et al. Total UK multicentre experience with a novel arterial occlusion device (Duct Occlud pfm). Heart 1996; 76: 520–524.
22. Rosenthal E, Qureshi SA, Reidy J, Baker EJ, Tynan M. Evolving use of embolisation for occlusion of the arterial duct. Heart 1996; 76: 525–530.
23. Tometzki AJ, Arnold R, Peart I, et al. Transcatheter occlusion of the patent ductus arteriosus with Cook detachable coils. Heart 1996; 76: 531–535.
24. Anil SR, Sivakumar K, Kumar RK. Coil occlusion of the small patent arterial duct without arterial access. Cardiol Young 2002; 12: 51–56.
25. Joseph G, Zacharias TU, George B. Severe intravascular hemolysis after transcatheter closure of a large patent ductus arteriosus using the Amplatzer duct occluder: successful resolution by intradevice coil deployment. Catheter Cardiovasc Interv 2002; 55: 245–249.
26. Kong H, Wilkinson JL, Coe JY, et al. Corrosive behaviour of Ampltazer® devices in experimental and biological environments. Cardiol Young 2002; 12: 260–265.