Percutaneous treatment of moderate-to-large patent ductus arteriosus with different devices: early and mid-term results

Giuseppe Santoro, Maurizio Cappelli Bigazzi, Marianna Carrozza, Maria Teresa Palladino, Berardo Sarubbi, Carmela Scarpati, Michele D'Alto, Maria Giovanna Russo, Raffaele Calabrò

Division of Pediatric Cardiology, Second University of Naples, V. Monaldi Hospital, Naples, Italy

Key words:
Congestive heart failure; Device; Left ventricular dysfunction; Patent ductus arteriosus.

Background. **Transcatheter closure is now accepted as the first-choice therapeutic option in patients with patent ductus arteriosus (PDA). However, this procedure is still challenging in large PDA and/or younger patients. This study evaluated feasibility and results of this approach in large, symptomatic PDA using different devices.**

Methods. **Between April 2000 and July 2004, 57 patients underwent attempt of transcatheter closure of a large PDA at our Institution. Nineteen patients (33.3%) were on pharmacologic therapy for congestive heart failure. PDA diameter was 3.2 ± 1.2 mm (range 1.8-9 mm), resulting in a pulmonary to systemic flow ratio of 2.1 ± 1.8 (range 1.4-5).**

Results. **The procedure was successfully performed in 54 patients (94.7%), using the Amplatzer duct occluder (ADO) device (34 patients) or a multiple detachable coil approach (20 patients). Complete PDA occlusion was recorded in 77.8% of patients at 24 hours, 92.6% at 1 month, and 94.4% at last follow-up control (23 ± 12 months). PDA morphology and pulmonary to systemic flow ratio did not influence the success rate of the procedure or the residual shunt. A trend toward a higher occlusion rate at any follow-up point was recorded in the ADO group (79.5 vs 75.0% at 24 hours, 97.1 vs 85.0% at 1 month, and 97.1 vs 90% at last follow-up control, p = NS for all comparisons).**

Conclusions. **Percutaneous closure might be considered effective and safe also in large, clinically significant PDA, by tailoring the device choice to the patient size and ductal morphology. In this setting, the multiple coil option revealed as effective as the ADO device over a mid-term follow-up.**

(Ital Heart J 2005; 6 (5): 396-400)

Received October 4, 2004; revision received January 3, 2005; accepted January 10, 2005.

Address:

Dr. Giuseppe Santoro

Via Vito Lembo, 14
84131 Salerno
E-mail:
santoropino@tin.it

Introduction

Patent ductus arteriosus (PDA) is a leading cause of congestive heart failure and/or left ventricular volume overload in pediatric age[1,2]; moreover, it carries a long-life risk of aneurysmal formation or subacute bacterial endocarditis[3-5]. Transcatheter closure is now widely accepted as the first-choice treatment of this malformation beyond neonatal age[6-15]. However, this approach is still challenging in large, high-flow PDA and/or in small-sized patients, with a considerable rate of procedural failures and residual shunt[10,13,16-20]. In this setting, several devices and techniques of transcatheter closure have been suggested[7,19,21-31]. However, in large clinical series[14,16-18,23,26], the Amplatzer duct occluder (ADO) device (AGA Medical Corporation, Golden Valley, MN, USA) and the multiple coil implantation have been reported as the most effective approaches. The former device shows a higher closure rate, but is not indicated in small infants due to the risk of aortic and/or pulmonary artery obstruction[14,16]. The latter approach is more versatile but shows a higher rate of embolization and residual shunt[17-19,23], although no significant difference in terms of feasibility and mid-term efficacy has been recently reported between these devices[32]. This paper reports on the early and mid-term results of percutaneous closure of moderate-to-large, clinically symptomatic PDA in a single-center series.

Methods

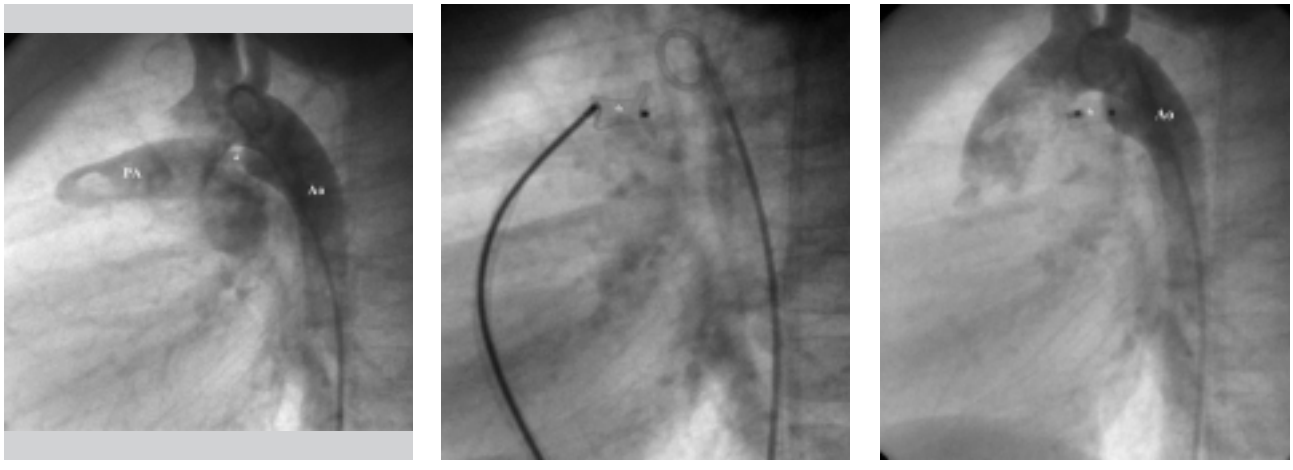
Patient population. All 57 consecutive patients with a large PDA who presented to our attention for transcatheter closure between April 2000 and July 2004 were included in the study. Inclusion criteria were: minimal diameter of the PDA > 3 mm and/or pulmonary to systemic flow ratio > 1.5:1, resulting in cardiomegaly at chest

X-ray and left heart enlargement (> 90th percentile) at echocardiography.

Interventional procedure. After having obtained informed consent from adult patients or children's parents, cardiac catheterization was performed under general anesthesia in pediatric patients or local anesthesia in adults. Transcatheter closure steps have already been widely detailed in the literature[6,10,16]. Briefly, after hemodynamic data recording, PDA shape and size were assessed from descending aortic angiography in the right anterior oblique and lateral views. Ductal shape was classified according to Krichenko et al.[33]. Ductal size was measured accounting for the magnification factor. Based on the patient size and/or PDA morphology, ductal occlusion was performed with the ADO device (34 patients) or multiple Cook detachable coils (Cook, Bloomington, IN, USA) (20 patients). The ADO device was considered the first-choice option in conical, window-like or short tubular PDA, in patients > 6 kg, while the multiple coil option was used in small-size patients and/or in elongated or tortuous PDA as well as whenever the aortic isthmus anatomy precluded the use of the ADO device. The ADO device used was at least 2 mm larger than the minimal ductal diameter and deployed by the pulmonary artery route (Fig. 1). In the multiple coil approach, the first coil used was about 2.0-2.5 times wider than the narrowest ductal diameter and long enough to produce at least 3 loops inside the ductal ampulla. Further coils were slightly smaller than the first one (1.5-2.0 times wider than the minimal ductal diameter) and deployed inside the "nest" yielded by the first coil. The multiple coil deployment was always performed simultaneously from the pulmonary and aortic sides, or using a double arterial approach, intertwining the coils to each other inside the ductal ampulla before the final release (Fig. 2). Control angiography was obtained 15-30 min after device implantation. Procedural and fluoroscopy times were calculated at the end of the interventional procedure. Success and complication rates were evaluated on the whole population and compared between the interventional groups. Since we do not perform any interventional procedure on outpatients and the pre- and post-procedure diagnostic evaluation is not affected by the implanted device, the procedural costs were calculated only in terms of disposable catheterization material and occluding device.

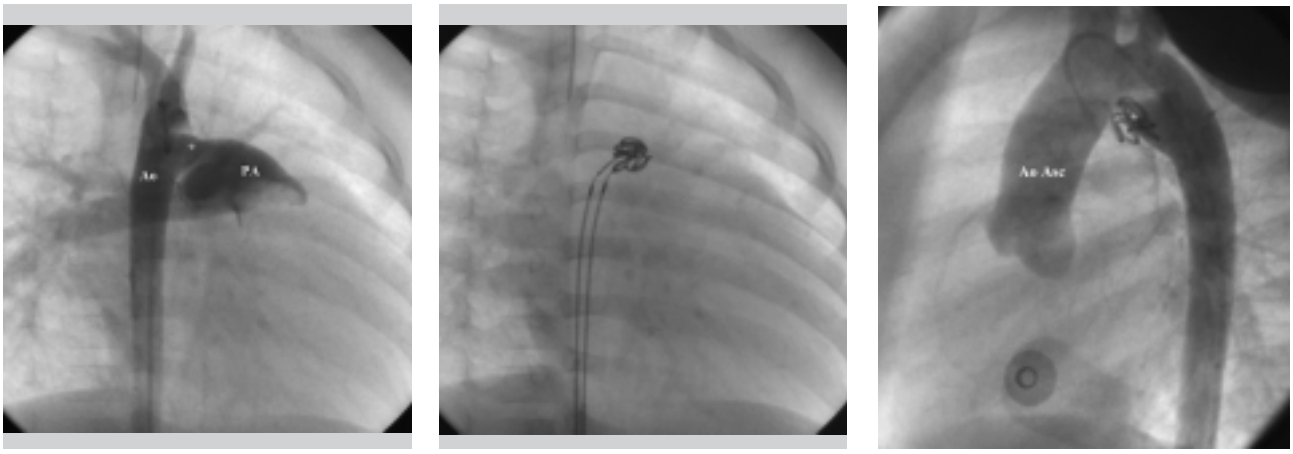
Follow-up. Clinical and echocardiographic follow-up was routinely performed at discharge, after 1, 6, and 12 months and, thereafter, once a year if any residual shunt persisted. PDA was considered completely occluded if no residual shunt was detected by echocardiography, while recanalization was considered if any ductal shunt was highlighted in a patient with a previously documented complete occlusion. Residual shunt was quantified according to the Rao's criteria[34], as none, trivial (color Doppler jet width < 1 mm), small (color Doppler jet width 1-2 mm), medium (color Doppler jet width 2-4 mm and possible left ventricular volume overload), and large (color Doppler jet width > 4 mm and left ventricular volume overload). Aortic and/or pulmonary artery flow abnormalities following device implantation were assessed by echocardiography and compared between groups.

Statistical analysis. All analyses were performed using SPSS for Windows version 10.0 (SPSS Inc., Chicago, IL, USA). Results are expressed as mean ± SD. Comparisons between groups were performed using the unpaired Student's t-test (procedural and fluoroscopy times, procedural costs) or the χ^2 test (procedural feasibility, and occlusion rate at follow-up). Significance was defined as a p value < 0.05.



A B C

Figure 1. A: *aortic angiography in lateral view showing a 2.4 mm large, conical patent ductus arteriosus* (*)*, resulting in a significant left-to-right shunt (pulmonary to systemic flow ratio 2.2:1).* B: *a 4/6 mm Amplatzer duct occluder device* (*) *in place before the final release.* C: *angiographic control after device implantation showing complete shunt disappearance. Ao = aorta; PA = pulmonary artery.*



A B C

Figure 2. A: *aortic angiography in right anterior oblique view showing a large, conical patent ductus arteriosus causing a marked opacification of the main pulmonary artery (PA).* B: *due to the patient's weight (4.750 kg), it was decided to perform patent ductus arteriosus closure using the multiple coil approach. Thus, two controlled-release coils were simultaneously delivered from the arterial site (bilateral femoral artery entry), with complete patent ductus arteriosus closure at the angiographic control* (C). *Ao = descending aorta; Ao Asc = ascending aorta. * ductal ampulla.*

Results

Between April 2000 and July 2004, among the 158 patients submitted to elective transcatheter PDA closure at our Institution, 57 presented a large PDA according to the criteria described above. Nineteen patients (33.3%) were on pharmacologic therapy for congestive heart failure or recurrent pulmonary edema episodes. Transcatheter closure was successfully performed in all but 3 infants (94.7%), due to the failure to implant the ADO device (2 patients) or repeat embolization of multiple coils (1 patient). PDA size and shape did not influence the procedural feasibility and residual shunt. Clinical, hemodynamic and angiographic data at procedure of the remaining patients are summarized in table I. The mean ADO device minimum diameter was 6 ± 2 mm (range 4-14 mm, median 6 mm). Forty-two coils were implanted in 20 patients (3 coils in 2 patients and 2 coils in 18 patients). After the procedure, PDA complete occlusion was achieved in 77.8% of patients at discharge, rising to 92.6% at 1 month and to 94.4% at last follow-up control. Overall, a trivial residual shunt was recorded in 3/54 patients over a mid-term follow-up (23 ± 12 months, range 3-44 months). The ADO device implantation was significantly less time-consuming than the multiple coil approach (71 ± 28 vs 96 ± 46 min, $p < 0.03$), but without any significant difference in fluoroscopy time (10.2 ± 1.9 vs 8.9 ± 2.2 min, p = NS). Neither procedural feasibility (94.4 vs 95.2%, p = NS) nor occlusion rate at any follow-up time-point (79.5 vs 75.0% at 24 hours; 97.1 vs 85.0% at 1 month; 97.1 vs 90.0% at last follow-up control, p = NS) between the ADO device and the multiple coil groups were significantly different. No ductal recanalization or late complications occurred in either group. In particular, no flow abnormality at the pulmonary artery/aortic isthmus site was detected at follow-up Doppler analysis. Procedural costs were higher using the ADO device than the multiple coil approach (3811 ± 38 vs 1378 ± 158 €, $p < 0.0001$).

Table I. Clinical, hemodynamic and angiographic data of patients submitted to patent ductus arteriosus (PDA) percutaneous closure.

Age (years)	10.3 ± 16.0 (range 4 months-67 years, median 3 years)
Weight (kg)	30 ± 27 (range 4.5-94, median 17)
Body surface area (m^2)	0.93 ± 0.57 (range 0.26-2.1, median 0.72)
PDA diameter (mm)	3.2 ± 1.2 (range 1.8-9, median 3.0)
PDA shape (%)	
Conical	68.5
Tubular	25.9
Window-like	5.6
Qp/Qs ratio	2.1 ± 1.8 (range 1.4-5, median 1.5)
PA pressure (mmHg)	24 ± 7 (range 15-49, median 22)
Aortic pressure (mmHg)	59 ± 17 (range 53-119, median 66)
Procedural time (min)	79 ± 38 (range 20-215, median 70)
Fluoroscopy time (min)	9.0 ± 1.2 (range 7.4-10.2, median 9.1)

PA = pulmonary artery; Qp/Qs = pulmonary to systemic flow ratio.

Discussion

A large PDA is a common cause of congestive heart failure in pediatric age and sometimes it may be an unexpected cause of left ventricular volume overload in adolescents and adults[1,2]. Over time, transcatheter approach revealed safe and effective in treating this malformation using different available devices[7-9,11,13,14,24]. However, procedural failures, residual shunt and local obstructive complications still curb their application in large PDA and/or younger patients[10,14,16-18,23,35-39]. In this setting, ductal closure has been sometimes performed using non-dedicated devices[21,28,30], although the most commonly used approaches are nowadays the ADO device or the multiple coil implantation[10,14,16-18,23,26]. The ADO device has been proved highly effective in large series[14,16,26]. However, its deployment is quite troublesome in small infants, with a non-negligible risk of aortic or pulmonary artery obstruction, so being indicated in patients > 5 kg[40]. On the other hand, the multiple coil approach is suitable for a wider range of patients but it is technically more challenging and shows a significant rate of procedural failures and residual shunt[17-19]. To overcome these drawbacks, several technical changes in coil deployment have been suggested[19,31,41], with a consequent significant increase in procedural complexity. In this setting, the use of multiple controlled-release coils that can be easily intertwined to each other during a simultaneous deployment, could theoretically make the closure of large PDA simpler, safer and more effective.

In agreement with the literature[40], our first-choice option for large PDA closure is the ADO device, whenever patient size, aortic isthmus morphology as well as PDA shape allow its implantation. However, all these factors should not be considered an obstacle to percutaneous treatment of a large PDA, since the multiple coil approach is as much effective in patients unsuitable for the ADO device implantation. In fact, in our experience, by using the technique of the simultaneous intertwining of multiple detachable coils, the percutaneous treatment has been possible also in most of the patients not suitable for ADO device implantation. In our series, a high rate of procedural success was recorded regardless of patient age and ductal size, with an early occlusion rate as high as 92.6%, rising to nearly 95% over a mid-term follow-up. The multiple coil approach was more time-consuming than the ADO implantation, but without any difference in feasibility, fluoroscopy time, and mid-term results. Indeed, a trend toward an earlier complete PDA closure after the ADO device implantation was recorded, but no significant difference between these two techniques was found at any time-point of the follow-up (Fig. 3). Finally, despite the use of the controlled-release coils that are significantly more expensive than the classic Gianturco coils, the multiple coil approach is still significantly cheaper than the ADO device approach.

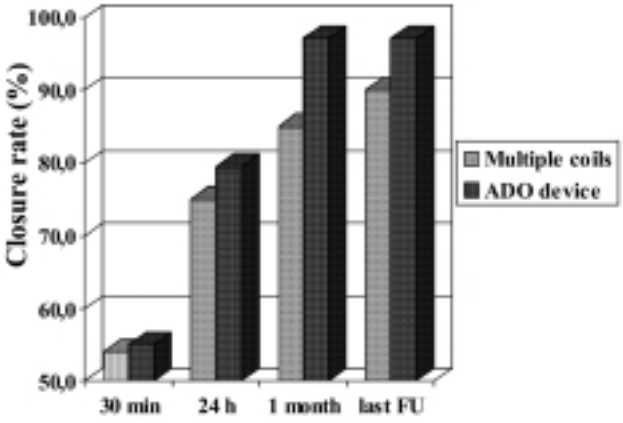


Figure 3. *Time course of shunt disappearance after patent ductus arteriosus closure using the Amplatzer duct occluder (ADO) device or multiple detachable coils. FU = follow-up.*

In conclusion, transcatheter closure can be safely and successfully performed in the majority of patients with large PDA, by "tailoring" the interventional approach to the patient size and ductal morphology. In our experience, the multiple coil approach using the controlled-release coils was technically more demanding, but cheaper in terms of catheterization material and as effective as the ADO device over a mid-term follow-up.

References

1. Heymann MA. Patent ductus arteriosus. In: Adams FH, Emmanoulides GC, Reimenscheider TA, eds. Heart disease in infants, children and adolescents. Baltimore, MD: Williams & Wilkins, 1994: 209-23.
2. Mullins CE. Patent ductus arteriosus. In: Garson A, Bricker JT, McNamara DG, eds. The science and practice of pediatric cardiology. Philadelphia, PA: Lea & Febiger, 1990: 1055-72.
3. Campbell M. Natural history of persistent ductus arteriosus. Br Heart J 1968; 30: 4-13.
4. Tutassaura H, Goldman B, Moes CA. Spontaneous aneurysm of the ductus arteriosus in childhood. J Thorac Cardiovasc Surg 1969; 57: 180-2.
5. Blazer DT, Spray TL, McMullin D, Cottingham W, Canter CE. Endarteritis associated with a clinically silent patent ductus arteriosus. Am Heart J 1993; 125: 1192-3.
6. Benson L. Catheter closure of the ductus arteriosus. In: Rao PS, ed. Transcatheter therapy in pediatric cardiology. New York, NY: Wiley-Liss, 1995: 321-3.
7. Rashkind WJ, Mullins CE, Hellenbrand WE, Tait MA. Nonsurgical closure of patent ductus arteriosus: clinical application of the Rashkind occluder system. Circulation 1987; 75: 583-92.
8. Tynan M. Transcatheter occlusion of persistent arterial duct. Report of the European Registry. Lancet 1992; 340: 1062-6.
9. Lloyd TR, Federally R, Mendelsohn AM, Sandu SK, Beekman RH. Transcatheter occlusion of patent ductus arteriosus with Gianturco coils. Circulation 1993; 88: 1412-20.
10. Hijazi ZM, Geggel RL. Results of anterograde transcatheter closure of patent ductus arteriosus using single or multiple Gianturco coils. Am J Cardiol 1994; 74: 925-9.

11. Rao PS. Which method to use for transcatheter occlusion of patent ductus arteriosus? Cathet Cardiovasc Diagn 1996; 39: 49-51.
12. Hijazi ZM, Geggel RM. Transcatheter closure of patent ductus arteriosus using coils. Am J Cardiol 1997; 79: 1279-80.
13. Bermudez-Canete R, Santoro G, Bialkowsky J, et al. Patent ductus arteriosus occlusion with detachable coils. Am J Cardiol 1998; 82: 1547-9.
14. Faella HJ, Hijazi ZM. Closure of the patent ductus arteriosus with the Amplatzer PDA device: immediate results of the international clinical trial. Catheter Cardiovasc Interv 2000; 51: 50-4.
15. Formigari R, Toscano A, Herraiz I, et al. Late follow-up of occlusion of the patent ductus arteriosus with the Rashkind device with emphasis on long-term efficacy and risk for infections. Am J Cardiol 2001; 88: 586-8.
16. Bilkis AA, Alwi M, Hasri S, et al. The Amplatzer duct occluder: experience in 209 patients. J Am Coll Cardiol 2001; 37: 258-61.
17. Owada CY, Teitel DF, Moore P. Evaluation of Gianturco coils for closure of large (> 3.5 mm) patent ductus arteriosus. J Am Coll Cardiol 1997; 30: 1856-62.
18. Akagi T, Iemura M, Tananari Y, Ishii M, Yoshizawa S, Kato H. Simultaneous double or triple coil technique for closure of moderate sized (≥ 3.0 mm) patent ductus arteriosus. J Interv Cardiol 2001; 14: 91-6.
19. 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.
20. Wang JK, Liau CS, Huang JJ, et al. Transcatheter closure of patent ductus arteriosus using Gianturco coils in adolescents and adults. Catheter Cardiovasc Interv 2002; 55: 513-8.
21. Bridges ND, Perry SB, Parness I, Keane JF, Jock JE. Transcatheter closure of a large patent ductus arteriosus with the clamshell septal umbrella. J Am Coll Cardiol 1991; 18: 1297-302.
22. Verin VE, Saveliev SV, Kolody SM, Prokubovski VI. Results of transcatheter occlusion of the patent ductus arteriosus with the Botallo occluder. J Am Coll Cardiol 1993; 22: 1509-14.
23. Hijazi ZM, Geggel RL. Transcatheter closure of large patent ductus arteriosus (> 4 mm) with multiple Gianturco coils: immediate and mid-term results. Heart 1996; 76: 536-40.
24. Grifka RG, Vincent JA, Nihill MR, Ing FF, Mullins CE. Transcatheter patent ductus arteriosus closure in an infant using the Gianturco-Grifka vascular occlusion device. Am J Cardiol 1996; 78: 721-3.
25. 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: 520-4.
26. Masura J, Walsh KP, Thanopoulos B, 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.
27. Rao PS, Kim SH, Rey C, Onorato E, Sideris EB. Results of transvenous buttoned device occlusion of patent ductus arteriosus in adults. International Buttoned Device Trial Group. Am J Cardiol 1998; 82: 827-9.
28. Sideris EB, Rao PS, Zamora R. The Sideris buttoned devices for transcatheter closure of patent ductus arteriosus. J Interv Cardiol 2001; 14: 239-46.
29. Huang TC, Hsieh KS, Lee CL, Lin CC. Safety and efficacy of using 0.052-inch Gianturco coil for closure of large (≥ 4 mm) patent ductus arteriosus. J Invasive Cardiol 2002; 14: 173-7.
30. Pedra CA, Sanchez SA, Fontes VF. Percutaneous occlusion of the patent ductus arteriosus with the Amplatzer device for atrial septal defects. J Invasive Cardiol 2003; 15: 413-7.
31. Kumar RK, Krishnan MN, Venugopal K, Sivakumar K, Anil SR. Bioptome-assisted simultaneous delivery of multiple coils for occlusion of the large patent ductus arteriosus. Catheter Cardiovasc Interv 2001; 54: 95-100.
32. Santoro G, Cappelli Bigazzi M, Palladino MT, Russo MG, Carrozza M, Calabrò R. Comparison of percutaneous closure of large patent ductus arteriosus by multiple coils versus the Amplatzer duct occluder device. Am J Cardiol 2004; 94: 252-5.
33. Krichenko A, Benson LN, Burrows P, Moes 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: 877-80.
34. 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: 820-6.
35. Ottenkamp J, Hess J, Talsma MD, Buis-Liem TN. Protrusion of the device: a complication of catheter closure of patent ductus arteriosus. Br Heart J 1992; 68: 301-3.
36. Dessy H, Hermus JPS, van der Heuvel F, Oei HY, Krenning EP, Hess J. Echocardiographic and radionuclide pulmonary blood flow patterns after transcatheter closure of patent ductus arteriosus. Circulation 1996; 94: 126-9.
37. Evangelista JK, Hijazi ZM, Geggel RM, Oates E, Fulton DR. Effect of multiple coil closure of patent ductus arteriosus on blood flow to the left lung as determined by lung perfusion scan. Am J Cardiol 1997; 80: 242-4.
38. Moore JD, Shim D, Mendelsohn AM, Kimbell TR. Coarctation of the aorta following coil occlusion of a patent ductus arteriosus. Cathet Cardiovasc Diagn 1998; 43: 60-2.
39. Duke C, Chan KC. Aortic obstruction caused by device occlusion of patent arterial duct. Heart 1999; 82: 109-11.
40. Hijazi ZM. Catheter closure of ductus arteriosus in adolescents and adults: what to use? Catheter Cardiovasc Interv 2002; 55: 519-20.
41. Grifka RG, Jones TK. Transcatheter closure of large PDA using 0.052" Gianturco coils: controlled delivery using a bioptome catheter through a 4 French sheath. Catheter Cardiovasc Interv 2000; 49: 301-6.