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Evaluation of Gianturco Coils for Closure of Large (≥3.5 mm) Patent Ductus Arteriosus

CARL Y. OWADA, MD, DAVID F. TEITEL, MD, PHILLIP MOORE, MD

San Francisco, California

Objectives. **This report evaluates the use of Gianturco coils to close large patent ductus arteriosus (PDAs) (≥3.5 mm) and describes transvenous delivery of 0.052-in. (0.132-cm) Gianturco coils.**

Background. **Coil closure of PDAs has become increasingly popular. However, the technique has significant limitations when used to close large PDAs. This report evaluates patient characteristics, PDA anatomy, hemodynamic variables, delivery technique and coil geometry to determine predictors of success.**

Methods. **Between January 1995 and January 1997, 16 of 118 patients undergoing catheterization for PDA closure were found to have large PDAs. Their median age and weight were 14 months (range 3 months to 43 years) and 8.5 kg (range 3.5 to 73), respectively. The mean PDA diameter was 4.3 mm (range 3.5 to 5.9). Closure of PDAs was attempted using transcatheter delivery of 0.038-in. (0.096-cm) and 0.052-in. coils. Differences in clinical, anatomic, hemodynamic and technical variables between successes and failures were compared.**

Results. **Eleven (69%) of 16 patients had successful closure of their PDA. Failures occurred only in patients <8 months of age with an indexed PDA diameter >7 mm/m and a pulmonary/systemic flow ratio ≥2.8:1. Use of 0.052-in. coils tended to reduce the incidence of embolization and the number of coils needed for closure.**

Conclusions. **Patients >8 months of age can have successful closure of large PDAs with currently available Gianturco coils. The 0.052-in. Gianturco coils can be used safely to close large PDAs in infants as small as 6 kg. Increased experience and improved coil design may improve closure rates of large PDAs in infants.**

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Since the introduction of nonsurgical closure of patent ductus arteriosus (PDA) by Portsmann et al. in 1967 (1,2) several ductal occlusion devices have been developed (3–8). Currently, the only device available for use throughout the United States is the Gianturco coil. Closing PDAs with Gianturco coils has become increasingly popular owing to the small sheath requirements, relative ease of delivery, high rate of successful occlusion, low rate of complications and low cost. However, despite various modifications of delivery techniques, successful closure has been limited to small- to moderate-sized PDAs (6,9–13). Large PDAs (≥3.5 mm in diameter) have been successfully closed nonsurgically using the Rashkind, Clamshell and button devices, although these devices remain investigational in the United States (14). This report evaluates the use of Gianturco coils for closure of large PDAs and describes our preliminary experience using transvenous delivery of 0.052-in. (0.132-cm) thick Gianturco coils. We compare patient characteristics, PDA anatomy, hemodynamic variables, delivery technique and coil geometry to determine predictors of success.

Methods

Patients. Of the 118 patients selected for PDA closure between January 1995 and January 1997, 16 had a patent ductus ≥3.5 mm in minimal diameter and constituted the study group. Their ages ranged from 3 months to 43 years (median 14 months). Five patients were <6 months of age. Their weights ranged from 3.5 to 73 kg (median 8.5) (Table 1). All 16 patients had attempted closure of an isolated PDA. Three had Down syndrome. Two had moderate pulmonary hypertension. Five had cardiorespiratory symptoms. All had echocardiographic findings of a large PDA, including a left atrium to aortic root dimension (LA/Ao) ratio >1.3 and an estimated PDA size of ≥3 mm by color flow mapping. All families gave written consent before the procedure.

Procedure. After hemodynamic catheterization, a descending aortogram was obtained. Ductal dimension was measured in the magnified lateral projection using the angiographic catheter as a reference. Quantitative angiographic assessment of shunt severity was a modification of that described by Lloyd et al. (9). To the four categories of angiographic shunt (trace, small, moderate and large) we added a fifth category of a trivial shunt, defined as opacification of the juxtaductal area, giving a

From the Division of Pediatric Cardiology, University of California San Francisco, San Francisco, California.

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Address for correspondence: Dr. Carl Y. Owada, Division of Pediatric Cardiology, Box 0544, University of California at San Francisco, 505 Parnassus Avenue, San Francisco, California 94143. E-mail: Carl_Owada@pedcardgateway.ucsf.edu.

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Abbreviations and Acronyms

BSA = body surface area
DAo = descending aorta
LA/Ao = left atrial/aortic root dimension ratio
LPA = left pulmonary artery
MPA = main pulmonary artery
PA = pulmonary artery
PDA = patent ductus arteriosus
Qp/Qs = pulmonary/systemic flow ratio

"smoky appearance" to the coil in the pulmonary artery (PA) that was slow to clear. Cefazolin (20 to 40 mg/kg body weight) was administered intravenously before coil delivery.

Twenty minutes after coil delivery a descending aortogram and right-sided saturation and pressure measurements were repeated. Patients who had successful closure of their PDA received two additional doses of cefazolin. Echocardiography was performed 1 to 5 h after catheterization to evaluate for flow disturbance in the left pulmonary artery (LPA) or descending aorta (DAo) and for evidence of a residual shunt.

Transvenous coil closure. Transvenous coil closure using 0.038-in. (0.096-cm) Gianturco coils (Cook Inc.) was performed as described by Hijazi and Geggel (11). Transvenous coil closure using 0.052-in. Gianturco coils (Cook Inc.) was performed using a coaxial system consisting of a hand-shaped 6F guiding catheter (Omniguide, MIS) over a 4F Berenstein catheter (MediTech). The system was advanced through a 6F femoral venous sheath anterogradely over a 0.025-in. (0.063-cm) exchange length Amplatz guide wire (Cook Inc.) across the PDA into the DAo. The guide wire and Berenstein catheter were removed and the guiding catheter tip was positioned in the aorta at the mouth of the ductal ampulla. The diameter of the coil was at least 1.7 times the minimal PDA diameter and the coil was long enough to produce at least three complete loops. The coil was advanced through the guiding catheter using the soft end of a 0.052-in. guide wire (Cook Inc.). Under fluoroscopic guidance at least 2¼ loops of coil (up to 3¼ loops for the longer coils) were advanced out of the catheter in the DAo. The entire system was then brought back into the ductal ampulla. Correct position was confirmed using a reference image of the lateral descending aortogram. The guiding catheter was then withdrawn over the wire into the main pulmonary artery (MPA) delivering the final ¾ loop of coil on the PA side of the ductus (Fig. 1). Additional 0.038-in. or 0.035-in. (0.089-cm) coils were placed by transvenous or transarterial approach to complete closure as necessary.

Transarterial coil closure. Transarterial coil closure of the PDA using 0.035-in. and 0.038-in. coils was performed as previously described using either a 4F or 5F Bentson or Berenstein catheter (MediTech) (6).

Table 1. Clinical, Anatomic and Hemodynamic Characteristics of 16 Patients With Large Patent Ductus Arteriosus

		Clinical			Anatomic					Hemodynamic		
	Patient No.	Age (yr)	Weight (kg)	Clinical Score	PDA (mm)	PDA/BSA$^{1/2}$ (mm/m)	PDA/DAo	Amp/BSA$^{1/2}$ (mm/m)	L/BSA$^{1/2}$ (mm/m)	LA/Ao	Qp/Qs	Diastolic Gradient (mm Hg)
Successful closure	1	3.24	12.7	3	4.6	6.2	0.44	16.0	7.4	1.4	1.9	2
	2	7.41	20.0	0	3.8	4.3	0.34	15.2	13.4	2.0	1.2	58
	3	2.73	12.5	1	4.3	5.7	0.40	16.0	8.0	2.3	1.8	8
	4	1.32	8.4	3	4.0	6.4	0.47	19.2	12.7	1.6	2.1	14
	5	43.35	73.0	1	5.1	3.9	0.28	14.6	7.3		1.4	41
	6	3.76	19.3	1	4.3	5.0	0.35	16.0	4.0	1.5	1.7	39
	7	0.32	6.2	1	4.2	7.5	0.52	19.9	9.4	1.8	3.3	18
	8	1.61	10.0	2	3.9	5.7	0.36	18.5	10.1	1.9	3.4	23
	9	0.94	8.6	1	3.6	5.7	0.37	12.9	12.8	1.7	1.9	38
	10	2.44	10.4	1	3.5	5.1	0.39	18.1	9.0	1.7	1.3	38
	11	0.58	6.8	3	4.5	7.7	0.50	17.9	14.6	1.5	3.7	11
Median		2.44*	10.4*	1*	4.2	5.7*	0.39*	16.0	9.4	1.7	1.9*	23
Failed closure	12	0.43	3.5	3	4.8	10.2	0.83	15.9	14.2	2.7	2.8	8
	13	0.48	7.0	3	4.0	6.9	0.44	15.1	8.2	1.9	3.5	13
	14	0.68	7.0	3	4.1	7.0	0.51	19.8	12.2	2.0	3.1	11
	15	0.50	5.5	3	5.9	10.7	0.79	19.8	13.8	1.9	3.9	3
	16	0.24	5.7	4	4.0	7.5	0.44	20.0	11.8	1.4	2.8	18
Median		0.48	5.7	3	4.1	7.5	0.51	19.8	12.2	1.9	3.1	11

*$p < 0.05$—successful and failed group differences were compared using the Mann-Whitney rank-sum test. Amp = ductal ampulla diameter; BSA = body surface area; Clinical Score = the sum of clinical characteristics: cardiorespiratory symptoms, bounding pulse, active precordium and pulse pressure >45 mm Hg, with each characteristic assigned 1 point; DAo = descending aorta; Diastolic Gradient = aortopulmonary pressure gradient measured in diastole; L = ampulla length; LA/Ao = left atrial/aortic root length ratio; LPA = left pulmonary artery; PDA = minimal diameter of the patent ductus arteriosus measured in diastole; Qp/Qs = pulmonary/systemic flow ratio.

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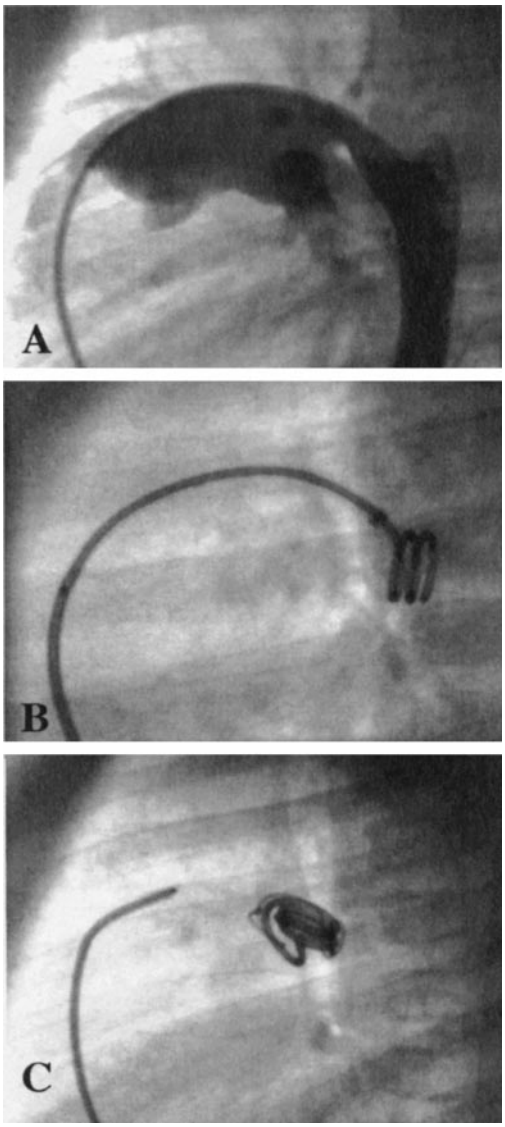

Figure 1. Sequential digital cine frames showing the delivery of a 0.052-in., 10-cm long, 8-mm helical diameter coil. **A,** Lateral angiogram demonstrates a large 4.5-mm PDA in a 6.8-kg infant. **B,** Two and one-quarter loops of coil have been advanced into the DAo adjacent to the ductal ampulla through a 6F guiding catheter. **C,** The coil completely delivered has three and one-quarter loops stacked along the inferior margin of the ductal ampulla and the remaining three-quarter loop on the PA side. A 0.035-in., 5-cm long, 5-mm helical diameter coil has been delivered over the superior margin of the primary coil to complete closure.

Coil retrieval. All embolized coils, those which spontaneously migrated to the PA, and malpositioned coils, those thought to have improper position with protrusion into the LPA or aorta, were retrieved through either the ipsilateral or contralateral femoral vein using a 6F to 8F Mullins sheath (Cook Inc.), 5F Bentson or Berenstein catheter and a 5- or 10-mm Nitnol snare (Micro Vena). Retrievals of 0.052-in. coils were accomplished through a 7F long sheath.

Analysis. Patients were retrospectively divided into successful (defined as no residual shunt detected by hemoximeter measurement and less than or equal to trace residual angiographic shunt) and failed closures (defined as greater than trace residual angiographic shunt). Patient characteristics, PDA anatomy, hemodynamic variables, delivery technique and coil geometry were compared between the two groups. Patient characteristics included age, weight and a clinical score (Table 1). The clinical score was derived by adding one point for each clinical finding that suggested a large PDA, including cardiorespiratory symptoms (tachypnea, diaphoresis, exercise intolerance, feeding difficulty or growth failure), bounding pulses, hyperactive precordium or a pulse pressure >45 mm Hg. Anatomic dimensions of the PDA included minimal PDA diameter in systole and diastole, length of the PDA and diameters of the LPA, ampulla and DAo at the level of the diaphragm. To adjust for patient size, each dimension was indexed by dividing by the square root of the body surface area (BSA) (15,16). This indexing procedure produced relative LPA and DAo dimensions that were similar in all patients irrespective of their BSA. Hemodynamic variables were quantified by determining the echocardiographic LA/Ao ratio, aortopulmonary diastolic gradient, pulmonary to systemic flow ratio (Qp/Qs) and degree of angiographic shunt.

Delivery technique of the primary coil was designated as either transvenous or transarterial. Variables of coil geometry included the ratio of coil helical diameter to PDA diameter, wire gauge, the ratio of wire gauge to helical diameter (an index of coil stiffness) and the need for additional coils as it related to the wire gauge of the primary occluding coil. The geometries of coils that were properly positioned were compared to those of coils that embolized or were malpositioned and required retrieval.

Statistical analysis. Minimal PDA diameter is expressed as mean value ± SD. Because of the skewed distribution, unequal variance and small sample size, differences of each variable between successes and failures were quantified using the Mann-Whitney rank-sum test. To determine the degree of correlation between patient age versus clinical score and PDA/DAo ratio versus Qp/Qs, we performed a Spearman rank correlation analysis. Differences between minimal PDA diameter in systole and diastole were evaluated using the paired *t* test. Statistical significance was achieved at $p \leq 0.05$.

Results

Patients and procedure. We found that all patients with large PDAs had moderate to large shunts by angiographic scoring. Overall, the minimal PDA diameter ranged between 3.5 and 5.9 mm (mean 4.3 ± 0.6) (Table 1). The differences in PDA diameter measured in systole compared with diastole did not achieve statistical significance ($p = 0.5$). Transvenous delivery of the primary coil was performed in 11 of 16 patients, whereas the remainder had transarterial coil delivery. A 0.052-in. coil was the primary coil in 10 patients, with an 0.038-in. coil the primary coil in the remaining six patients. All patients were discharged within 24 h of the procedure or had their PDA surgically ligated the next day.

Table 2. Procedural Characteristics and Results

Patient No.	Primary Coil		No. of Additional Coils for Closure	Shunt†			No. of Malpositioned Coils	No. of Embolized Coils	Maximal Size of Embolized Coil*
	Delivery Route	Coil Size*		Before	After	24-h Echocardiographic Follow-Up			
1	A	0.038-10-10	2	Large	Trace	None	—	—	
2	A	0.038-8-8	2	Moderate	Trivial	None	—	1	0.038-5-5
3	A	0.038-8-8	2	Large	Trivial	Trivial	3	3	0.038-8-8
4	V	0.052-9-9	1	Large	Trivial	None	—	4	0.038-8-8
5	V	0.052-12-12	0	Large	None		—	—	
6	V	0.052-8-8	1	Moderate	None	None	—	—	
7	V	0.052-8-8	0	Large	Trace	Small	—	—	
8	V	0.052-9-9	3	Large	Trace	Small	1	—	
9	V	0.052-10-8	1	Large	None	None	—	—	
10	A	0.038-8-6	0	Moderate	None	None	—	—	
11	V	0.052-10-8	1	Moderate		None	—	—	
12	V	0.038-5-5		Large	Operation	None	—	1	0.038-5-5
13	A	0.038-8-8		Large	Operation	None	—	5	0.038-10-10
14	V	0.038-8-8		Large	Operation	None	—	3	0.052-8-8
15	V	0.052-10-10		Large	Operation	None	—	1	0.052-10-10
16	V	0.052-8-8		Moderate	Operation	Trivial	2	—	

*Wire gauge (in.)-length (cm)-helical diameter (mm). †The shunt "before" and "after" was determined by angiography; shunt at "follow-up" was determined by echocardiography. A = transarterial; V = transvenous.

Successes. Eleven (69%) of 16 patients had successful closure of large PDAs using one to four Gianturco coils (Table 2). No patient had evidence of a residual shunt by the Fick technique immediately after coil placement. Eight patients had no audible murmur after the procedure: four of them had no angiographic shunt, two had a trivial shunt and one had a trace residual angiographic shunt. A postcoil aortogram was not obtained in one patient. Echocardiographic follow-up of these eight patients 1 to 5 h after the procedure showed no residual shunt. Three patients had a soft residual systolic murmur in association with a trivial to trace residual angiographic shunt. These small shunts were seen to persist on echocardiographic follow-up 1 to 24 h after ductal closure.

Failures. There were five patients in whom coil closure was not successful. Three patients had embolization in the setting of a coil helical diameter less than twice the minimal PDA diameter. Larger coils were not used owing to the small aortic dimensions of the patients. In the fourth patient, embolization occurred despite a helical diameter greater than twice the minimal PDA diameter. In this patient the PDA measured 4.0 mm. A well positioned 0.038-in., 10-cm long, 10-mm helical diameter coil embolized to the right pulmonary artery. Simultaneous delivery of a 0.038-in., 8-cm long, 8-mm helical diameter coil anterograde and a 0.038-in., 5-cm long, 5-mm helical diameter coil retrograde stayed in place for <1 min before embolizing to the LPA. A final attempt at closure using the snare technique (12) was unsuccessful. In the final patient failure was due to coil impingement on the proximal LPA. This patient had complete closure of a 4.0-mm PDA using a combination of a 0.052-in., 8-cm long, 8-mm helical diameter and 0.035-in., 5-cm long, 5-mm helical diameter coil. Despite good positioning with only one loop on the PA side, the coils caused mild LPA stenosis with a peak systolic gradient 20 mm Hg. This result was thought to be unacceptable, so the coils were removed. All five patients were referred for surgical ligation of their PDAs.

Success versus failure group comparisons. To better understand the limitations of the current method of ductal closure, we compared the characteristics of the two groups. Patients with failed closure were significantly younger (median age 5 months 3 weeks vs. 2 years 5 months, $p < 0.05$) and smaller (median weight 5.7 kg vs. 10.4 kg, $p < 0.01$) (Table 1). The clinical scores of failures were higher ($p < 0.02$), suggesting a greater hemodynamic effect of the PDA in the failure group, despite similar minimal PDA diameters between groups (mean 4.2 ± 0.5 mm vs. 4.6 ± 0.8 mm, $p > 0.2$). This apparent discrepancy is easily explained by covariance of patient age with clinical score ($p = 0.016$). Failures had a significantly larger indexed minimal PDA diameter compared with successes ($p < 0.01$) and a significantly larger PDA/DAo ratio (median 0.51 vs. 0.39, $p < 0.05$). In contrast, there was no difference in the indexed ampulla diameter or PDA length, suggesting the shape of the ducts were similar in both groups. Although there were no differences in the LA/Ao ratio or pulse pressure ($p > 0.2$) between the groups, failures had a significantly larger Qp/Qs (median 3.1 vs. 1.9, $p < 0.05$) and a suggestion of lower diastolic gradients between the DAo and PA (median 11 mm Hg vs. 23 mm Hg, $p = 0.09$). As expected, Qp/Qs correlated well with the PDA/DAo ratio ($p < 0.01$).

Although differences regarding the method of coil delivery or coil geometry did not achieve significance, certain trends were observed. We found a need for fewer coils to close large PDAs when a 0.052-in. coil was the primary coil (average 1.7 coils per patient with a 0.052-in. coil vs. 2.5 coils per patient with a 0.038-in. coil) (Fig. 2). Furthermore, there tended to be a lower rate of embolization or malposition when 0.052-in.

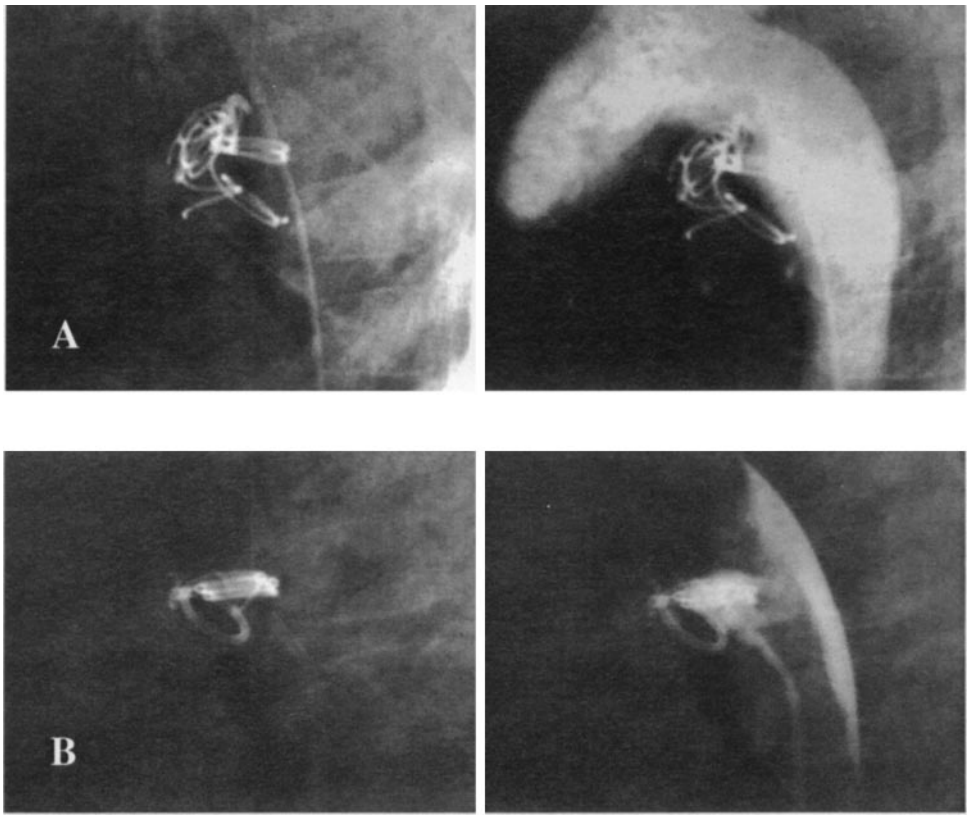

Figure 2. Comparison of 0.038-in. coils with a 0.052-in. coil to close similar sized PDAs. **A,** Lateral angiogram from Patient 1 after transarterial placement of three coils (0.038 in., 10 cm long, 10-mm helical diameter; 8 cm long, 8-mm helical diameter; 5 cm long, 5-mm helical diameter) shows a trace residual shunt that spontaneously closed within 3 h of the procedure. **B,** Lateral angiogram from Patient 6 after transvenous placement of a 0.052-in., 8-cm long, 8-mm helical diameter coil and transarterial placement of a 0.035-in., 4-cm long, 4-mm helical diameter coil. Contrast injection shows no residual shunt.

primary coils were used (0.6 coils per patient with a 0.052-in. coil vs. 2.4 coils per patient with an 0.038-in. coil). For example, failure in Patient 13 resulted from repeated embolization of 0.038-in. coils (five total), despite a helical diameter of 2.5 times the PDA diameter. In contrast, Patient 11, who had a similar sized PDA and shunt, had successful closure with a 0.052-in., 10-cm long, 8-mm helical diameter coil with a helical diameter <1.8 times the PDA diameter.

Complications. Complications were minimal with no instance of diminished femoral pulse or color flow disturbance in the DAo. None of the coils embolized to the DAo. All embolized or malpositioned coils were retrieved successfully (Table 2). Three patients showed mild color flow disturbance or increased flow velocity in the LPA. Two of these patients had multiple 0.038-in. coils placed in their PDAs (Fig. 2). The third patient, an 11-month old with a 3.6-mm PDA, had a 0.052-in., 10-cm long, 8-mm helical diameter coil delivered with one and one-half loops on the PA side. The distal coil loop could be seen near the LPA orifice. Pressure pullback measurement demonstrated a 14-mm Hg gradient across the proximal LPA; Doppler velocity was 2.5 m/s. One patient received a red blood cell transfusion to correct for exacerbation of physiologic anemia (hematocrit change from 27% to 24%).

Discussion

Successful closure of PDAs >3.5 mm in diameter can be achieved in nearly 70% (confidence interval 46% to 92%) of all patients using currently available Gianturco coils. We had no failures in patients >8 months of age. There tended to be a higher incidence of failure when a 0.038-in. coil was used as the primary occluding coil. Large 0.052-in. coils can be used safely and effectively to close large PDAs in infants as small as 6 kg (Fig. 3). Anatomic, hemodynamic and technical factors (delivery method and coil geometry) influence success.

Anatomic factors. Anatomic factors that may influence success include PDA size, PDA shape and the size of contiguous structures relative to the ductus. In our experience, neither absolute PDA diameter nor PDA shape influenced success. Only relative PDA size (indexed PDA diameter and PDA/DAo ratio) was important. This suggests that the size of the patient and DAo are the limiting factors of success with currently available coils. Modifications of delivery technique and coil design are needed to overcome these size limitations.

Hemodynamic factors. A hemodynamic effect that may influence success is the degree of left to right shunt. The force exerted on a coil from a large shunt may promote embolization. In support of this notion, the failure group had significantly larger shunts than the successful group. Shunt size is obviously not independent of anatomic factors, and, as expected, the largest shunts occurred in patients with relatively large PDAs. Inherent to the technique of using currently available coils for closure of large PDAs is a significant incidence of residual shunt, and therefore the presence of shear force that could promote embolization, during and after initial coil placement. Modifications in technique and coil design to ensure immediate, complete closure with a single coil

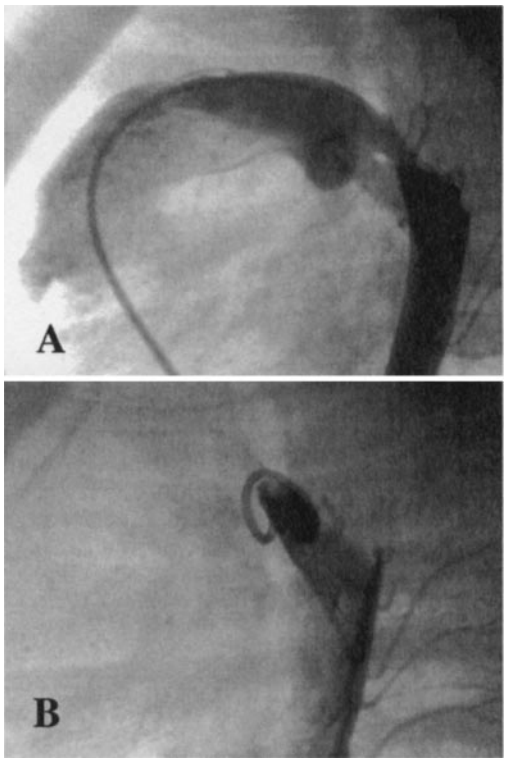

Figure 3. A, Lateral angiogram from Patient 7, who weighed 6.2 kg, shows a 4.2-mm PDA. **B,** Contrast injection through a 4F Bentson catheter demonstrates the 0.052-in., 8-cm long, 8-mm helical diameter coil to be well placed in the ductal ampulla with a trace residual shunt.

should significantly reduce the embolization rate associated with large left to right shunts.

Technical factors. Technical factors that may influence success include delivery method, coil positioning and coil geometry. We found no difference in the success rate between the transarterial or transvenous method of coil delivery. However, there may be theoretic advantages of transvenous delivery in large PDAs. First, the use of an arterial sheath in small infants poses some risk for pulse loss. Second, transvenous delivery allows the coil to form completely before being pulled into the ductal ampulla. Our impression is that this optimizes apposition to the ampulla wall and leads to more immediate, complete closure. This contrasts with transarterial delivery, where the coil springs into the ductal ampulla, creating an additional left to right force, additive with shunt flow, which may encourage embolization. Such a force may be compounded when using the stiffer 0.052-in. coils. For these reasons, we recommend the transvenous method for delivery of 0.052-in. coils.

Coil geometry. Another technical factor, coil size, which consists of wire gauge, length and helical diameter, may influence the success of ductal closure. Lloyd et al. (9) recommend using 0.038-in. coils with a helical diameter at least twice that of the minimal PDA diameter and length enough to form three complete loops. Following these guidelines, we have found the need for placing multiple coils (three to five coils) to occlude large PDAs, which increase procedure time, risk of LPA stenosis and risk of embolization (Fig. 2). In addition, 0.038-in. coils have embolized in the setting of large left to right shunts despite optimal helical diameter and delivery position. This has led us to use 0.052-in. coils to close large PDAs. These larger, stiffer coils have a greater stability in PDAs with large shunts, allowing us to successfully use a helical/minimal PDA diameter ratio as low as 1.7:1 with a trend toward less incidence of embolization. We also found a trend toward needing fewer coils for complete closure.

The geometry of the 0.052-in. coil in the PDA and the location of residual shunts, when present along the superior margin, suggest that placement of more loops of coil in the ductal ampulla may effect closure with a single coil. These stiffer coils tend to form a tight stack within the ductal ampulla, aligning along the inferior edge, without protruding into the aorta (Fig. 1, B and C; Fig. 2B; and Fig. 3B). Because the true wire thickness of a 0.052-in. coil is 1.1 mm, it stands to reason that to occlude a 4-mm PDA with a single coil, four complete loops are needed in the ampulla. Thus, with a minimum of one-half loop on the PA side, the coil length required to completely close a 4-mm ductus using a 0.052-in., 8-mm diameter coil would be 12 cm.

Longer coils that ensure the height of the ductal ampulla coil stack to be equal to the PDA diameter may allow for further reduction in the minimal helical diameter necessary to prevent embolization. For example, an 0.052-in., 10-cm long, 8-mm helical diameter coil was used to successfully close a 4.5-mm PDA with a Qp/Qs of 3.7:1. Despite inadequate length to form four complete loops in the ductal ampulla, a coil to PDA diameter ratio $<1.8:1$ and a residual shunt after delivery, the coil did not embolize (Fig. 1). The residual shunt along the superior margin was closed with one additional coil. These considerations may ultimately minimize coil protrusion into the DAo and LPA and may in turn overcome the anatomic limitations seen in small infants.

Study limitations. Limitations of this study include patient variability within a small sample size, covariance and retrospective study design. The variability in patient age and size forced a nonparametric method of data analysis with only 65% power to detect differences between successes and failures. Furthermore, this analysis assumes that each variable tested is independent. The variables examined, however, are not entirely independent, with patient age varying linearly with clinical score and relative PDA size varying with degree of hemodynamic shunt. Because covariance is not accounted for in this statistical model, results should be interpreted with caution. Finally, this retrospective review introduces biases imposed by variables that cannot be controlled. These variables include an operator learning curve, trend over time toward the use of 0.052-in. coils as the primary coil and operator differences in delivery technique. Fourteen of the 16 patients had the procedure performed by one of the authors (P.M.), thus minimizing operator differences.

Conclusions. Successful closure of large PDAs can be achieved in almost 70% of patients and, in our experience,

100% (confidence interval 66% to 100%) of patients >8 months of age using standard delivery techniques of currently available Gianturco coils. Our preliminary experience suggests that 0.052-in. coils can be used safely to close large PDAs in infants as small as 6.2 kg. Closure failures occurred in patients <8 months of age with an indexed PDA diameter >7 mm/m and a Qp/Qs ≥2.8. The stiffer characteristic of 0.052-in. coils may offer advantages over 0.038-in. coils for the closure of PDAs with large shunts. Longer coil lengths may improve the closure rate and allow a smaller helical to minimal PDA diameter ratio to be used. Increased experience with 0.052-in. coils and improved coil design may improve the rate of large PDA closure in infants.

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