PEDIATRIC AND CONGENITAL HEART DISEASE

Original Studies

Angiographic and Hemodynamic Predictors for Successful Outcome of Transcatheter Occlusion of Patent Ductus Arteriosus in Infants Less Than 8 Kilograms

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Transcatheter occlusion of patent ductus arteriosus (PDA) using Gianturco coils (GCs) has been performed for the past decade. However, little has been written regarding anatomical and hemodynamic predictors for successful occlusion of the PDA in infants. This report is to evaluate the outcome of transcatheter occlusion of PDA in symptomatic infants less than 8 kg and to assess predictors of successful occlusion. Retrospective review of catheterization charts and cineangiograms of 42 symptomatic infants who underwent cardiac catheterization for attempted transcatheter occlusion of their PDA was conducted. The hemodynamic and angiographic data evaluated included the length/diameter (L/D) ratio, defined as the length divided by the narrowest diameter of the ductus arteriosus, and preocclusion pulmonary artery pressures. Thirty-one out of 42 patients (74%) had successful occlusion. Twenty-nine out of 42 infants had an L/D ratio > 3. Of these, 26 (90%) had successful occlusion of their PDA. Thirteen out of 42 patients had an L/D ratio ≤ 3. Of these, 8 (62%) had unsuccessful occlusion. Complications encountered were transient loss of femoral arterial pulse (n = 6), coil embolization (n = 5), hemolysis (n = 2), and mild left pulmonary artery obstruction (n = 2). No permanent loss of femoral arterial pulse was noted. These complications resulted in no mortality and minimal morbidity. The L/D ratio was the strongest predictor of successful outcome, with an L/D ratio greater than 3.0 being more amenable to transcatheter occlusion (odds ratio of 4.6). Other predictors for success included lower preocclusion systolic, diastolic, and mean pulmonary artery pressure and smaller ductal diameter. Our conclusion was that infants less than 8 kg with an L/D ratio > 3.0 can safely and successfully undergo transcatheter occlusion of their PDA using transcatheter coils. *Catheter Cardiovasc Interv 2004;61:117–122.* © 2004 Wiley-Liss, Inc.

Key words: patent ductus arteriosus; congenital heart disease; occlusion of patent ductus arteriosus; pediatrics; cardiac intervention

INTRODUCTION

Transcatheter coil occlusion of the patent ductus arteriosus (PDA) using Gianturco coils (GCs; Cook, Bloomington, IN) has been performed since 1991 [1]. There have been several reports demonstrating the safety, efficacy, and value of transcatheter occlusion of the PDA in children greater than 8 kg [2–7]; however, few reports have been published on the efficacy and safety in performing this procedure using GCs or Flipper coils (FCs; Cook) in symptomatic infants less than 8 kg [8]. Furthermore, angiographic predictors for successful occlusion of PDA in infants < 8 kg have not been addressed. The purpose of this study was to determine angiographic and hemodynamic predictors

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for successful transcatheter occlusion of PDA in patients less than 8 kg.

MATERIALS AND METHODS

Forty-two symptomatic patients weighing less than 8 kg were taken to the cardiac catheterization laboratory for attempted transcatheter occlusion of their PDA between January 1995 and May 2003. The mean weight of the patients was 6.46 ± 1.37 kg; mean age was 8.4 ± 4.36 months. Indications for closure included congestive heart failure (n = 17) and left-sided volume overload (n = 25). There were no other associated cardiac lesions.

A prograde right heart catheterization was performed in 39 out of 42 (93%) patients to determine right heart pressures and saturations. Biplane proximal descending cineangiography was performed to demonstrate type, length, and minimal diameter of the ductus prior to attempted coil occlusion.

Placement of GCs or FCs was attempted in 38 out of 42 patients. In the remaining 4 patients, no occlusion was attempted due to the large size of the PDA. The retrograde approach was exclusively used in 34 out of 38 patients and the combined prograde and retrograde approach was used in 4 patients. In 15 patients the snare or bioptome method was used to deliver 0.038″ GCs, in 12 patients the free-hand technique was used to place 0.038″ GCs, and in 11 patients FCs either alone or in combination with GCs were used. The diameter of the GCs or FCs deployed was approximately twice that of the narrowest ductal diameter. Following the cineangiogram delineating ductal size and anatomy, a 4 Fr JB glide catheter (Boston Scientific, Boston, MA) was advanced retrograde across the ductus. In deployment of GCs or FCs, 0.5 loop of the coil was advanced on the pulmonary end of the ductus, with the remainder advanced on the aortic end. When the bioptome technique was used, a 6 Fr short sheath was placed in the femoral vein, and a 4 Fr Cook sheath was advanced prograde across the ductus into the descending aorta. A 0.052″ or 0.038″ GC was loaded on a 3 Fr Cook bioptome and advanced through the sheath and placed within the ductus. For the snare technique, a 5 mm Microvena snare (Microvena, White Bear Lake, MN) was advanced through a 4 Fr JB glide catheter placed prograde through the ductus into the descending aorta. The end of a GC was snared from a 4 Fr JB glide catheter placed retrograde into the descending aorta, and the GC was pulled within the ductus, leaving 0.5–1.0 loop on the pulmonary end. The snare was then released off the GC. Fifteen minutes after placement of either Gianturco or Flipper coils, a follow-up cineangiogram was performed to document any residual shunt. If the operator determined the residual shunt to be more than trivial, further coil placement was
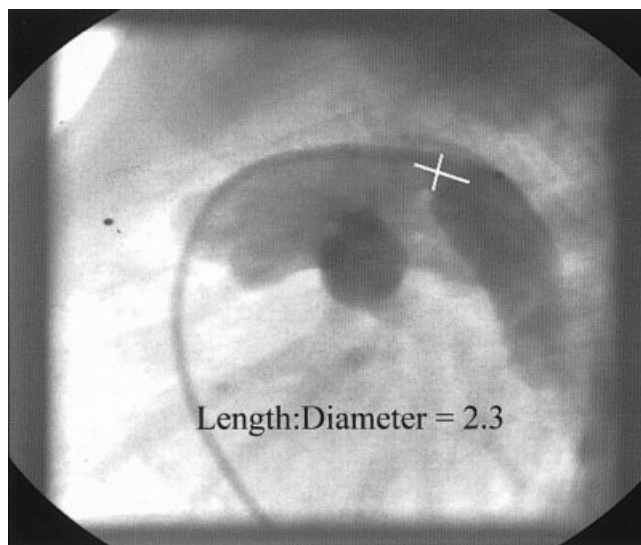

Fig. 1.   Lateral view of a PDA depicting the measurements of the length and narrowest diameter.

performed. All patients received 50–100 units/kg of heparin during the procedure and 25 mg/kg of IV cefazolin following placement of the coil within the ductus. Following the procedure, 36 out of 38 patients were transferred back to the floor for 23-hr observation. Two patients, both ventilator-dependent, were transferred back to the intensive care unit where they were successfully extubated the following day.

Hemodynamic data, including systolic, diastolic, and mean pulmonary arterial pressures, were obtained before coil embolization. Angiographic data collected included minimal ductal diameter and length-to-diameter ratio (L/D), defined as the length divided by the narrowest diameter of the ductus arteriosus (Fig. 1).

Echocardiograms were performed in 27 out of 38 patients within 24 hr following the occlusion procedure and at varying intervals thereafter. In the remaining 11 patients, a postcatheterization echocardiogram was not obtained, with the first follow-up echocardiogram being obtained 6 months postocclusion. Data collected included the presence and severity of left pulmonary artery (LPA) or aortic obstruction and the presence of a persistent shunt. LPA stenosis/obstruction was considered trivial if the peak velocity was less than 2.2 m/sec, and mild if greater than 2.3 m/sec.

Follow-up clinical information included the presence of a murmur and a femoral arterial pulse. A persistent shunt on echocardiogram was considered significant if it was accompanied by a murmur and trivial in the absence of a murmur (silent PDA).

The procedure was considered successful if proper positioning of the coil was obtained, no left pulmonary

TABLE I. Demographic Data of Successful vs. Unsuccessful*

	Successful	Unsuccessful	Significance
Age (months)	8.88 ± 3.93	8.49 ± 5.71	NS
Weight (kg)	6.60 ± 1.28	5.96 ± 1.59	NS

Age and weight of successful versus unsuccessful groups undergoing attempted coil embolization of their PDA. No significant difference was observed between the two groups.

artery or aortic obstruction occurred, no more than a trivial (silent) shunt was documented immediately after occlusion, and no interventions were required following coil occlusion of the PDA. The procedure was considered unsuccessful if occlusion was not attempted due to the size/shape of the PDA, proper positioning of the coil was not attained, an audible shunt was documented immediately following occlusion, and/or an intervention was required following occlusion of the PDA.

Statistical Analysis

Outcome was dichotomized as a factor variable (unsuccessful coil or successful coil) and compared against several continuously scaled dependent variables. Differences in mean values were considered statistically significant at a P value < 0.05 (two-tailed). If the continuous variable was significantly different between successful and unsuccessful outcomes, a break point was noted in the raw data, with the continuous variables further dichotomized and compared with successful vs. unsuccessful outcomes with chi-square analysis. Logistical regression was performed on the most predictive variables, with odds ratios being calculated. The variables entered were patient weight, ductus arteriosus length, diameter, L/D ratio, and systolic, diastolic, and mean pulmonary artery pressure.

RESULTS

Thirty-one out of 42 (74%) patients taken to the catheterization laboratory underwent successful transcatheter occlusion of their PDA. Of the 11 patients where transcatheter occlusion was unsuccessful, 4 had unsuccessful coil placement, 2 had hemolysis that required repeat coil embolization 2 and 5 days later, respectively, 1 patient had a mild residual shunt following placement of five coils, and in 4 patients no attempt was made to occlude the PDA due to its large size. There was no difference between age or weight between successful and unsuccessful outcomes (Table I).

Using the classification by Krinchenko et al. [9], 24 patients had a type A ductus, 3 had type B ductal anatomy, 7 had type C anatomy, 1 had type D anatomy, and 7 had type E ductal anatomy. Two patients' ductal anatomy changed during the procedure, one from a type E to
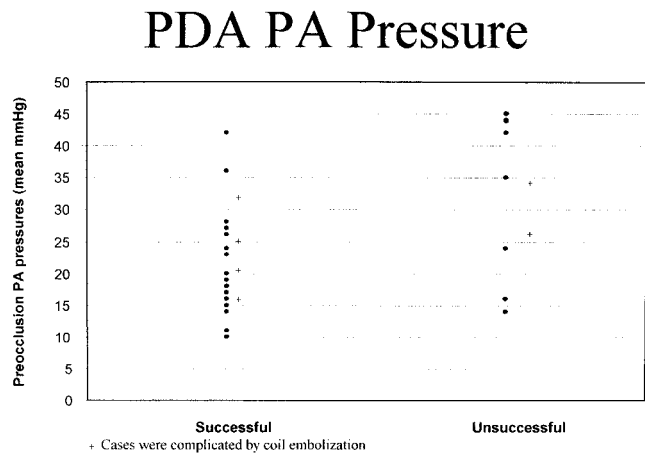
PDA PA Pressure

Fig. 2. Histogram depicting successes and failures on the x-axis and the mean pulmonary artery precoil occlusion pressures on the y-axis. The majority of successful procedures occurred at pulmonary artery mean pressures < 30 mm Hg. The cases marked by plus signs were cases complicated by coil embolization.

a type C, another from a type B to a type D. The median ductal length was 8.3 mm (range, 3.8–15.6), and the median narrowest ductal diameter was 2.4 mm (range, 1.3–4.5). The group's overall median L/D ratio was 3.5 (range, 1.4–12).

Hemodynamic Predictors of Success

Complete hemodynamic data were obtained in 39 of 42 patients prior to undergoing attempted PDA occlusion. In comparing successful versus unsuccessful outcomes, the preocclusion systolic (27.5 ± 11 vs. 46.8 ± 17.1 mm Hg), diastolic (14.5 ± 5.7 vs. 23.3 ± 9.7 mm Hg), and mean (20.1 ± 7.8 vs. 34.3 ± 12.9 mm Hg) pulmonary arterial pressures were significantly lower in the successful group ($P < 0.002$). Of these measurements, the mean pulmonary arterial pressure was the strongest predictor of successful outcome ($P < 0.001$). Five out of seven patients with a mean PA pressure > 35 mm Hg had unsuccessful coil occlusion of their PDA (Fig. 2).

Angiographic Predictors of Successful Outcome

Length/diameter ratio. Twenty-nine out of 42 infants had an L/D ratio > 3. Of these, 26 (90%) had successful occlusion of their PDA. Thirteen out of 42 patients had an L/D ratio ≤ 3. Of these, five (38%) underwent successful occlusion, two having the complication of coil embolization occur (Fig. 3). The mean L/D ratio for unsuccessful outcome (2.8 ± 0.95) was significantly less in comparison to the successful group (4.4 ± 2.0; $P < 0.01$). Eight of 11 patients with unsuccessful occlusion of their PDA had L/D ratios < 3.0.
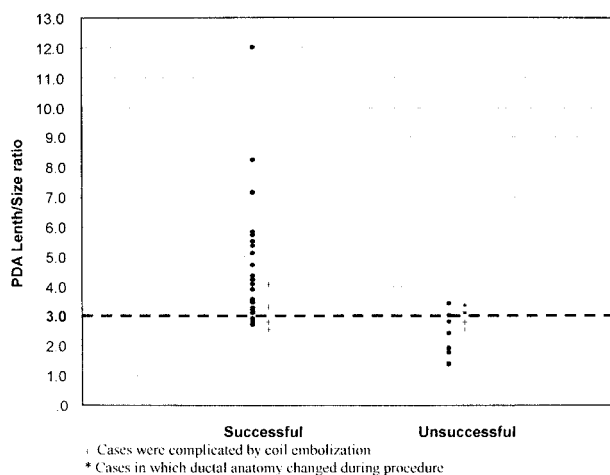
PDA Length/Diameter Ratio

Fig. 3. Histogram depicting successes and failures on the x-axis and the length/diameter ratio on the y-axis. As depicted, the majority of failures and complications occurred in patients with an L/D ratio of ≤ 3.0. Two patients represented by asterisks had ductal morphology that changed during the procedure. Patients represented by plus signs had coil embolization as a complication.
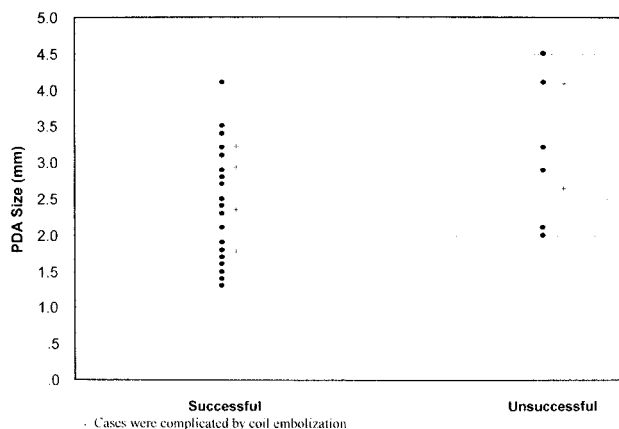
PDA Size (mm)

Fig. 4. Histogram depicting successes and failures on the x-axis and PDA size in the y-axis. Cases marked by plus signs had coil embolization as a complication.

Two patients (marked by asterisks in Fig. 3) with L/D ratios > 3.0 in whom successful occlusion was not achieved were noted to have ductal morphology that changed during the procedure. The ductal morphology of the patient with an initial L/D ratio of 3.4 changed from a type D to a shorter type B ductus, and the morphology of the patient with an initial L/D ratio of 3.0 changed from a type E to a tubular type C ductus.

Narrowest dimension. The unsuccessful group's narrowest dimension (3.3 ± 1.0 mm) was significantly larger than the successful group (2.3 ± 0.7 mm; $P < 0.01$; Fig. 4).

Echocardiographic Follow-Up

Early echocardiographic follow-up was obtained in 25 patients undergoing successful embolization of their PDA (median, 0.75 days; range, 0.5–1 day). Of those, 16 patients (64%) had complete occlusion and 9 (36%) demonstrated a persistent shunt. Intermediate follow-up evaluation was obtained in 20 patients at a median time of 10 months (range, 2–62). No residual shunt was noted in 15 patients. Three patients demonstrated a mild shunt and two had a trivial shunt. Two patients who had no residual shunt immediately following coil occlusion had developed a trivial and mild shunt upon examination 6 months later. Of the 10 patients who had early echocardiographic evidence of a trivial shunt, 7 showed no evidence of a residual shunt at intermediate follow-up, 1

had a persistent trivial shunt, and 2 developed a mild shunt. Three of four patients who developed worsening of their shunt at follow-up had L/D ratios < 3.0 (2.6, 2.7, and 2.9).

Complications

No mortality was observed. Transient loss (< 24 hr) of femoral arterial pulse was observed in 6/42 patients (14%). Heparin therapy was required in two patients. No patient experienced permanent loss of femoral arterial pulse. A total of seven coils embolized in six patients. In two, the coil was retrieved from the right pulmonary artery; in four, the coils were retrieved from the LPA. In four patients, the PDA was successfully occluded. Mild LPA stenosis was observed in two patients who required three and four coils, respectively, to occlude the PDA completely. One patient had persistent echocardiographic evidence of mild LPA stenosis at his 43-month follow-up, with the second patient not having been seen for follow-up. No aortic obstruction was observed. Two patients developed hemolysis 2 days after having three coils and one coil placed, respectively. Both patients were subsequently taken back to the catheterization laboratory where two and three more coils were placed with hemolysis resolving.

DISCUSSION

Transcatheter occlusion of a PDA was first performed in 1969 using the Portsmann ductal occluder device [10]. In 1979, Rashkind [11] developed a device that had greater appeal and was more successful in closing PDAs. The large size of the delivery systems necessary for these

devices, the relatively frequent incidence of residual shunting following placement, and the relatively high cost [12,13] led to an alternative technique for transcatheter closure of the PDA using stainless steel coils [1]. In 1993, Lloyd et al. [2] reported the use of Gianturco coils in patients with larger ductus diameters. PDA occlusion procedures using coils offer a simpler and less expensive alternative than procedures performed with earlier devices. Due to these factors, transcatheter coil occlusion of PDAs has gained considerable favor over the past decade and is the most frequently performed transcatheter procedure for occlusion of small- to moderate-sized PDAs and has been seen as an acceptable alternative to surgery (7).

Selection of patients suitable for transcatheter closure of a PDA using GCs or FCs has been primarily limited to larger patients (> 10 kg). Few reports have been written regarding the use of current transcatheter PDA occlusion techniques in small infants. This procedure can be technically more difficult in this group for two reasons. First, these patients often have larger PDAs relative to their overall size, which may lead to increased risk of complications or failures in attempting to perform PDA coil occlusion. Second, infants requiring early closure of a PDA often have symptoms of congestive heart failure, pulmonary overcirculation, and/or failure to thrive—the indication(s) for early intervention. Older patients are more often asymptomatic and are primarily brought to the cardiac catheterization laboratory for PDA occlusion to eliminate their risk of bacterial endocarditis. Hijazi et al. [8], in a multi-institutional study, reported successful closure of 20 out of 24 infants weighing less than 8 kg. Their study predominantly concentrated on comparing transarterial (retrograde) versus transvenous (prograde) approaches for PDA coil occlusion. They did not evaluate predictive factors for success or failure. Others have alluded to the fact that shorter ductal length [3], larger ductal diameter [14], and a decreased L/D ratio [15] may make a ductus less amenable to transcatheter occlusion using standard GCs in older patients. It would be helpful to know hemodynamic and/or anatomic predictors for successful outcome and complications in small infants undergoing PDA occlusion.

In our experience, an L/D ratio equal to or greater than 3.0 was the best angiographic predictor for successful outcome. Regarding hemodynamic predictors of success, precoil embolization mean pulmonary artery pressure was the best predictor of successful outcome. There were no significant differences between successful versus unsuccessful groups regarding age, weight, or technique used to deliver the coils.

There appeared to be a relationship between an L/D ratio < 3.0 and a persistence of the left-to-right shunt at intermediate follow-up. This finding is consistent with the report from Daniels et al. [15]. In their study of 25 older patients undergoing attempted transcatheter coil occlusion of a PDA, 4 out of 7 (57%) with an L/D ratio less than or equal to 3.0 had evidence of residual left-to-right shunting, whereas only 2 out of 16 (12.5%) with an L/D ratio > 3.0 had a residual shunt at intermediate follow-up. This is further supported by Moore's findings that the type B ductus was associated with the development or persistence of a residual shunt at intermediate follow-up [3].

In evaluating complications that occurred in our study, we specifically addressed coil embolization, LPA and/or aortic obstruction, hemolysis, and loss of femoral pulse. In our study, coil embolization occurred in six patients. These patients had smaller L/D ratios, with 4/6 having L/D ratios < 3.0. Daniels et al. [15] reported a similar risk of embolization in older patients. Hijazi et al. [8] reported coil embolization as a complication in 7 out of 24 infants. There have been numerous reports describing various delivery techniques allowing for controlled delivery of standard 0.038″ and 0.052″ GCs in the United States [16,17]. The addition of the retrievable FCs will likely play a larger role in PDA closure in this subgroup of patients. Finally, the recent approval of the Amplatzer PDA device (AGA, Golden Valley, MN) may also have a role in closure of PDAs in infants over 5 kg [18]. Though we feel coil embolization is a safe procedure, we had two patients whose L/D ratios were 2.3 and 2.7, respectively, suffer hemolysis shortly after the procedure. Both patients underwent repeat cardiac catheterization with complete occlusion being achieved with concurrent resolution of hemolysis. No patient suffered permanent loss of the arterial pulse in either our study or that of Hijazi et al. [8]. Two patients developed mild LPA stenosis, which in one patient persisted at 43-month follow-up. Hijazi and Geggel [14] also noted LPA stenosis in two infants where multiple coils were required (five coils each) for successful PDA closure. They felt that larger coils might be the cause of LPA obstruction, though use of multiple coils may also play a role in encountering this complication.

Transcatheter coil occlusion of PDAs in infants less than 8 kg can be performed safely and with minimal morbidity. In our experience, an L/D ratio more than 3.0 was associated with a greater likelihood of success and decreased incidence of encountering complications or the development of a residual shunt. We recommend the use of a controlled-release technique in patients with L/D ratios less than 3.0 in order to improve proper coil positioning and decrease the likelihood of coil embolization. The Amplatzer PDA device, which has been recently approved, may also be of use in this particular subset of patients.

Study Limitations

Data for this study were collected during a period of time that includes learning curves for four interventional cardiologists. Furthermore, many of the procedures were performed prior to the development and use of more controlled delivery techniques. Four patients were taken to the catheterization laboratory early in our experience for transcatheter coil occlusion of their PDA; however, no attempts were made to occlude the PDA once the patients were in the laboratory due to the large size of the PDA. It is possible that with more current delivery techniques, which provide the interventionalist more control during delivery of the coil(s), coil occlusion may have been attempted in these patients. The limited number of patients enrolled in our study could have introduced certain biases in our results.

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