Transcatheter Occlusion of Patent Ductus Arteriosus With Gianturco Coils

Thomas R. Lloyd, MD; Raymond Fedderly, MD; Alan M. Mendelsohn, MD; Satinder K. Sandhu, MBBS; Robert H. Beekman III, MD

Background. Transcatheter occlusion with Gianturco coils has been attempted in a small number of patients with tiny (≤1.5-mm diameter) patent ductus arteriosus, and preliminary results have been encouraging. The present study extends this method to larger ductus sizes and makes recommendations for proper coil size selection.

Methods and Results. Coil occlusion was attempted in 24 consecutive patients with patent ductus arteriosus who did not require other cardiac surgery. Median patient age was 4.2 years (8 months to 30 years), and mean ductus diameter was 1.7±0.8 mm. Two instances of coil embolization occurred in the first 4 patients, with successful coil retrieval. Based on this experience, we proposed that the coil helical diameter should be twice or more the minimum ductus diameter, with coil length sufficient for three or more loops. With these recommendations, coils were successfully implanted in the subsequent 20 consecutive patients. Of the 22 patients with successful coil implantation, 15 (68%) had no residual shunting, and 7 had trace residual shunting by angiography. The continuous murmur was abolished in all 22 patients. No significant complications occurred, and all patients were discharged within 24 hours of successful coil implantation. No change in the systolic pressure gradient between main and left pulmonary artery or ascending and descending aorta was observed.

Conclusions. Transcatheter occlusion of patent ductus arteriosus can be safely and effectively achieved in patients with ductus diameters up to 3.3 mm. Coil occlusion does not cause obstruction to flow in the left pulmonary artery or descending aorta. Coils should be selected to provide a helical diameter twice or more the minimum ductus diameter and a length sufficient for three or more loops. (Circulation. 1993;88[part 1]:1412-1420.)

KEY WORDS • Brief Communications • occlusions • patent ductus arteriosus

Transcatheter occlusion of the persistently patent ductus arteriosus has been performed with a number of investigational, purpose-designed devices.1-3 A technique for occluding the very small ductus arteriosus with Gianturco embolization coils has been described recently, with successful occlusion in 3 of the 4 patients reported.4 We report our experience with this technique of transcatheter ductal occlusion in 24 patients, including the use of larger coils and occlusion in patients with larger ductus diameters than previously reported.

Methods

Patients

All patients over the age of 6 months who presented to the authors' institutions between April 1992 and April 1993 with persistently patent ductus arteriosus were potentially eligible for transcatheter occlusion. Patients were excluded if they had other cardiovascular defects requiring surgery or if they had pulmonary artery hypertension of sufficient severity to contraindi- cat surgical ductus closure. Patients were not excluded on the basis of ductus morphology. Informed consent was obtained from adult patients or from the parents of younger patients. Procedures were performed at University Medical Center, Tucson, Ariz, between April 1992 and June 1992 (n=3) and at C.S. Mott Children's Hospital, Ann Arbor, Mich, thereafter (n=21).

Procedure

Complete right- and left-heart catheterization was performed using the percutaneous, transfemoral route. Minimum diameter of the ductus arteriosus was determined from the aortic cineangiogram. The ductus arteriosus was then crossed from the aortic side using a 5F Judkins right coronary artery catheter (Baxter Healthcare, Irvine, Calif). Catheters with 3.5-cm curves were used for patients who weighed <40 kg, and catheters with 4.0-cm curves were used in larger patients. Catheter tip position within the pulmonary artery was confirmed by fluoroscopy, oximetry, and pressure monitoring. The method of coil occlusion is illustrated in Fig 1. The Gianturco coil, selected as described below, was inserted into the coronary catheter and advanced with a 0.038-in. Newton wire (Cook Inc, Bloomington, Ind) or a movable core wire (Argon, Athens, Tex) to the tip of the catheter. Under lateral fluoroscopic monitoring, a length of coil sufficient to produce 2/3-1 loop was
advanced into the pulmonary artery. The coronary catheter and coil were then withdrawn until the extruded loop of coil reached the pulmonary arterial orifice of the ductus arteriosus. This position was achieved when the extruded loop began to straighten or when the extruded loop failed to continue moving with the coronary catheter. At this point the coronary catheter was carefully withdrawn into the descending aorta. If necessary, the wire guide was simultaneously advanced to avoid any further withdrawal of the first extruded loop from the pulmonary artery. The remainder of the coil, having been extruded from the catheter in the descending aorta, forms into loops at the aortic orifice of the ductus arteriosus, often lying within the ductal ampulla. Right- and left-heart catheterization was repeated, as was aortic cineangiography. Cephalothin was administered intravenously before insertion of the occluding coil, and cephalaxin was administered orally for 24 hours following the procedure. Patients with allergies to cephalosporins received other anti-staphylococcal antibiotics. Endocarditis precautions are discontinued 6 months after successful ductus occlusion.

**Coil Selection**

Gianturco coils of 0.038-in. wire diameter (Cook Inc, Bloomington, Ind) were used in all patients. Based on our experience with the first 4 patients, we developed the following criteria for coil selection, which were applied to the subsequent 20 patients: The helical diameter of the coil was 5 mm or 8 mm and was at least twice the minimum diameter of the ductus as determined by angiography. The length of the coil was sufficient to produce at least three loops, allowing one loop at the pulmonary artery end of the ductus and at least two loops at the aortic end. When the ductus arteriosus was elongated or complex or when difficulty in implanting the coil or in seating it within the ductal ampulla was anticipated, we have selected longer coils to provide more than three loops. The 5-mm helical diameter coils of 5 cm length and 8-mm helical diameter coils of 8 cm length produce approximately three loops, 8-mm helical diameter coils of 10 cm length produce approximately four loops, and 5-mm helical diameter coils of 8 cm length produce approximately five loops.

**Statistical Analysis**

Procedural success was defined as implantation of a coil into the ductus arteriosus that remained in place at the time of hospital discharge. Clinical success was defined as absence of the continuous murmur. Angiographic success was defined as absence of residual ductal shunting in the postocclusion aortic cineangiogram. Aortic cineangiograms obtained prior to coil occlusion were reviewed to determine the angiographic classification of the ductus as described by Krichenko and coworkers. Aortic cineangiograms that densely filled the aortic isthmus were reviewed to characterize ductal shunting before and after coil occlusion according to the following angiographic scale (Fig 2): Trace residual shunts opacified a portion of the pulmonary artery bifurcation and did not opacify the main or branch pulmonary arteries; small shunts partially opacified the main pulmonary artery in diastole; moderate shunts densely opacified the main pulmonary artery with some degree of opacification of the branch pulmo-

nary arteries during diastole, and usually produced a distinct levophase; and large shunts densely opacified the branch pulmonary arteries to an extent similar to the aorta. Shunts were also considered large if the pulmonary artery systolic pressure was ≥50 mm Hg or if clinical evidence of congestive heart failure was present. Shunt sizes before and after coil occlusion were compared using the Wilcoxon sign-rank test. Continuous variables are reported as mean±SD, except for patient age and weight, which exhibited a skewed distribution and are therefore reported as median and range. Systolic pressure gradients between left pulmonary artery and main pulmonary artery and between aortic arch and descending aorta measured before and after coil implantation were compared by repeated-measures ANOVA. We selected P<.05 to indicate a significant difference.

**Results**

**Study Population**

Coil occlusion of patent ductus arteriosus was attempted in 24 patients (Table), ranging in age from 11 months to 30 years (median, 4.2 years) and in weight from 7.5 to 94.5 kg (median, 15.9 kg). All patients exhibited typical continuous murmurs. Concomitant cardiovascular conditions included mild aortic stenosis in 1 patient, mild pulmonary stenosis in 1 patient, moderate aortic stenosis with mitral regurgitation in 1 patient, and congenital complete heart block with cardiomyopathy and moderate pulmonary hypertension (pulmonary artery pressure 72/15) in 1 patient. Two patients had a residual patent ductus arteriosus following surgical ligation, and 1 patient had undergone prior balloon pulmonary valvuloplasty. Balloon aortic valvuloplasty was performed immediately prior to coil occlusion of the ductus arteriosus in 1 patient. Minimal ductal diameter ranged from 0.5 to 4.0 mm (mean, 1.7±0.8 mm), and angiographic classification of the ductus arteriosus included 15 patients with type A, 1 with type B, 2 with type C, 3 with type D, and 3 with type E. Pulmonary artery systolic pressure ranged from 16 to 72 mm Hg (mean, 24.3±11.4 mm Hg). General anesthesia was used for 18 procedures, and 6 were performed using local anesthesia and sedation.

During this same 12-month period, transcatheter occlusion was not attempted in 12 eligible patients whose cardiologists referred them for surgical rather than transcatheter closure or whose parents refused transcatheter occlusion. These patients ranged in age from 8 months to 7 years (median, 3 years), and Doppler echocardiography predicted a substantial (40 to 87 mm Hg; median, 60 mm Hg) peak instantaneous pressure gradient across the ductus arteriosus in all 12 patients. Patient age and peak Doppler gradient were not statistically different between these patients and those who underwent transcatheter coil occlusion.

**Complications and Procedure Variations**

Migration of the Gianturco coils from the ductus arteriosus after delivery occurred in 2 patients. In the second patient of our series, a 5-cm-long, 5-mm helical diameter coil was placed in a patent ductus arteriosus of 4.0-mm minimum diameter. Angiography and right-heart catheterization after occlusion revealed a trace
residual shunt (Fig 3). The patient began coughing and developed cyanosis responsive to supplemental oxygen 15 minutes after occlusion. Fluoroscopy confirmed migration of the coil to the right pulmonary artery. Retrieval forceps were used to remove the coil from the pulmonary artery and deliver it to the femoral vein, where it was retrieved by a cutdown procedure. In the fourth patient of the series, a 5-cm-long, 8-mm helical diameter coil, delivered to a 1.3-mm minimum diameter, type E ductus, embolized to the left pulmonary artery immediately on release. The length of the coil selected was sufficient for no more than one loop on the aortic side of the ductus, and the length and diameter of the ductus prevented that loop from forming as anticipated, allowing the coil to escape through the ductus arteriosus. This coil was retrieved percutaneously with a basket retrieval device (Medi-tech, Watertown, Mass). Surgical closure of the ductus arteriosus was subsequently performed in both patients. No coil has embolized to the aorta. No instances of coil migration have been observed in the 22 patients whose coil size conformed to the above criteria.

In 1 patient with previous ductus ligation, the small residual ductus required dilation with the dilator of a 6F transseptal sheath to allow a 5.5F Cobra catheter to cross the ductus and deliver the coil. In 3 patients, initial coil loops were inadvertently pulled through the ductus as the catheters were withdrawn into the aorta but before the coils had been completely extruded from the catheters. In each instance, the catheter and coil were easily withdrawn through the arterial sheath, and subsequent coil occlusion of the ductus was accomplished. In 1 patient, a coil of 5-mm helical diameter and 8-cm length was thought to protrude too far into the descending aorta after implantation and was removed with a wire snare. A shorter (5-cm) coil was then implanted, with excellent results (Fig 1).

No patient required a blood transfusion. Diminished lower extremity pulse was observed only in the 11-month-old patient who underwent balloon aortic valvuloplasty immediately prior to coil occlusion of the patent ductus arteriosus. No clinically evident instances of hemolysis have occurred, and there have been no infections of the coils or catheter entry sites. All patients were discharged from hospital within 24 hours of successful coil implantation.

Oclusion Results

Procedural success was achieved in 22 of 24 patients (92%), including the last 20 consecutive patients (the other 2 patients, with coil migration to the pulmonary artery, are described above). Coil migration was not observed in any of these 22 patients at hospital discharge or in follow-up. No patient had a residual continuous murmur at the time of discharge, although most patients had vibratory precordial murmurs. Therefore, clinical success was achieved in 22 of 24 patients in whom procedural success was achieved. Oximetry failed to detect residual shunting in any patient after successful coil placement. In the 22 patients with procedural success, the angiographic grade of ductal shunting was significantly reduced (P<.0001). Prior to occlusion 5 patients had small and 17 had moderate shunts; postocclusion angiograms showed trace residual shunts in 7 patients and no residual shunt in 15 patients (angiographic success in 68%, Fig 4).

No patient developed a significant pressure gradient from main to left pulmonary artery or from ascending to descending aorta following coil occlusion of the ductus arteriosus. The peak systolic gradients before and after coil implantation were 2.5±4.1 mm Hg and 1.8±2.0 mm Hg between the main and left pulmonary artery (P=.92) and −0.7±3.4 mm Hg and −1.6±3.3 mm Hg between ascending and descending aorta (P=.29). Radiation time ranged from 5.0 to 55.6 minutes, with a median of 19.9 minutes. Three of the longest procedures were those involving coil retrieval from the pulmonary artery and ductus dilation in a residual postoperative ductus (46.4 to 55.6 minutes).

Discussion

We have achieved clinically successful occlusion of persistently patent ductus arteriosus in 22 of 24 patients, with 7 trace residual shunts at the time of occlusion. We have also demonstrated that the coil occlusion technique does not cause measurable obstruction to the aorta or the left pulmonary artery, as a larger device might. Occurrence of residual shunting was not significantly related to minimum ductus diameter (1.8±0.8 mm versus 1.5±0.7 mm in those with no residual shunt, P=.29) or to any apparent “learning curve” (trace residual shunts occurred in 3 of the first 11 cases versus 4 of the last 11 cases). Proposed methods to reduce residual shunting after ductus occlusion with the Rashkind PDA Occluder have included soaking the device in thrombin before implantation and balloon occlusion of the ductal orifice after implantation. We have not attempted either method with the coil occlusion technique and therefore have no data concerning potential efficacy. We are reluctant to use balloon occlusion because of the potential risk of dislodging the coil, but thrombin pretreatment of the coils might be of some help. Although our follow-up is limited, color flow Doppler has demonstrated spontaneous resolution of trace residual shunts from 3 weeks to 6 months after coil
implantation. If clinically significant (ie, audible) residual shunting were to persist beyond 6 months after coil implantation, we speculate that additional coils could be used to complete the ductus occlusion.

We believe that clinical success is the most important outcome because, as Latson7 and Hosking et al8 have pointed out, no cases of endarteritis have been reported in patients with a Doppler-detected, clinically silent patent ductus arteriosus. Tiny, silent ductus shunts have been reported in 0.5% of children with innocent murmurs9 and appear to have a benign clinical course. The “natural history” of silent residual ductal shunts in patients with ductal occlusion devices is unknown. Our results with coil occlusion are comparable to other closure techniques. We identified small, clinically silent residual shunts in 32% of patients, similar to the 53% prevalence of residual shunts at 1 day and 38% at 1 year after occlusion with the Rashkind PDA Occluder System.8 Furthermore, contemporary diagnostic techniques have demonstrated residual shunting after surgical ductus ligation in 18% to 23% of patients.10,11

As originally described,9 the coil technique for occlusion of patent ductus arteriosus was suitable only for the very small ductus; the previous report of this technique notes success in 5 patients with ductus diameters from 1.2 to 1.5 mm using coils of 3-mm helical diameter and 4-cm length.12 Coil embolization to the pulmonary artery occurred in a patient whose ductus diameter was 2.5 mm.9 By using larger coils of 5-mm and 8-mm helical diameter and of sufficient length to ensure three loops or more, we have been able to extend this procedure to

### Patients in Whom Coil Occlusion of Patent Ductus Arteriosus Was Attempted

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*N indicates no shunt; T, trace shunt; S, small shunt; M, moderate shunt; L, large shunt; and E, coil embolized to pulmonary artery.

"Before" and "after" refer to shunt size before and after attempted coil embolization of the patent ductus arteriosus.
patients with minimum ductus diameters up to 3.3 mm. Our 2 cases of technical failure occurred early in our experience (within the first 4 cases) and appeared related to use of coils of inadequate size. In the first instance, too small a coil was chosen (5-mm helical diameter, 4-mm minimum ductus diameter, Fig 3), and in the second, too short a coil was chosen (8-mm helical diameter, 5-cm length, two nominal loops). These experiences led us to choose 8-mm diameter coils for minimum ductus diameters $\leq$ 2.5 mm and 5-mm diameter coils for smaller ductus diameters. The experience of Moore and coworkers suggests that 3-mm diameter coils may be adequate for ductus diameters $\leq$ 1.5 mm.

Gianturco coil occlusion of patent ductus arteriosus is limited primarily by ductus size. No ductus arteriosus larger than 3.3-mm minimum diameter has been successfully occluded, although none has been attempted with 8-mm coils. Patient size is a less important issue, because the delivery catheter is small (5F), the catheter course is relatively straight, and the device is flexible. Coronary catheters suitable for delivering Gianturco coils have been described that are only 4F, which would further extend the applicability of this technique to smaller patients. The Rashkind PDA Occluder requires an 8F sheath for transvenous occlusion of patent ductus arteriosus in patients similar to ours (ie, with ductus diameters less than 4 mm, in whom 12-mm Rashkind devices would be used), and the device presents some difficulties traversing the right heart in smaller patients. The buttoned device for ductus occlusion is somewhat more flexible and is designed to be suitable for a wide range of ductus sizes but requires a 7F delivery sheath. Neither of these investigational devices is widely available, in contrast to Gianturco coils, which are in widespread use. Furthermore, interventional pediatric cardiologists and radiologists are familiar with the use of Gianturco coils for occlusion of other aortopulmonary communications, although the technique for ductus occlusion differs as described above. An important advantage of the coil technique is the ease with which the coils can be removed if the coil position is unsatisfactory. A final advantage of the Gianturco coil over the investigational devices for ductus closure is cost. A package of coils, a 5F coronary catheter, and an appropriate guide wire can be purchased for less than $60. Based on our experience, the coil technique appears to be suitable for the majority of patients requiring elective closure of the persistently patent ductus arteriosus.

**Conclusions**

Our experience indicates that patent ductus arteriosus can be occluded using Gianturco coils. Successful
ductus occlusion has been accomplished with minimum ductus diameters of up to 3.3 mm, more than twice the previously reported ductus size to which this technique has been applied. Coil occlusion of the ductus does not cause obstruction to normal flow at the pulmonary artery or aortic ends of the ductus. We recommend using coils with helical diameters at least twice the minimum ductus diameter and of sufficient length to produce three to five loops (one on the pulmonary arterial end and two to four on the aortic end of the ductus). Larger numbers of treated patients and longer follow-up will be necessary to more precisely define the efficacy, safety, and most appropriate indications for this procedure. Issues of cost effectiveness should also be addressed in further studies.

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