Transcatheter Occlusion of PDA by Detachable Coil Occluder and Amplatzer Device

Mahmood Meraji, MD; Noor Mohammad Noori, MD; Semira Mehralizadeh, MD and Yousof Aarabi, MD

Abstract

Background- The aim of this study was to report the results of using PDA occluders (coil occluder and Amplatzer device), which has continued since December 1999 at the pediatric department of Rajaee Heart Center.

Methods- Between December 1999 and September 2002, 193 cases of PDA were admitted at the pediatric ward. Seventy cases underwent transcatheter occlusion of PDA by the detachable coil occluder, and in 53 cases PDA was occluded by the Amplatzer device.

Results- Successful coil placement was accomplished in 68 cases. Two cases of intravascular hemolysis were observed due to residual shunt .In one of them, acute tubular necrosis ensued, and peritoneal dialysis was performed. However, after surgical PDA closure, the renal performance

was recovered eventually. Also, two cases of coil detachment to the LPA were observed with no long-term sequala on pulmonary function. Fifty-two of the 53 Amplatzer occlusions were successful. Only one failure was observed due to the small size of the Amplatzer in comparison to the duct diameter.

Conclusion- Retrograde and antegrade transcatheter closure of the PDA by the detachable coil occluder and Amplatzer device has been performed successfully in our department. The problem that we face has been PDA sizing and also the retrieval of detached coils ***(Iranian Heart Journal 2005; 6 (1,2): 43-47).***

Key words-Patent ductus arteriosus ■ transcatheter occlusion ■coil occluder ■ Amplatzer device

Patent ductus arteriosus (PDA) is one of the most common congenital heart defects.[1] In the USA the incidence of PDA in children born at term is between 0.002% and 0.006% of live births. The incidence increases in children born prematurely, children with a history of perinatal asphyxia and possibly, children born at high altitudes. A large number of surgical and transcatheter techniques for the interruption or closure of PDA have been reported as a safe alternative to surgery.[2] The earliest report of catheter closure was in 1966. Since then, many devices have been used to achieve closure.

From the Department of Pediatric Cardiology, Shaheed Rajai Cardiovascular Medical Center, Valiasr Ave., Tehran, Iran.
Correspondance to: M. Meraji, MD, Department of Pediatric Cardiology, Shaheed Rajaie Cardiovascular Medical Center, Valiasr Ave., Tehran, Iran. Phone: +9821-23922509, +9821-23922510 Fax: +9821-22055594, +9821-22048174

The different types of devices used include the buttoned device, the botalloccluder device, the Gianturco Grifka Vascular Occlusion Device (GGVOD), the amplatzer duct occluder and the Gianturco coils[3] For small PDAs, the coil is the choice number one; however; for moderate to large PDAs, the Amplatzer device is the first choice.[4,5] There has been a high rate of embolization of the coil to the peripheral pulmonary arteries, which is not release controlled.

Recently, this problem has been resolved with controlled –release Jackson coils, and they have become widely used by pediatric cardiology centers.[6,7] In this study, the immediate and short term outcomes of transcatheter closure of PDA by the detachable coil occluder and the Amplatzer duct occluder device are assessed.

Methods

Between December 1999 and September 2002, 193 cases of PDA were admitted to the pediatric ward, and 123 patients underwent percutaneous PDA closure at Shaheed Rajaee Heart Center. The inclusion criteria for the coil occluder device were small PDAs with a diameter of equal or less than 2 mm at angiography and a body weight of more than ten kilograms. The inclusion criteria for the Amplatzer device were clinical and echocardiographic features of moderate to large PDAs with an internal diameter of more than 4 mm. Occlusion was achieved via the anterograde arterial and venous approach. Follow-up valuations were performed by 2D-Echocardiogram, color flow mapping and Doppler measurement of the descending aorta and left pulmonary artery velocity at 24 hours and 1, 3, 6 and 12 months after implantation. Seventy cases (47 female and 23 male) underwent transcatheter occlusion of PDA by the detachable coil occluder. In 53 patients (38 female and 15 male) PDA was occluded by the

Results

Of 70 procedures of PDA occlusion by the coil occluder device, 66 were completely successful (94%). Pulmonary–systemic flow ratio (QP/QS) was 1.15-1.5 (mean1.3). The smallest internal dimension ranged from 1.5 mm to 4 mm (average 2.4 mm). Thirty patients had PDA closure with the smallest available coil (IMWC-3-PDA-4). Twenty-four had closure with the midsize coil (IMWC-5-PDA-4 or 5-PDA-5). Sixteen patients received large-sized PDA coils (IMWC-6.5-PDA-4). Five patients received two or three coils, and the other PDAs were occluded with one coil.

We experienced two cases of intravascular hemolysis 12 hours after the procedure due to residual shunt. In one of these cases, acute tubular necrosis ensued, and peritoneal dialysis was performed. Fortunately, the hemolysis was relieved after the complete surgical closure of the residual PDA, and renal performance returned to normal eventually. We also experienced two cases of coil detachment into the LPA that could not be retrieved, but at follow-up no pulmonary residual problem was observed. Complete closure was accomplished by ortography 10-15 minutes after the procedure in at least 51 patients, and color flow imaging study 24 ours after the procedure showed no residual leak in 9 patients in whom post

implantation angiogram had shown small residual leak. Complete closure was confirmed in 7 after 7 days and in 3 patients up to one month later. Follow-up revealed 2 insignificant residual shunts that had disappeared spontaneously at six months. After one year's follow-up, no patient had persistent residual leak that necessitated surgical or interventional procedure (100% closure). None of the patients underwent additional catheterization. During the study period, 53 PDAs were occluded by the Amplatzer device, and the results were excellent. The mean duct diameter was 4.7 mm. The pulmonary to systemic flow ratio (QP/QS) varied between 1.9-2.2 (mean 2.04). No displacement of the Amplatzer occurred, and there was only one failure due to the small size of the Amplatzer in comparison to the PDA diameter. At the angiography 10-15 minutes after the procedure, 37 patients had no residual shunts.

At 24 hours' follow –up by color flow mapping, only one residual leak was observed, which was relieved at one week's follow–up, and at 6 months' follow-up no residual shunt was observed (Table I).

Table I: Patients and Data

Procedure	**Coil**	**Amplatzer**
Sex	Female (47) Male (23)	Female (38) Male (15)
Age	0.7-17 yr (5.2)	0.7-17 yr (5.6)
Weight	5-45 kg (18 kg)	5-45 kg (18.5 kg)
PDA Diameter	1.5-4 mm (2.4)	2-12 mm (4.7)
Coil and Amplatzer Size	4-8 (5 loop)	4-16 mm (6.6 mm)
Complication	2	1
Residual Shunt	20	0
Unsuccessful	0	1

Discussion

Embolization of the device, residual shunt, stenosis and reversion to surgery are potential risks associated with the closure of PDAs with devices. Over a 33-month period, a total number of 70 percutaneous PDA occlusions were performed. Two major problems were encountered during this period. One was residual shunt and hemolysis as the consequence of the shunt (which was observed in two patients 12 hours after implantation of the detachable coil) and the other was embolization of the coil to the left pulmonary artery (LPA). A study by Jaeggi et al.[8] compared the Cook detachable coil with a preceding series of Rashkind umbrella series. Long term shunt persistence after single coil deployment in moderate sized ducts was as frequent as that with the Rashkind device; and the use of multiple coils was advocated.

Residual leaks are high with the Rashkind device[9], and there is a high risk of embolization with multiple coils.[10] Bulbul et al.[11] demonstrated that the closure of PDA was more complete when using coils compared with the Rashkind device.[12, 13] In a report by Jaeggi et al., a visible residual shunt at post– implant angiography in moderate ducts was associated with a high incidence (59%) of long term echocardiographic shunt patency and a need for repeat interventions for audible residual shunts. (32%) More recently, Wang et al. reported a series of 55 patients who underwent transcatheter PDA closure using Gianturco coils For patients with small PDA (<3mm), the authors reported 100% successful coil deployment, and no distal device embolizations. However, as the PDA size increased, so too did the rate of unsuccessful coil deployment, residual left-to-right shunt and, most importantly, coil embolization (37%) in patients with ductal diameter >4mm)[14].

As seen in our study, the two cases with residual shunts were of moderate PDAs sized 4 mm. Residual leak led to hemolysis, but after PDAs had been ligated surgically and the shunt had been removed, no permanent renal dysfunction was observed at one year's follow-up.

In 1996, Tometzki et al.[15] published a six- center British study. Implantation of the Duct-Occlud device was feasible in 44 of 51 cases with persistent arterial ducts. The minimum diameter of the PDA ranged from 1.0 to 4.3 mm (mean 2.1 mm) The PDA in the remaining 7 patients was judged too large for the device and Rashkind devices used. In 39 patients, coil implantation was performed using the transvenous route. In five patients, the device was deployed from the aorta. Embolization of the Duct-Occlud device occurred in three cases (5.8%). In one patient, the device embolized hours after placement, and a second-procedure was required for removal. In one patient, the device could not be retrieved from a distal branch of the right pulmonary artery, so it was left in place. In another patient, a 3-mm fragment of the device became entangled in the tricuspid apparatus. The patient had another device successfully deployed, and after 12 months' follow-up the fragment remained in situ with no evidence of tricuspid valve regurgitation. In 40 (91%) of the 44 patients in whom the Duct-Occlud device was used, complete occlusion at 24 hours could be demonstrated on color flow Doppler Echocardiography. Another nation-wide multicenter trial of Duct-Occlud was reported by

Oho et al.[16] in 1998. The Duct-Occlud was used in 35 patients aged 0.5to 27.2 years (median 7.6 years). The smallest diameter of PDA was 2.0 0.7 mm (range 1.0 to 3.3 mm). Pulmonary– systemic flow ratio (QP: QS) was 1.3 0.3 (range 1.0 to 2.2). The coils were successfully implanted in 32 (91%) of patients. Of 31 patients who were followed 6 months after the procedure, 26 (84%) had no residual shunt, and five (16%) had a trivial residual shunt. One patient had infective endocarditis 1 month after the procedure but recovered completely. There were no incidences of coil embolization, hemolysis, late coil migration or obstruction of the pulmonary artery or the aorta.

In our study, only two cases of coil detachment to the LPA were observed. Unfortunately, they could not be retrieved because of a lack of suitable devices. But at one year's follow–up, no residual pulmonary problem was encountered.

As it is emphasized by other reports [6,7,10] the selection of the most suitable device (coil occluder versus Amplatzer device) according to the duct diameter is a very important component influencing the result. Lee et al.[17] and Arora et al.[18] published the only previous series of PDA closure using the Amplatzer Duct Occluder in adult patients. In their series of 5 patients with PDA, Lee et al. reported a procedural success rate of 100%. Complete echocardiographic closure was seen in all the patients within 24 hours, and there were no complications. Similarly, in a series of 27 patients with PDA, Arora et al. reported only one unsuccessful placement of an Amplatzer Duct Occluder device. Furthermore, complete occlusion without a residual shunt was observed in 100% of patients within 24 hours of device placement, and no complications were seen. In our series of patients, we observed similar favorable results. Of 193 patients with PDAs of a wide variety of sizes, 53 had occlusion by the Amplatzer device, and 100% success was observed. In over 67 % of the cases, immediate angiographic closure was observed. By 24 hours post-procedure, complete closure was observed in 98% of the cases, and by 6 months post-procedure, complete closure was observed in 100% of the cases. Unfortunately, late follow-up on one of the patients who did not have complete closure by 24 hours is not available. Of the patients who completed 6-months' and 1-year's follow- up, 100% had complete closure of their PDAs. The complication rate was low, and none were attributed to the implantation of the Amplatzer device but rather to the catheterization procedure itself (groin complications and allergic reaction).

Conclusion

We believe that the selection of an appropriate device for the closure of PDA in children should depend on the angiographic diameter of the ductus. If the PDA is small with a diameter <3 mm, then, depending on the operator's preference, either coil closure or the Amplatzer device may be considered. For patients with a PDA >3 mm, we believe that the Amplatzer device deployed from the venous side is the best available option.

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