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Research Article

Transcatheter Closure of Patent Ductus Arteriosus- Observational Data Comparing Device and Coil

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Abstract
Background: *Transcatheter closure of PDA has largely replaced surgical ligation in different age groups. Coils and Amplatzer Duct Occluder (ADO) are the most frequently used closure devices.*
Aim: *Aim of the study is to compare our data on the outcome and complications of transcatheter coil closure of PDA with that of device closure.*
Methods: *From April 2014 to April 2017, 57 patients underwent transcatheter closure of PDA in our centre and were included in the study. Echocardiographic, angiographic data and procedure results were analysed.*
Results: *During the study period 24 patients underwent PDA coil closure and 33 patients underwent device closure. Coils were used mostly in small and moderate sized PDA whereas ADO was used in moderate to large PDA. Procedure success was 96.9% for device and 91.6% for coil closure. In the immediate post-procedure period residual shunts tended to be more in coil closure group. Complications were rare in both groups.*
Conclusions: *Transcatheter closure of PDA is very safe and effective and achieves near complete occlusion in most cases. Coil closure is nearly as effective as device closure in small and moderate sized PDA.*

Introduction

Patent ductus arteriosus (PDA) is a common congenital heart defect with a reported incidence of 1 per 2000 live births and accounts for approximately 5–10% of patients with congenital heart disease.[1] In preterm infants, the incidence is about 8 per 1,000. The two major complications, and hence, causes of death in patients with PDA, are heart failure and bacterial endocarditis. Closure of PDA is indicated in any patient with signs of left ventricular volume overload due to a ductus. In cases of PDA with pulmonary arterial hypertension, closure may be performed if there is net left to right shunting with reversible PAH. Clinically silent and very tiny PDAs are usually not closed.[2]Over time, trans-catheter closure became the first-choice therapeutic option regardless of PDA diameter and patient size in most of the cases. Coils and the Amplatzer Duct Occluder (ADO)are used most frequently for PDA

closure worldwide, with a high success rate and few complications.[3,4] However, trans-catheter PDA closure in preterm or low-body weight infants remains highly challenging.[5,6] Similarly trans-catheter closure may be challenging in very large PDAs.

Trans-catheter coil embolization was commonly used in children and adults with small or medium-sized PDA with a high success rate. Recently most of the centres perform trans-catheter PDA closure with ADO especially in medium- to large-sized PDA. Closure with device is costlier compared to coil closure. In the present study, our experience in closing PDA using the Amplatzer duct occluder (ADO) is compared with PDA closure using Gianturco coils.

Materials and Methods

All patients who underwent transcatheter PDA closure from April 2014 to April 2017 were included in the study. Pre-procedure evaluation included clinical examination, ECG, chest radiography and 2 D echocardiography. Coil closure was used mostly in small to moderate sized PDA whereas device closure was mostly done in moderate to large PDA. We analysed the clinical, echocardiographic and angiographic profile of patients who underwent procedure and compared the the safety and efficacy of coil occlusion of PDA with that of device closure.

Procedure

PDA Closure Using Coils

The Gianturco coil is made of stainless steel wire of varying helical diameters and lengths to which Dacron fibers have been attached to increase thrombogenicitiy. After the implantation of the Gianturco coil, occlusion occurs as a result of thrombus formation and subsequent organization. The Gianturco coil can be either 0.038" (about 0.9 mm) or 0.052" (1.1 mm). Generally the coil diameter should be at least twice the size of the narrowest diameter of the coil. Usually for PDAs with up to a diameter of 2.5 mm, a single coil is utilized and larger ones usually need two or more coils. All patients receive 50 units/kg intravenous heparin after insertion of a femoral arterial sheath to avoid the risk of femoral arterial thrombosis. A descending aortic angiogram in lateral projection is obtained using pigtail catheter. The minimum PDA diameter, aortic ampulla dimension and ductal length are measured. A 4 F or 5 F right coronary artery catheter (Cordis, Miami, FL) is used as the delivery catheter. The Gianturco coil is pushed in position by the use of a 0.038-inch wire. The delivery of the coils can be done anterogradely or retrogradely according to the preference of the operator. Most coil loops should be in the ampulla of the PDA so that only one loop should reside in the pulmonary artery. [Figure 1-Panel- A] If the narrowest diameter of the PDA was> 2.5 mm, more than one coil is usually deployed. Approximately 5-10 minutes after coil implantation, selective angiography is performed to document occlusion. If necessary, additional coils are implanted. Color-Doppler echocardiography is performed during procedure and before discharge.

PDA Closure Using ADO

The procedure of device closure is similar till measurement of ductus size. A 4 or 5-French multipurpose catheter or GL catheter is introduced into femoral vein, positioned in the main pulmonary artery and advanced into the descending aorta via the ductus. If the catheter cannot be advanced across the ductus by itself, we use 0.035” Terumo guide wire to cross the ductus. In most cases a 0.035” extra-stiff exchange-length J-tipped Amplatzer guide wire is positioned in the descending aorta and the multipurpose catheter removed. Then, an appropriate-sized Mullins sheath is advanced over the wire, across the right heart and ductus and its tip positioned in the descending aorta. An ADO device whose pulmonary end is 2 mm larger than the narrowest diameter of the PDA is selected for implantation. The selected ADO is screwed onto the delivery cable and loaded in to sheath under water to avoid air trapping. The device is then advanced through

the sheath under fluoroscopic guidance. When the tip of the device reaches the tip of the sheath, the entire system is withdrawn until the tip of the sheath is in the descending aorta just distal to the aortic ampulla of the ductus. Then, holding the device in place, the sheath is withdrawn to release and deploy the aortic disc of the device. Pressure monitoring is done through the side arm of the sheath. The entire system is slowly pulled till the pressure at the tip of sheath falls indicating that it is in the pulmonary artery. If satisfactory, the sheath is further retracted holding the device in place, to release the pulmonary end of the device. [Figure 1 Panel-B] An aortogram is done to check the position of the device and any residual shunt. Pinching of the device by the ductus is a good sign of correct positioning of device. If the device is in good position, the delivery cable is rotated counter clockwise until the device is released thus implanting the device. The delivery cable and sheath are withdrawn into the inferior vena cava and removed. Recently in most cases arterial access is avoided especially in children. Ductus sizing is mostly done with a descending aortic angiogram using pigtail catheter introduced over the wire through PDA. We do not use heparin if there is no arterial access.

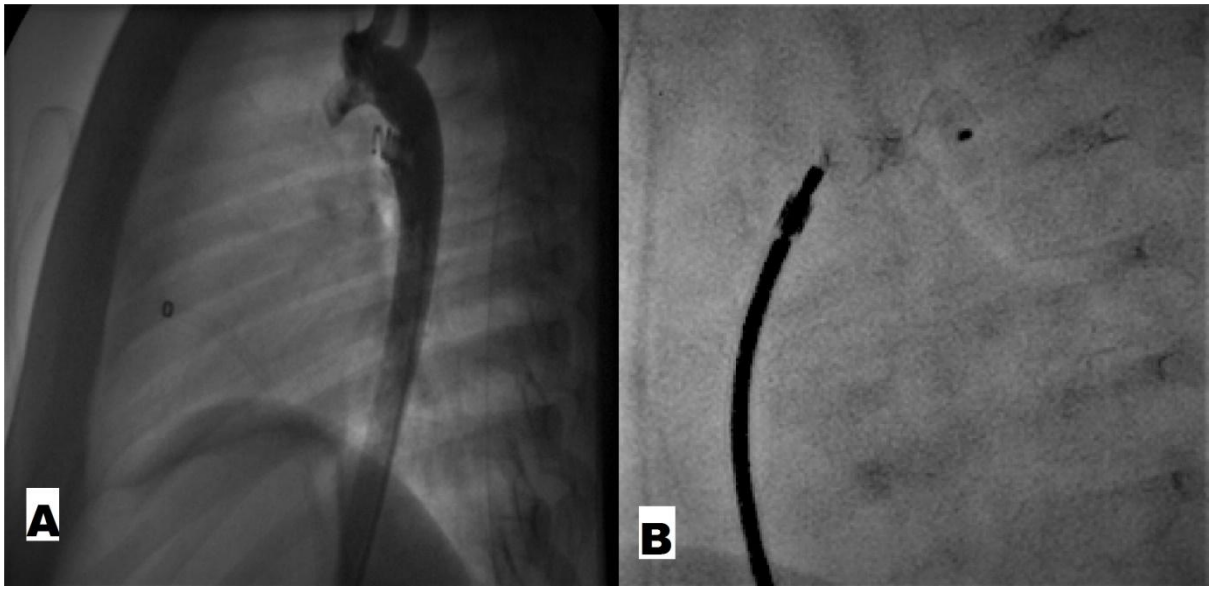

Figure 1- Panel A- Descending aortogram in lateral view after release of coil. Sinle loop is seen in pulmonary artery whereas the rest of loops are compacted in the ampulla. No residual shunt. PANEL B- Flouroscopy lateral view image showing ADO after release before unscrewing from delivery cable.

Results

A total of 57 patients underwent the procedure of which 21 were males and 36 were females. The mean age was 8.8±10.5 years (Range 8 months – 58 years). Mean weight was 19±13.3kg (Range 4 to 60 kg). PDA coil closure was done in 24 patients whereas 33 patients underwent device closure with ADO.

Echocardiographic & Angiographic features.

The echocardiographic and angiographic features of the two groups are given in table 1.

Duct size and ampulla diameter were significantly less in the coil group compared to the device group as expected. The mean pulmonary artery pressure was similar among two groups.

Table 1 Echocardiographic and Angiographic features of PDA

variable	Device closure(No:33)	Coil closure(No:24)	P value
Duct size mm (echo)	3.16± 0.81 Range:1.8-5.9	2.25 ± 1.1 Range:1.5-4.1	0.0007
Ampulla diameter mm (echo)	7.98 ± 2.17 Range:5-12	5.7 ± 2.25 Range:3.1-7	0.0003
PA mean pressure (mm Hg)	21.64 ± 11.2 Range:10-63	18.6 ± 3.5 Range:14-25	0.205
Duct size mm(angio)	3.25 ± 0.86 Range:1.8-5.8	2.6 ±0.68 Range:1.5-4.2	0.003

Procedural details

The technical details, procedure success and complications are given in table 2.

Table 2. Procedural results and complications

Variables	Device closure(No:33)	Coil closure(No:24)	P value
Fluoroscopy time (min)	17.03±8.32	17.16±9.36	0.95
Procedure time (min)	39.42±13.68	42.17±15.68	0.48
Procedure success	32(96.9 %)	22(91.6%)	0.38
Device/Coil embolisation	1(3.03%)	2(8.3%)	0.38
Residual shunt at -immediate -24 hours after -6 months	 1(3.03%) 0 0	 4(16.6%) 2(8.3%) 1(4.1%)	 0.075 0.094 0.24
Haemolysis	0	0	

Fluoroscopy and procedural time were similar in both groups. There was successful implantation in more than 90% of cases. ADO device diameter ranged from 4/6 mm to 8/10 mm. We used 0.038" Gianturco coils in all patients of coil closure group. More than one coil was required in 14 patients. All PDAs with size > 2.6 mm required>1 coil. When the results of PDAs with size less than 3 mm were compared procedure success was 100% in both groups with no residual shunt at 6 months, device/coil embolization or haemolysis.

Discussion

Transcatheter PDA occlusion has become the treatment of choice for most PDAs in term infants, children and adults[7]. Transcatheter closure of PDA utilizing coils has been used worldwide in thousands of patients. There are numerous reports describing its efficacy and safety. In general, the success rate of deployment in most series is higher than 90% especially in small PDA. Residual shunts were present in about 18% patients 24 hours after the procedure which decreased to 9% at follow-up[8]. In the multicenter US trial, successful implantation of ADO was accomplished in 435 (99%) of 439 patients. Complete acute angiographic occlusion was achieved in 384 (76%), which increased further to 89% on the following day by Echo-Doppler studies. Complete closure was shown in 359 (99.7%) of 360 patients at one year follow-up[4].

Complications of trans-catheter closure of PDA include residual shunts, haemolysis, embolization of coil/device, narrowing of left pulmonary artery and acquired coarctation. Incomplete closure is more common after coil closure. Residual shunts were present in about 18% patients 24 hours following implantation of free Gianturco coils and on follow-up decreased to 9%. Residual shunts were reported in 5 to 34% immediately after ADO implantation which decreased on follow-up to 0 to 3%[4,8]. Intravascular haemolysis may occur in patients with residual shunts due to high velocity shunting[9,10]. Transcatheter orsurgical closure of the residual shunts usually resolves haemolysis. Embolization may occur in about 1.5 to 9% in case of coils and 0 to 4% in case of ADO[8,11]. Embolization may occur to the pulmonary arteries

or, rarely, to aorta and systemic arteries and requires trans-catheter snaring or surgical retrieval[12,13]. Careful evaluation of the sizeand morphology of the ductus during selection of device reduces the incidence of embolization. Device-induced left pulmonary artery stenosis or coarctation of the aortamay occur rarely, particularly in small infants with large PDA requiring a large device[14,15].

Our study showed successful implantation in91.6% of cases for coil closure and 96.9% for ADO device closure. Failure of implantation was due to embolization of coil/device in all the cases. All the three cases had embolization in to the left pulmonary artery. Surgical retrieval was done in case of device embolization whereas transcatheter snare retrieval was successful in coil embolization. Both these cases were successfully treated with device closure. Device embolization was due to undersizing of the device due to probable error in assessing the size of PDA. All of the device closure patients except one had complete closure immediately. Residual shunt disappeared in the other case after 24 hours of follow-up. As expected residual shunt was more in the coil closure group which also improved on follow up. None of the patients had haemolysis. Our study has important limitations like lack of comparability of size of PDA among the two groups which can affect conclusions. This is only an observational study. Moreover most of the coil closures were done in the initial period of study and device closures in the latter period. However comparing the cost of the procedure, device costs are about 3 times that of coils in India. Hence coil closure should be used as an alternative to device closure in small and moderate sized PDA in our country.

Conclusions

Trans-catheter closure of PDA is very safe and effective and achieves near complete occlusion in most cases. Complications are rare and can be managed successfully in most cases. Coil closure may be considered as an alternative to device in small and medium sized PDA especially when cost considerations occur.

Conflicting Interest: Nil

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