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Original article

Transcatheter occlusion of patent ductus arteriosus: success rate and complications 5 years experience: single center in isfahan

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Summary. *Background and aim:* Percutaneous occlusion of patent ductus arteriosus (PDA) has become increasingly attractive with the evolution of devices and techniques. This study aimed to report the total experience of a novel arterial occlusion device (Duct Occlude pfm) and Amplatzer. *Methods:* A descriptive study which selected non-randomized pediatric patients with patent ductus arteriosus (PDA) was performed between May 2007 to February 2012 on 99 children aged 8 months to 16 years who underwent attempted closure of PDA. Transcatheter occlusion was attempted in all the cases of coil through a 4-5 F and for Amplatzer 6-7 F delivery catheter. *Findings:* Devices were successfully deployed in 98% of patients. Amplatzer was used for thirty four patients (34%) due to medium to large PDA and coil was selected for sixty five patients (66%) due to small to medium size PDA.One day after the procedure, complete occlusion was accomplished in 42 (69%) out of 61 patients in whom the detachable coil device had been used on color-flow Doppler echocardiography. Embolization of a coil occurred on 1 occasion. *Conclusion:* Methods of detachable coil and Amplatzer type occlusion system compares favorably with other methods of transcatheter PDA occlusion.

Key words: Amplatzer occlude; Coil device; Duct Occluder pfm; Patent ductus arteriosus

Introduction

Patent ductus arteriosus (PDA) is a common congenital heart defect in which a normal fetal structure (the ductus arteriosus), connecting the pulmonary artery and descending aorta, persists beyond the first 10 days of life(1). Since three decades ago, different devices were designed and made to resolve this disorder.

Occlusion of arterial duct by coil and Amplatzer duct occluder has begun by the pediatric cardiology specialists since 1992(2). During this period of time transcatheter occlusion was the selected treatment method for all the children aged more than a few months (3). The success rate of this method is more than 97% and the patient would be able to do his/her full activities at the next day without any significant mortality or major complication(4).

Special devices such as Amplatzer duct occluder can be used for large PDAs(5). Arterial duct occlusion has been started since 2007 in Isfahan and the results are investigated in this study.

Patients and methods

In this descriptive study which done between May 2007 to February 2012, 99 children aged 8 month to 16 years enrolled in the study. Patients were asses-

sed by echocardiography with a Medison System (X8) with a transducer appropriate to size and body weight.

Inclusion and exclusion criteria

Patients who had clinical and echocardiographic features of a moderate to large PDA and weighed >5000 g included in the study. These patients had one or more of the following: symptoms and signs of cardiac failure, failure to thrive, frequent respiratory infections, bounding pulses and cardiomegaly on chest radiography. Frequent respiratory infections were defined as more than six events a year.Patients who had body weights less than 5000 g, severe pulmonary hypertension, and associated cardiac anomalies requiring surgery were excluded from this study. Informed consent was obtained from the parents of all patients.

Device and procedures

Demographic data pulmonary artery pressure and presence of residual shunt in the patients were examined. All the patients underwent anatomic and hemodynamic examination through catheterization and angiography. Also, arterial duct size was measured using lateral aortogram and the required device with appropriate size was determined. The ductal size was defined as the narrowest diameter of the ductus measured on the lateral or the 30-degree right anterioroblique view, using thecatheter size as a reference.Usually, arterial duct occlusion with the Nit-Occlud PDA occlusion device (pfm, Germany) or cook coil was done for cases with small to medium arterial duct, and Amplatzer device (AGA) or Lifetech was used in cases with medium to large arterial duct. The delivery system entered into arterial duct through femoral artery or vein. In cases that coil was used, one or two rings were implantedin pulmonary artery side, and three or four of the rings were inserted into arterial duct aortic ampulla. Before deploying the device, Cefazolin (50 mg/kg) (JaberebneHayan Company) was prescribed to prevent endocarditis. After implanting the device, in most of the cases that arterial duct occlusion was attempted through the femoral vein, aortography was done to verify the results of the procedure. After making sure about the successful insertion of the device, arterial duct was detached from the carrier system. Most of the times when Amplatzer has been used for arterial duct occlusion, aortopulmonary pressure was measured as ascending and descending aortic pressure. In patients in whom the arterial duct was not completely occluded after insertion of the device, control echocardiography was performed the other day. The most of patients were discharged from hospital after 24 hours.

Follow up

All patients underwent clinical investigation, chest radiography and transthoracic echocardiography before discharge and one week after discharge. Thereafter, patients underwent echocardiography at 1, 3, 6 and 12 months after the procedure. Special attention was paid to residual ductal flow and left pulmonary artery or aortic arch stenosis.

Statistical analysis

Results are expressed as mean ± SD. Device characteristics present as number and percentage. For the statistical analysis, the statistical software SPSS version 20.0 for windows (SPSS Inc., Chicago, IL) was used.

Results

During 5 years of study period, 99 patients were enrolled. Data regarding age and sex of the participants are describe in Table 1. The mean age was 4.0 ± 3.2 years. The ratio of male to female was 34 to 65.The mean pulmonary blood flow to systemic flow (Qp/Qs) ratio was 1.98±0.7.

The average of PDA diameter at its narrowest

Table 1. Data regarding study variables

Variables	Data
Age (Year)	4± 3.2 (0.7- 16)
Male:Female	34:65 (1.9 / 1)
Qp/Qsratio	1.98 ± 0.7(1.2/ 4)
PAP(mmHg)	35 ± 14(15 - 80)

point was 3.7 ± 0.9 mm. In 52% of the patients, pulmonary artery pressure was almost normal while in 8% of the cases it was close to systemic pressure. Totally, 40% of the cases had mild pulmonary hypertension. The mean of pulmonary arterial pressure in the patients was 35±14 mmHg. Arterial duct size in 24% of the patients was small, 58% moderate and 18% large. In 69% of the patients coil was used while Amplatzer device was utilized for the rest of the patients (Table 2). In 59% of the patients, left-to-right shunt was completely occluded after deploying of the device and in the rest of the patients (39%) the mild shunt was removed 24 hours after color- flow Doppler echocardiography. Only in one patient, another coil was implanted near the previous coil due to residual shunt after one year (table 2). Table 3 shows the rate of Immediate Closure.

Discussion

Porstmann in 1967 for the first time performed percutaneous closure of a PDA (6). Since then various devices and coils have been introduced in clinical practice(6).The major drawbacks of these devices and coils are the high incidence of residual shunt, complexity of delivery system, large delivery sheaths and their unsuitability for large PDAs or small children. Masura et al. reported the successful use of a new self-expandable Nitinol device (ADO) to occlude moderate to large PDAs(7). Similarly, Chessa et al. reported transcatheter closure has become an effective therapy in most patients with PDA (8).

Table 2. Variables Data

	Number of cases	Percent
Coil pfm	59	60
Coil COOK	6	6
Amplatzer	34	34
Total	99	100

Table 3. Immediate Closure rate

	Amplatzer %(N)	COOK %(N)	PFM %(N)	Total %(N)
10 Min	81%(27)	83%(5)	46%(27)	70%(69)
24 hours	87%(29)	100%(6)	82%(48)	90%(89)

Our current study is mainly focused on clinical results in using pfm and cook coil for small and medium size PDA (66%) and Amplatzer for medium to large size PDA. The immediate occlusion was achieved in 46%, 83% and 81% of patients for pfm, COOK coil and Amplatzer respectively. After 24 hours, the rate of occlusion shown by echocardiography was 82%, 83% and 87%, for pfm, COOK and Amplatzer respectively. Overall complete occlusion rate immediately after implantation was 68.4% which is similar to results of a Korean study which done by Choi et al. They claimed that evolution of devices, cumulative experience, and health insurance covering the cost of devices have contributed to good outcomes for percutaneous occlusion of PDA (9). Fortescue et al. presented a case series of 1808 patients with transcatheter closure of PDA in 2010. PDA occlusion rate was 94% and major complications were 1.5 %(10).

European registry report, using "double umbrella" technique has successful outcomes for percutaneous transcatheter occlusion of patent arterial duct (ductus arteriosus) .It was used in 94% of the cases in which shunt was removed completely. Shunt was removed was in 53% and 83% of the patients, 24 hours and one year after the procedure, respectively. So they concluded that transcatheter occlusion of the arterial duct is a safe and effective alternative to surgical closure(11).

Similar results have been reported by Hosking(12). He used to apply the second device for transcatheter occlusion, so the residual shunt was 11% during 40 months of clinical follow-up(12). In this study, left to right shunt was removed after 24 hours in 98% of the cases. Coil was employed for the small PDAs while Amplatzer was used for larger arterial duct. As a result, the residual shunt level was smaller 24 hours after the operation compared to other studies.

For the first time Moore et al. has reported single-coil technique(13). With using single coil technique, the coil catheter was inserted in the arterial duct using retrograde and catheter 5 or 5.5. They mainly focused on clinical results in using helical coils with diameter of 3.5 to 8 mm. These coils were not connected to the catheter wire and had embolic potential(13).

Thanopoulos et al. by using PDA occlusion with the use of a swivel-disk device (SDD) or a plug occluder (PO concluded, the SDD and the PO are promi-

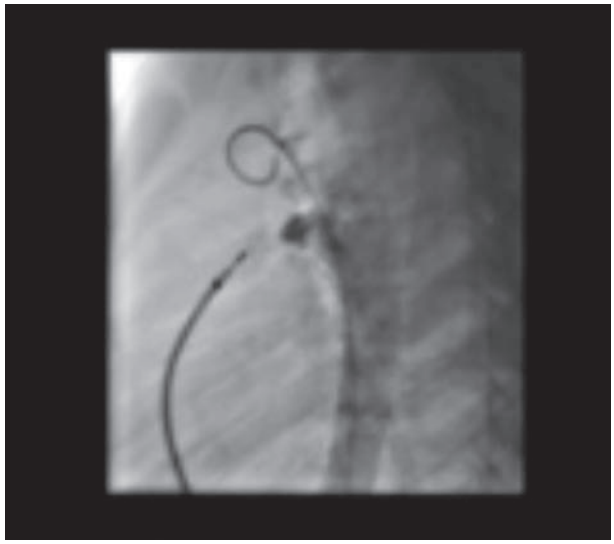

Figure 1. Still frame cine image in the lateral projection in the descending aorta of a child with a 3.5 mm PDA.

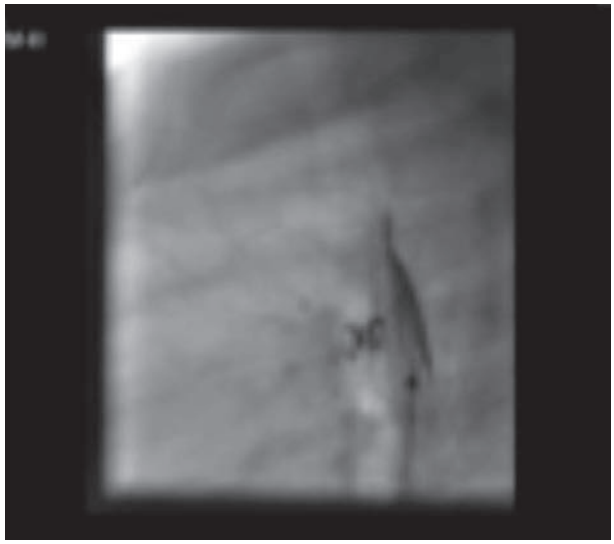

Figure 2. Still frame cine image in the lateral projection in thedescending aorta showing the device in the proper position. There is atrivial residual shunt through the device.

sing additions to the armamentarium for PDA closure (14).

Hijazi et al. used anterograde technique with single or multiple Gianturco coil by 4 Fr catheters(5-6 coils with diameter of 2-8 mm)(16). Embolisation of the device occurred in only 3 out of 33 cases, which was slightly more than expected (3 out of 51). With using single or multiple Gianturco coil technique, the control advantage in detaching was lower (16).

Pfm coil has the advantage that after detaching it takes the form of the arterial duct. Krichenko et al. anatomically classified the arterial ducts and believe that tubular arterial ducts are difficult to be occluded by the coil(17). The advantage of this new device is that it remains fully retrievable therefore allowing its removal and re-implantation if a satisfactory position is not at first obtained. In Addition, a recent study demonstrated PDA device closure without arterial access can be accomplished safely and effectively in vast majority of patients including infants (18).

Conclusion

The results of this study showed Transcatheter therapy by coil or Amplatzer PDA occlude is a safe and effective method of occlusion in children. Methods of detachable coil for small and moderate size PDA favorably compare with other methods of transcatheter PDA occlusion. Therefore, further clinical evaluations and longer follow up are needed to assess any potential limitation related to the use of this device in very young children.

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