

TRANSCATHETER CLOSURE OF PERSISTENT DUCTUS ARTERIOSUS USING THE AMPLATZER DUCT OCCLUDER IN INFANTS

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ABSTRACT

Background: Despite technical improvements over the years, interventional closure of persistent ductus arteriosus in infants remains a challenge.

Objectives: To assess safety, efficacy, and follow up results of closure of symptomatic persistent ductus arteriosus in infants using the self-expanding and repositionable Amplatzer device.

Setting: Queen Alia Heart Institute (QAHI), a tertiary cardiac center, Amman-Jordan.

Patients and Methods: Between June 2000 and May 2004, a total of 21 infants (12 males, 9 females) with symptomatic persistent ductus arteriosus were considered for treatment by transcatheter. Their age ranged from six months to 12 months (median 9.5 months) and bodyweights ranged from 5.5-9.8kg (median 7.4 kg). Indications for closure were one or more of the followings: failure to thrive, frequent respiratory symptoms, tiring on feeding, cardiomegaly on chest X-ray and left atrial and ventricular overload on 2-dimensional echocardiography. The procedure was carried out under sedation with fluoroscopic control. The Amplatzer duct occluder device was used.

Results: Concurrent angiographies showed immediate closure in 16 patients while 5 had trivial shunting. Within 24 hours, Doppler examination showed complete closure in all patients. (Closure rate: 100%). There was no mortality related to the procedure, no aortic obstruction, left pulmonary artery stenosis or device embolisation. One patient had loss of femoral artery pulse that was successfully treated by intravenous heparin. Technical problems occurred in three patients during delivery of the device which was solved by changing the delivery sheath or using a snare to stabilize the sheath. There have been no late complications or re-opening of the duct on follow-up till date. Patients with recurrent respiratory symptoms had no significant recurrences, infants who had failed to thrive had significantly increased growth and all have normal left atrial and ventricular measurements.

Conclusion: Transcatheter closure using the Amplatzer duct occluder is an efficacious and safe treatment for symptomatic patent ductus arteriosus in infants.

KEYWORDS: PDA, Amplatzer Duct Occluder, Infants

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INTRODUCTION

Patent Ductus Arteriosus (PDA) is a common form of congenital heart defect with an incidence of one in 2500 to 5000 live births¹. Transcatheter occlusion of Persistent Ductus Arteriosus (PDA) with various occluders and coils is a well-established alternative to surgical duct ligation in children and adults but there are only occasional reports on symptomatic infants²⁻⁹. Despite technical improvements over the years, interventional closure of large ducts in infants remains a challenge. We conducted this study to assess the immediate and short-term results of closure of patent arterial ducts using the self-expanding and repositionable Amplatzer device with special reference to

infants less than one-year age.

METHODS

Between June 2000 and January 2004, we considered transcatheter closure of Persistent Ductus Arteriosus (PDA) using Amplatzer duct occluder in 21 infants presenting with a Persistent Ductus Arteriosus (PDA). Patients are selected based on the presence of a PDA with left-to-right shunt. Their age ranged from six months to 12 months (median 9.5 months) and bodyweights ranged from 5.5–9.8 kg (median 7.4 kg). The patients are evaluated with a physical examination, chest X-ray, electrocardiogram (ECG) and a transthoracic two-dimensional echocardiogram. All patients had one or more of the following clinical and echocardiographic findings consistent with significant PDA: respiratory symptoms, poor weight gain, tiring on feeding, cardiomegaly on chest X-ray and left atrial and ventricular volume over-load, which were the indication for early closure in this group.

The device

The Amplatzer duct occluder (AGA Medical Corporation, Golden Valley, Minnesota, USA) is the first device of its kind approved by the FDA for treatment of PDA. It is a self-expandable, mushroom-shaped device made from a 0.004-inch thick Nitinol wire mesh (a thin retention disc, 4 mm larger in size than the diameter of the device ensures secure positioning in the mouth of PDA). The PDA is closed by the induction of thrombosis, which is accomplished by polyester fibers sewn securely into the device. Platinum marker bands are applied to the wire ends and laser welded. The shape is then formed by heat treatment. All devices are cone-shaped and 7mm in length, with a recessed screw, sizes are given from the larger to the smaller diameter^{10,11}.

Closure protocol

Informed consent was obtained from the parents of all patients. The procedure was carried out under sedation with fluoroscopy control. After percutaneous puncture of the femoral vein and artery, routine right and left heart

catheterization is performed to assess the degree of shunting and to evaluate the pulmonary vascular resistance. Pullback gradients from the Left Pulmonary Artery (LPA) to the Main Pulmonary Artery (MPA) and from the ascending to the descending aorta are obtained to rule out any obstruction. A biplane angiogram in the lateral projection is then performed with a catheter in the proximal descending aorta to opacify the PDA (Fig. 1). The PDA size measured and the PDA is classified by its shape¹². A device is selected so that the smaller end is at least 2-mm larger than the narrowest portion of the PDA. A catheter is passed from the MPA through the PDA into the descending aorta. A stiff exchange guide wire is placed with the tip in the distal descending aorta. A 5- to 6-F long sheath is then passed over the wire into the descending aorta. The appropriate-sized ADO device is then screwed onto the delivery cable and pulled into the loader under water to prevent air entry into the device or sheath. The device is then advanced to the tip of the sheath in the descending aorta without rotation of the cable. The sheath and device are then pulled back into a position just distal to the ampulla. The sheath is retracted and the retention skirt is allowed to open in the descending aorta. The sheath and ADO device are pulled back inside the ampulla. The position of the device is confirmed with repeated angiograms in the descending aorta using a pigtail catheter and adjusted until the retention skirt is well seated in the ampulla (Fig.2). When good position is achieved, the sheath is retracted.

Further and the tubular part of the device is opened within the PDA. Another angiogram is performed in the descending aorta to confirm final device position (Fig. 3). Up to this step, the device can be repositioned or retrieved. If device position is satisfactory, the pin vise is then fixed onto the delivery cable and the device is released with counter clockwise rotation. Repeat pullback pressures are obtained from the LPA to MPA and ascending to descending aorta to evaluate for possible gradients. A follow-up chest radiograph and a two-

dimensional echocardiography evaluation for residual shunting, LPA patency and descending aortic flow is performed prior to discharge. The patients receive a dose of an appropriate antibiotic (commonly cefazolin at 20 mg/kg) during the catheterization.

Follow up

All patients underwent, chest X-ray, and transthoracic echocardiography before discharge and at two months. Thereafter, patients weight, and respiratory symptoms were assessed and all underwent echocardiography at 3, 6, 12 and 24 months after the procedure to detect residual ductal flow and left pulmonary artery or aortic arch stenosis and to detect left heart volume overload.

RESULTS

According to Krichenko's angiographic classification¹², the ducts were of type A (n = 18) and type E (n = 3), and devices with a maximum cone diameter of 6 mm (n=17), 8mm (n=4), were chosen to achieve occlusion. The procedure time varied between 45–90 minutes (median 60 minutes), with a fluoroscopy time of between 7.5–29 minutes (median 11 minutes). Technical problems in advancing the device through the long sheath occurred in two of the 21 cases (9.0%). Complete occlusion was shown on post-deployment angiographies and color Doppler echocardiography 24 hours after device placement in all patients. Complications related to the procedure, thrombosis of the femoral artery (one patient), this was managed by overnight continuous heparin infusion 20 IU/kg and the pulse gained by the morning. All patients were discharged on the next day. At follow up (after 10 months–3.0 years), we have seen no late complications such as, recanalisation, device migration, or device related obstruction of the pulmonary arteries or descending aorta. All patients with respiratory symptoms became free and all gained appropriate weight and reported improvements. There were no evidence of left atrial and ventricular volume in any patient. There was no mortality.

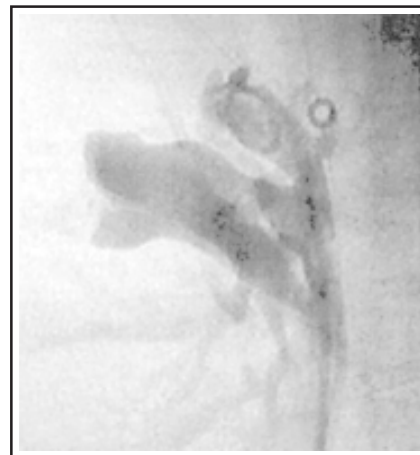


Figure 1: Lateral aortogram showing the persistent ductus arteriosus (PDA diameter 2.2 mm).

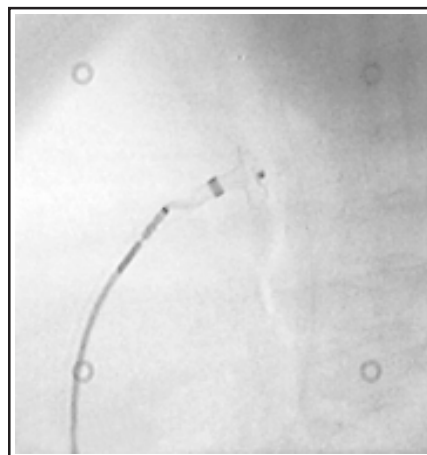


Figure 2: Fixation of the Amplatzer duct occluder retention disc within the aortic ampulla.

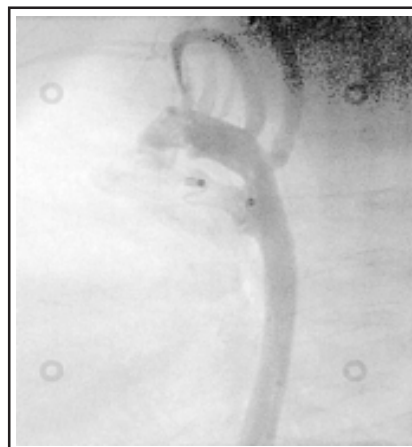


Figure 3: Final angiogram after releasing the Amplatzer duct occluder.

DISCUSSION

Since the first percutaneous closure of a PDA performed by Porstmann² various devices and coils²⁻¹¹ have been introduced in clinical practice. The accurate placement of coils can be technically difficult and the other currently available FDA- approved devices is Gianturco-Grifca vascular occlusion model and Rashkind occluder are not applicable for all PDA types, require an 8-French sheath for delivery or suffer from high rate of residual shunting and require repeat procedure in up-to 30% of patients^{13,14}. In 1998 the Amplatzer duct occluder (AGA Medical Corporation, Golden Valley, Minnesota, USA) approved by the FDA for treatment of PDA and reports have proven excellent success, with a complete closure rate of 100% at one month follow up and no complications^{10,11,15,16} for all types of PDA. However, few reported data about the use of Amplatzer duct occluder in very young children, specially infants under one year of age^{17,18}.

The recently published results of the international clinical trial with the Amplatzer duct Occluder¹⁹ reported 15 procedures related complications in 316 patients (4.5%) who underwent attempted transcatheter closure of a ductus arteriosus. Complications included haemolysis, left pulmonary artery stenosis, device protrusion into the aorta causing coarctation,²⁰ device misplacement, and one death following device embolisation. Looking at the original data file, which was kindly provided by the AGA Medical Corp, it became clear that complications were more common in younger patients (complication rate in the group of patients under one year of age, 8.2%; complication rate in older patients 3.8%).

Butera G et al. conducted a study in very young symptomatic patients, aged <3 years and concluded that in experienced hands, percutaneous closure of moderate and large PDA in very young symptomatic children is safe and effective¹⁷. However in his group of patients all complications occurred in subjects less than one year, which includes: mild inguinal

haematoma in two patients and thrombosis of the right femoral artery in one patient. In Fischer G, et al study, the procedure was not successful in two small infants of 2.6 and 4kg body weight and finally had to be abandoned because of excessive procedural and fluoroscopy time¹⁸. In all the other cases they were successful in placing the occluder and there was subsequent complete occlusion with good results on follow up. Indeed Fischer pointed out that the critical point of the procedure is when the device, connected to the delivery cable, has to be advanced around the curve of the right ventricular outflow tract towards the pulmonary artery. In infants this curve is tight, being more or less a right angle. Additionally, he found that the long sheath provided by the manufacturer often became kinked and so may not be strong enough to negotiate this curve while maintaining its integrity. Furthermore, a larger sheath than recommended was often needed to ensure the smooth advance of the device. Exchanging the sheath for another or the use of a snare technique to stabilize the sheath helped to overcome this drawback, but prolonged the procedure and fluoroscopy times.

In our institution, we encountered these difficulties in three patients (14%) where we had to use the snare technique to stabilize the sheath in one patient and to exchange the sheath for another two patients. This drawback has been reported to occur also in five (20%) of a cohort of older patients whose bodyweight was between 10–20 kg¹⁸. Another recently published paper reported a single center experience with the Amplatzer duct occluder in 209 patients,²¹ among whom 27% were infants weighing <5kg where kinking of the delivery sheath occurred in only one infant. On the other hand G Butera did not report similar technical difficulties. In Radhakrishnan et al clinical trial of nonsurgical closure of large PDA, the unsuccessful attempt was in a malnourished patient weighing 4.7kg with a large PDA²².

Although the manufacturer does not recommend the use of the Amplatzer duct occluder

in patients with a body weight of less than 5kg, Fischer et al included seven patients under that weight (from 2.6–4.4 kg) in their treatment cohort¹⁸ and he concluded that his experience in small infants supports the manufacturer's recommendation that the procedure should not be attempted in patients below 5kg body weight.

On follow up all infants became free of symptoms, gained significant weight and retained a normal left atrial and ventricular parameters on 2-dimensional echocardiography. There were no mortality or reported late mortality to date and the results of our follow up are in agreement with many others¹⁸⁻²².

CONCLUSION

Although the procedure might be technically more difficult compared to older children, Transcatheter closure using the Amplatzer duct occluder is an efficacious and safe treatment for symptomatic patent ductus arteriosus in infants weighing more than 5.0 kg.

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