Original Article

Early Results of Transcatheter Closure of Patent Ductus Arteriosus: Retrospective Study of 61 Patients

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Introduction

Patent ductus arteriosus (PDA) accounts for 6 – 11% of all congenital heart defects.[1,2] Complications of PDA include congestive heart failure, repeated chest infections, pulmonary hypertension, and an increased risk of infective endocarditis. Transcatheter closure of PDA has largely replaced surgical ligation in different age groups.[3–7] Currently, surgical intervention is restricted to premature babies or small infants with large symptomatic PDA, cases with unfavorable duct anatomy, and whenever the cost of the closure devices is unaffordable.[1]

PDA was the first example of congenital heart disease to be treated by transcatheter closure, which becomes an established form of treatment for the majority of patients with PDA and as a safe alternative to surgery.

The per-cutaneous technique was first described by Porstmanur *et al*.,[8] since then various devices such as Rashkind PDA umbrella,[9] button device,[10] PDA coils[11] and most recently the Amplatzer duct occluder (ADO) have been introduced.[12,13] The ADO device was designed to provide the most desirable characteristics for a percutaneous closure device that can be used in most if not all patients with PDA. These include user – friendly delivery system, high complete closure rate, small delivery system (allowing its use in small infants), trans-venous delivery route, ability to adapt to various PDA sizes and types, and the ability to retrieve or reposition the device prior to release from a secure delivery system.

Common complications of trans-catheter closure of PDA include residual shunt, left pulmonary artery (LPA) obstruction, protrusion of the device into the aorta, and embolization of the device.[14–16] Incidence of complications increases with certain types and large size ducts, and with the use of multiple coils for occlusion.[17] There are only a few reports correlating outcome and complications with the learning curve and experience.[18–20] In this study, we are reporting our initial experience with PDA closure using Amplatzer duct occluder (ADO). Our focus was on reporting the complications of trans-catheter closure of PDA using PDA closure devices.

This study was carried out to evaluate the safety and efficacy of Amplatzer device for the transcatheter closure of PDA in our setup.

Material and method

This retrospective and descriptive study was carried at

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Ch. Pervez Elahi Institute of Cardiology, Multan from Feb 2009 to Aug. 2012, during which 61 patient who underwent cardiac catheterization in an attempt to close the PDA by trans-catheter approach using Amplatzer duct occluder device (AGA Medical Corporation, Golden Valley, MN), were evaluated. The patients were diagnosed to have persistent patency of ductus arteriosus (PDA) based on evaluation with a physical examination, x-ray and transthoracic echocardiography / Doppler study were planned to undergo cardiac catheterization to close the PDA by transcatheteroccluder device. Patients with PDA who had cardiac catheterization as diagnostic procedure only were excluded.

Although, the manufacturer exclusion criteria were body weight of less than 5 kg and associated cardiac anomalies, which would require cardiac surgery, exception is made for severe medical condition that necessitate early closure of PDA.

General exclusion criteria include pelvic vein or inferior vena cava thrombosis, sepsis (local and generalized), any type of serious infection less than one month prior to procedure, malignancy with life expectancy less than three years and demonstrated intracardiac thrombi on echocardiography.

Procedure Protocol

Procedure is usually done under local anesthesia and sedation. Access in the femoral vein is obtained with placement of a 5 – 7 F sheath. A 5 – F sheath is placed in the femoral artery. Heparin is used according to the operators' preference. All of our patients were given intravenous heparin with dose of 50 – 75 U/kg.

Mean PA pressure and aortic pressure is recorded. Angiogram in the lateral projection is then performed with a catheter in the proximal descending aorta to clarify the PDA. The PDA size is measured and the PDA is classified by its shape.[21]

The device is selected so that the smaller end is at least 2 mm larger than the narrowest portion of the PDA. An end – hole catheter is passed from the main PA through the PDA into the descending aorta. A stiff exchange guide wire is placed with the tip in the distal descending aorta.

A 5 – 7 F long sheath is then passed over the wire into the descending aorta. The appropriate-sized device is then loaded. The device is then advanced to the tip of the sheath in the descending aorta. The sheath and device are then pulled back into a position just distal to the ampulla. The position of the device is confined with repeated angiograms in the descending aorta and adjusted until the retention skirt is well seated in the ampulla.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, the device can be repositioned or retrieved if needed. If device position is satisfactory, the device is released.Repeat pull back pressures are obtained from ascending to descending aorta to evaluate for possible pressure gradient.

The patient receives intravenous antibiotics for 24 hours and usually discharged on second day after evaluation by x-ray chest, and echo & Doppler study and kept on oral antibiotic for 5 days. Observation of sub acute bacterial endocarditis prophylaxis is recommended for six months or until complete closure is obtained. Patients are instructed to avoid contact sports for one month.

Results

These 61 (22:39 male: female 36.1% and 63.9%) patients underwent cardiac catheterization. Mean age was 7.8 years (ranging from 7 months to 28 years). Mean weight was 23.9 Kg (ranging from 5.5 kg to 84 Kg). Mean fluoroscopy time was 8 minutes. In all patients, duct occlusion was achieved immediately using AGA Amplatzer duct occluder in all patients without residual shunt as revealed by aortogram. Echocardiogram done within 24 hours showed same results. No duct occluder embolized in our study. Upper end of the device protruded into aorta in 6 patients (9.8%) with no gradient on pullback gradient from ascending aorta to descending aorta. No LPA obstruction documented in our patients. There was loss of pulse in 5 (8%) patients which managed successfully with heparin infusion with no further complication.

Discussion

This study was designed to analyze theearly results of percutaneous closure of PDA after reviewing the result our experience in using Amplatzer duct occluder device as alternative to surgical closure of PDA. The results of this work are compared with the corresponding results of various published works.

Regarding the age of the patients different age groups included, even the two challenging extremes, i.e.,

infants and adults. Three patients (4.9%) were less than one year of age and the least age was 7 months. While in Butera *et al*. study,[22] in which 16 symptomatic children with mean age of 18.8 ± 10 months were included and their PDAs were successfully occluded by ADO device and without any complication. So they concluded that closure of moderate to large PDA in very young, symptomatic children is safe and effective technique and resolves the patient's clinical problems.[22]

In adults, surgical closure carries risk not encountered in pediatric patients. Friability and / or calcification of the ducts, atherosclerosis, and aneurysm formation may provide technical challenges.[23] All adults patients (> 12 year of age, n = 13 / 61.21%) included in this study, had successful device deployment. Similar favorable results in adult patients where encountered by Lee *et al*.,[24] Arora *et al*.[25] Hong *et al*.[26]

The manufacturer does not recommend the use of ADO in patients with body weight of less than 5 kg, so we excluded the patients less than 5 kg. However, other studies had included patients with weight less than 5 kg. Fischer *et al*., series[27] included 7 patients under that weight (from 2.6 – 4.4 kg). In all except 2 patients Fischer *et al*., were successful in placing the ADO and there was subsequent complete occlusion with good result on follow-up. However, the procedure was not successful in two small infants of 2.6 and 4 kg body weight because of technical difficulty (kinking of the sheath at right ventricular outflow tract) and excessive procedural and fluoroscopy time.[27]

Similarly, two unsuccessful attempts were mentioned in Shrivastava *et al*.,[28] study from 41 attempts of PDA closure by ADO, 4 months old patient, because of aortic obstruction; Another one year old (4.8 kg) patient in which her PDA was considered too big for the device, considering her age and low weight. In Fischer *et al*. study[13] the procedure was unsuccessful in 2 out of 12 infants because of the technical problems (kinking the sheath) which resulted in excessive procedure time. While no unsuccessful attempts were mentioned in Waight *et al*.,[29] Butera*et al*.[22]

Several complications had been encountered by other series. A significant aortic obstruction, requiring surgical removal of the device was reported by Duke[30] in 2 years old girl after ADO device deployment. While in Hong *et al*. study[26] complications were encountered in four patients (from 37 Patients), one had AV fistula of femoral artery, two had groin hematoma and one had allergic reaction, none were attributed to device implantation, but rather the catheterization procedure itself. In Waight *et al*., study[28] only one patient was noted to have post procedural complication of mild coarctation of the aorta requiring stent implantation (total complication rate was 1.2%). Other studies did not record any complications.[22,23] In published results of the international clinical trial with ADO reported 15 procedure related complications in 316 patients who underwent attempted trans-catheter closure of PDA. Complication included hemolysis, left PA stenosis, device protrusion into aorta, causing coaractation, device misplacement, and one death following device embolization.[13,31] No late complications were recorded on follow-up in this study or any other study related to device implantation. In Bilkis*et al*,[32] series they reported one death following device embolization, while no death recorded in other series.[13,31]

There was no device embolization, LPA obstruction. There was protrusion of retention disc into aorta, in 6 (9.8%) with no clinical or echo gradient across aorta. Pulse loss occurred in 8% patients which was managed successfully with heparin infusion. There was no residual shunt on angiogram. Echocardiography was done next day. There were no residual shunts on aortogram and echocardiogram.

Conclusion

ADO device is effective alternative for PDA occlusion. It meets with most of the desirable characteristics of percutaneous closure device that can be used in most if not all patients with PDA. Long term complications need to be evaluated in our setup.

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