Patent ductus arteriosus (PDA) device closure with venous only access- A retrospective analysis

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ABS TRACT

BACKGROUND

Patent ductus arteriosus (PDA) can be closed percutaneously by device with and without an arterial access. Conventional technique involves a femoral arterial as well as a femoral venous access for closure. Here we summarize our experience in closing the PDA without an arterial access.

Methods

From November 2011 till March 2018, 228 patients were evaluated clinically and echocardiographically for PDA device closure and 201(88%) were found suitable. These 201 patients who underwent transcatheter PDA closure via femoral venous access were included in study. Detailed 2D echocardiography and doppler assessment was performed before procedure. During transcatheter closure angiograms were performed in two views by the venous catheter positioned at the PDA ampulla into the descending aorta. All PDAs were closed by Amplatzer duct occluder-I (ADO1 device). Detailed echocardiographic assessment was performed in each case before releasing the device from the delivery cable and at 5 minutes and 10-minute interval thereafter till there was no significant flow across the duct. Echocardiography was performed immediately after the device deployment, at 12 hours and at 24 hours.

RESULTS

Total 201 patients underwent PDA device closure via femoral venous access. The mean age was 1year and 6 months (range 6months to 47 years). The mean weight was 15kg (range 5 to 66kg). Females constitute 67.6% (136 patients). 9 patients (4.4%) have Down syndrome. 12 (5.9%) have additional cardiac problems. In 108 patients 6x8 size device was placed (53.7%), 44 patients 4x6 size device (21.9%), 30 patients with 8x10 size device (14.9%) and few patients with other sizes. Two patients developed immediate complications which were addressed appropriately.

CONCLUSIONS

PDA device closure without an arterial access can be performed safely and effectively by an experienced interventional cardiologist. Patient selection and detailed assessment of PDA prior to procedure is of paramount importance. This transcatheter closure without an arterial access makes procedure simpler with low morbidity and complications.

KEYWORDS

Congenital heart disease; Patent ductus arteriosus; Device closure; Amplatzer duct occluder

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INTRODUCTION

PDA is a common congenital heart disease with a reported occurrence of 0.87 per thousand live births and constitute 6- 11% of all congenital heart disease[1,2]. First transcatheter method was developed by Porstman et al. in late 1960s, later by Rashkind et al. in late 1970s[3]. Since then the technique has successfully replaced surgical PDA ligation as the primary option in all age groups. The technique has evolved over time and has been better defined in technique as well as device design. FDA approved Gianturco coil, Gianturco- Grifka vascular occlusion device and Amplatzer duct occlude for PDA device closure.

The symptoms and clinical features of PDA vary considerably with the quantity of pulmonary blood flow, the pulmonary vasculature resistance, and the presence of coexistent cardiac anomalies[4]. The evolution and advances in echocardiography has helped a lot in the diagnosis of PDA, determining the size of the duct and its hemodynamic implications non-invasively with a high degree of accuracy. Echocardiography has aided the interventionist in modifying the technique of transcatheter closure of PDA in several ways. Presence and size of the PDA can be measured accurately using echocardiography before closing the defect. Doppler techniques are used to estimate the pulmonary artery pressure[5]. All PDAs that are apparent by physical examination should be closed. Whether to close very small PDAs that are detected serendipitously by echocardiography in the absence of typical physical findings is controversial[6]. PDA can be closed with a variety of devices at the time of cardiac catheterization.

Initially transcatheter PDA closure was done using single or multiple embolization and was attempted successfully both by antegrade as well as retrograde approach[7,8]. In 2003, the AMPLATZER Duct Occluder (ADO) became the first FDA approved device for PDA closure[9]. The strategy for PDA closure by coil varies from operator to operator and includes both antegrade and retrograde approaches. For PDA device closure, venous access must be obtained for device Delivery. Femoral arterial access was an integral part of the technique for angiographically determining the size of the duct, size of the ampulla, providing a landmark during closure and for check angiograms to assess the adequacy of closure. Arterial access adds on to the morbidity, prolongs procedure and fluoroscopy times, needs additional expert wound care and has a small but definite added risk of arterial injury, bleeding, arterial thrombosis, lower limb ischemia and need for enhanced use of heparin. Arterial access is used to obtain angiograms during device delivery. A few authorities have come out with their experience in performing transcatheter closure of PDA without an arterial line. Angiography may be obtained from the venous side by passing a wire antegrade across the duct and exchanging the catheter for appropriate catheter. We are reviewing our experience in closing the PDA without arterial access in a larger cohort and that too across a broader age range with some technical differences from the previous series[10].

PATIENTS and METHODS

This is a retrospective study From November 2011 till March 2018 comprising a review of all patients who underwent transcatheter PDA closure during this period. After an initial experience with a large number of patients using the conventional technique with a combined femoral arterial and venous accesses and using single coil, multiple coils and ADO devices we resorted to deployment of PDA devices in suitable cases using a femoral venous acess only. Device closure was performed for any hemodynamically significant PDA. Detailed Echocardiographic evaluation of the heart was done in all cases including assessment of the PDA size, PDA type, presence and size of PDA ampulla, assessment of branch pulmonary arteries and main pulmonary artery, as well as careful assessment of the aortic arch. Hemodynamic Doppler assessment is performed to assess the PDA shunt as well as the PA pressure. Cases were carefully selected for closure without an arterial line following strict exclusion criteria as below

(1)Inadequate echocardiographic definition of the PDA and aortic arch.

(2)Large ducts with echocardiographic signs of pulmonary hypertension for which full diagnostic hemodynamic assessment is essential prior to attempted PDA device closure.

(3)Small infants with large ducts requiring bigger devices which can potentially cause descending aortic obstruction.

(4)Those without a good ampulla preventing the use of ADO 1 design device.

(5)Recanalized ducts following surgical closure.

(6)Patients with additional lesions requiring hemodynamic assessment and/or intervention.

Cross over to a hybrid approach was decided as the default strategy if,

(1)Where contrast opacification on injection into the duct ampulla from venous side was insufficient to delineate the duct clearly.

(2)There was difficulty in securing a stable device deployment without major vascular compromise.

(3)Device seemed to be of inappropriate size on attempted deployment.

(4)Device dislodgment occurs requiring a snare assisted retrieval.

Informed consent was obtained in all cases. Procedures were performed under general anesthesia in children younger than 12 years and in those who could not tolerate the procedure under local anesthesia. Local anesthesia was used in older children and adults. Blood pressure was monitored noninvasively. Heparin 50 unit/kg bolus was administered after securing vascular access. This study was approved by the institute's research and ethical committees.

ECHOCARDIOGRAPHIC ASSESSMENT OF PDA

Detailed pre procedure echocardiographic assessments of all cases were done using Philip's EPIC 7 and Philip's HD 11 XE echocardiography system, Andover, MA, USA by the primary operator. 2-Dimensional echo evaluations were done as per the standard protocol. PDA was visualized in high parasternal short axis view. Measurement of the PDA opening into the pulmonary artery was done in multiple cardiac cycles and the largest measurement was accepted. The ampulla was visualized and measured carefully in suprasternal view along with careful assessment of aortic arch for any possible coarctation or any arch anomaly. Doppler assessment of the duct flow in the main and branch pulmonary arteries and the descending thoracic aorta were estimated and any flow acceleration noted. The device size was provisionally decided as 2mm larger than the measured duct size.

DUCT CLOSURE

As previously decided cases selected for a venous line only approach was prepared under anesthesia, femoral vein accessed using a micro puncture needle for pediatric cases and a standard puncture needle for adults. In cases where an inadvertent femoral arterial puncture occurred an appropriate guidewire was inserted and retained till the procedure was over. An arterial sheath was not inserted. PDA is crossed from the venous side using a straight tipped 0.032-inch Terumo wire. (Terumo corp. Tokyo, Japan) through a 5F/6F Multipurpose angiographic catheter (MPA) (cook medical inc, Bloomington, IN). The catheter tip was parked in the descending thoracic aorta just beyond the PDA ampulla, guide wire removed. A 10 ml leur lock syringe loaded with contrast was used for injection in all cases. 3-5 ml of contrast was injected by hand injection in infants and children and 5-8 ml for adults. Angiography was done in the left lateral projection in all cases and in left anterior oblique (LAO) projection when further delineation was required. Injection into the ampulla causes a contrast spillage through the duct into the pulmonary artery in all cases causing adequate opacification to assess the size of the PDA. In cases where the catheter recoil on injection prevented a proper visualization, a "Y connector" used for coronary angioplasty was connected to the catheter and a 0.014 inch coronary guide wire was passed through the catheter and parked in the descending aorta. Hand injection of contrast was done through the side arm of the Y connector. This helped to prevent catheter recoil and obtain good quality angiogram. Relation of tracheal air shadow with the duct ampulla was carefully noted in the lateral projection and served as angiographic landmark for positioning the aortic retention disc. The angiographically measured duct size was compared with the echocardiographic measurement. Device size was selected as 2mm larger than the smallest angiographic diameter. The MPA catheter was exchanged over a support wire with a Mullins sheath (William Cook Europe) of specified size for the selected device. The device was deployed in accordance with the standard procedure. Once device is deployed echocardiographic evaluation was repeated at 5 minutes to assess adequacy of closure, residual shunt, turbulence or gradient if any in the left, right pulmonary artery and post ductal aorta. Lower descending thoracic aorta was assessed echocardiographically from an epigastric window for any spectral broadening or turbulence. If a continuous flow was seen through the duct at five minutes, echocardiography was repeated at 10 minutes interval for 30 minutes. If a continuous flow persisted device was upsized by 2mm. If there is no residual continuous flow the device was released from the delivery cable without further angiogram and echocardiography repeated before the Mullins sheath used for device deployment was removed. Echocardiographic assessment was repeated at 12 hours, 24 hours (pre discharge) and at 30 days post procedure.

Patients were discharged on next day. All patients had 1 month follow up after the procedure, then after 3 months, 6 months and then annually. Follow up variables include clinical condition, ECG, and detailed echocardiography concentrating on assessing the device position, presence of residual shunt, assessment of branch pulmonary arteries and aortic arch patency as well as assessing cardiac function and excluding the presence of pericardial effusion. Statistical analyses were performed using SPSS statistics software. Values are expressed as frequencies and percentages or mean and standard deviations and range as appropriate.

Results

During this period 228 patients were evaluated clinically and echocardiographically for a venous line only approach for PDA closure and 201(88%) were found suitable. These 201 patients underwent PDA device closure at department of cardiology, Government medical college, Calicut, India.

The mean age was 1years 6 months (range 6months to 47 years). The mean weight was 15kg (range 5 to 66kg). Females constitute 67.6% (136 patients). 9 patients (4.4%) have Down syndrome. 12 (5.9%) have additional cardiac problems.

	Mean	Sd	Minimum	Maximum
Height(cm)	88.4	19.3	61	172
Weight(kg)	15	14.14	5	66
Age(years)	1.5	8.43	0.5	47

Table 1: Demographic Data

PDA was closed by Amplatzer Duct Occluder type 1 (ADO1) device or another brand of same design. Size and type of PDA devices used is outlined in

	Device size	Percentage
05-apr	2	1
04-jun	32	15.9
06-may	1	0.5
06-aug	123	61.2
08-oct	30	14.9
10-dec	5	2.5
14/16	2	1
Dec-14	6	3
Total	201	100

Table 2: PDA Device Size Used

In 123 patients 6/8 size device was placed (61.2%), 32 patients 4/6 size device (15.9%), 30 patients with 8/10 size device (14.9%) and few patients with other size devices.

In our study, the mean procedure time was 18.3 min ± 3.6 min, the mean fluoroscopic time was 7min ± 2.1 min and the mean contrast given was 18 ml ± 11 ml

	Mean	Sd	Minimum	Maximum
Contrast(ml)	18	11	7	28
Flouro(min)	7.3	2.1	2	22
Procedure time(min)	18.3	3.6	12	40

Table 3: Procedure Details

Two patients had immediate complication. Both had device embolization requiring snaring of device, and were subsequently closed with 2 mm higher sized device. One of these had common iliac artery injury during snaring of the device requiring surgical intervention. No patient had residual shunt and no patient had arch obstruction.

Closure of the PDA through interventional cardiac

DISCUSSION

catheterization is a well-established way of management[11-13]. This is accomplished mainly using Embolization coils (William Cook Europe) or Amplatzer duct occluder (ADO) type 1 or less commonly ADO 2(AGA Medical Corporation, Golden Valley, MN). Other devices include Lifetech Duct occluder (ShenZhen Lifetech Scientific Inc), Cocoon PDA device (Vascular Innovtion Co Ltd, Thailand) or Oclutech ductal occluders (Occlutech International AB, Sweden) which have a basic design same as ADO[14,15].

The conventional technique involves pre procedure assessment using echocardiography, and an interventional approach using both femoral arterial and venous access. An arterial access carries an additional procedure and flouro time, use of a pressure injector with added contrast usage, additional manpower and technique to attain hemostasis and a small but definite risk of access site and vascular complications including limb ischemia more so in small children and infants and added morbidity. A few investigators have described PDA closure without an arterial line. We hereby describe our experience in a larger cohort with some technical differences from the previous reports[10].

Echocardiography helps in management of PDA by confirming the diagnosis, estimating the size, assessing the hemodynamics, delineating anatomy of the duct and related great vessels, assessing the need for closure, anatomical feasibility of percutaneous closure, and estimating the route and size of device for closure. Using a venous line only technique will be based on the echocardiographic assessment of the PDA, for example: if the PDA is so small, it cannot be crossed from the venous side and a retrograde approach should be used. If it is too large an arterial line will be essential to make sure that using a large device will not compromise the aortic arch[16,17]. Also in small infants with small or no ampulla, or with some isthmus hypoplasia, putting a device might cause arch obstruction, so arterial line will be essential in such cases. Doing detailed hemodynamic assessment in the cath lab for patients with PDA depends up on the echo findings. For those with no evidence of significant pulmonary hypertension there is no need for detailed hemodynamic assessment which might prolong the timing of the procedure. PDA is closed through the venous side. The arterial line is used for continuous monitoring of the blood pressure, doing arterial blood gas as needed, as well as doing aortogram pre and post PDA device closure. Avoiding arterial line (sheath) may prevent the possible complications of arterial puncture including thrombosis, bleeding, longer catheterization and fluoroscopic time and probably prolonged hospital stay.

Complications such as arterial disruption, or acute occlusion, may be limb-threatening. PDA closure using a venous access alone is possible and safe in experienced hands, provided that there is appropriate echocardiographic assessment, careful PDA definition by angiogram at the PDA ampulla or proximal descending aorta. The advantages of avoiding arterial access include, reducing the heparin dose, and elimination of the inherent risks of arterial puncture (bleeding, femoral artery thrombosis). The procedure time, as well as the fluoroscopic time is shorter and many patients can potentially be discharged early. It is important to have a good positioning of the catheter at the PDA ampulla-proximal descending aorta using either hand injection or pump injection with low PSI (pounds per square inch) for angiographic PDA assessment. Angiograms can also be performed through the long delivery sheath. Arterial access may be required in some patient especially small infants, patients with large ductus, those who need careful assessment of the aortic arch and isthmus as well as those requiring detailed hemodynamic assessment, depending up on the interventionist decision and plan of intervention during the pre-intervention assessment.

CONCLUSION

PDA device closure without an arterial access can be performed safely and effectively with experienced hands. Patient selection and appropriate pre intervention detailed echocardiography and procedure planning are essential for accomplishing device closure of PDA with or without arterial access. The procedure is simplified considerably and many patients can potentially be discharged on the day of the procedure.

Conflict of Interest

None

Ethical Standards

Patient/family consent was taken for the procedure including explanation of the details of the procedure, vascular access as well as the possible complications.

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