Original article

Contemporary outcomes of percutaneous closure of patent ductus arteriosus in adolescents and adults

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ARTICLE INFO

Article history:
Received 5 April 2017
Accepted 5 August 2017
Available online 9 August 2017

Keywords:
Patent ductus arteriosus
Amplatzer duct occluder
Cera device
Residual shunt

ABSTRACT

Background: Catheter based treatment has gained wide acceptance for management of patent ductus arteriosus (PDA) ever since its introduction. Percutaneous closure in adults can be challenging because of anatomical factors including large sizes, associated pulmonary arterial hypertension (PAH) and co-morbidities. This study aimed to provide comprehensive contemporary data on the safety and efficacy of percutaneous device closure of PDA in adult and adolescent population at a large referral center.

Methods: This single-center retrospective analysis included 70 patients (33 adolescents and 37 adults) who underwent successful percutaneous device closure of PDA between January 2011 and February 2017. Baseline patient demographics, clinical characteristics, procedural and device related variables, and immediate outcomes during hospital stay were recorded. Patients were followed up for residual shunt and complications.

Results: Of 70 PDA device closure cases, 71.4% were females; the mean age was 23 years (range: 10-58years). Devices used were 4-Cook’s detachable coils, 64-occluders (ADO-I and II, Lifetech, Cardi-O-Fix), 1-vascular plug and 1-ventricular septal occluder device. Device success was achieved in all including those with very large PDAs. At 24-h post-procedure, the success rate of transcatheter intervention was 95.7%. At 6-months follow up, complete closure was observed in all (mean follow up duration-531 days). In patients with severe PAH, significant immediate and sustained reduction of the mean pulmonary pressure was observed (77 mmHg to 33 mmHg; P = 0.014). No procedure-related complications including death, device embolization and stenosis of aorta or pulmonary artery occurred.

Conclusions: In contemporary practice, percutaneous device closure is an effective and safe treatment option for adolescent and adult PDA patients.

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1. Introduction

Patent ductus arteriosus (PDA) is abnormal communication between the descending thoracic aorta and the pulmonary artery that results from persistent patency of the foetal ductus arteriosus, and accounts for 6–11% of all congenital heart defects.\(^1\) While most cases of PDA are detected and treated in infancy and early childhood, it has a prevalence of 0.05% in adulthood.\(^2\) Prior to the era of surgical and percutaneous closure, untreated PDA had an annual mortality rate of1% (20–29 year age group) and 1.8% (30 years of age and above).\(^3\) Successful closure of PDA can significantly reduce the long-term risk of endocarditis, arrhythmias and mortality. Percutaneous transcatheter closure of PDA has been established as a safe and effective alternative to surgical closure in infants, but contemporary data focussing on adolescents and adults are limited. In the current era, surgical closure is mainly indicated for large and complex forms of ductus not amenable for transcatheter closure and ductus associated with additional complex cardiac anomalies requiring surgical management. Percutaneous closure of the ductus in adults can be challenging because of anatomical variations, associated findings and complications such as pulmonary arterial hypertension (PAH), left ventricular systolic dysfunction, infective endocarditis, calcification and aneurysm formation. Much of the published data of PDA device closure in adults is focussed on the Amplatzer duct occluder (ADO I and II, AGA Medical Corporation, Golden Valley, Minnesota, USA) whose largest available size is 16/14 mm.\(^4,5\) Devices larger than this size are now available from other manufacturers (Lifetech Scientific and Starway Medical Corporation, both China), and has made device closure of very large ductus feasible. However, there is a paucity of data on the use of these devices in adults. Aim of this

 Abbreviations: ADO, Amplatzer duct occluder; PAH, pulmonary arterial hypertension; PDA, patent ductus arteriosus; PVR, pulmonary vascular resistance; SVR, systemic vascular resistance; VSD, ventricular septal defect.

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retrospective analysis was to present our recent data on 70 adolescent and adult patients who underwent percutaneous PDA closure using contemporary devices.

2. Materials and methods

2.1. Study design, population and setting

Between January 2011 and February 2017, 266 patients with PDA underwent catheterization study with intent to perform device closure at Christian Medical College Hospital, a large referral center performing interventional procedures for paediatric and grown-up congenital heart diseases in India (Fig. 1). For the current retrospective analysis, we included all patients 10 years or older who underwent successful percutaneous PDA closure during the above-mentioned period. Adolescence was defined by age group 10–19 years and adults as those who were 20 years or older. All patients had complete physical examination followed by routine blood chemistry, 12-lead electrocardiography, chest radiograph and transthoracic echocardiography. Demographics, clinical and procedural details were recorded for each patient.

2.2. Procedure details

Transcatheter device closure of PDA was indicated in any of the following: signs of left ventricular volume overload, patients with PAH but with pulmonary artery pressure (PAP) <2/3 of systemic pressure or pulmonary vascular resistance (PVR) less than 2/3 of systemic vascular resistance (SVR), small PDAs with continuous murmur, and patients with PAH and PAP > 2/3 of systemic pressure or PVR > 2/3 of SVR if the net left to right shunt was more than 1.5 or favourable response on pulmonary vasoreactive/balloon occlusion testing, provided the anatomy is suitable. Device occlusion procedures were performed by experienced operators and usually done under local anesthesia for adults. General anesthesia was reserved for those under 15 years of age and adults who requested it. A single dose of intravenous antibiotic was administered (cefazolin) 25 mg/kg of body weight (max 1 g) 30 min before the procedure. Femoral arterial and venous access was obtained for all patients following which they received 100 international unit (IU)/kg (maximum 5000 IU) of intravenous heparin. After hemodynamic measurements, aortic angiogram was performed in lateral, right oblique, and/or left oblique views to visualize the ductus. PDA was categorized based on the angiographic classification described by Krichenko et al. Conventional antegrade approach was used to cross the PDA in most patients, while snare assisted retrograde approach was utilized in whom the conventional approach failed. The choice of the device was at the discretion of the operator and was influenced by ductus morphology, availability of device sizes and cost considerations. In general, detachable coils were used if the PDA size was ≤3 mm at the narrowest diameter (usually at the pulmonary arterial end of the duct). Duct occluders were used for PDAs that were >3 mm. The duct occluder sizes were at least 2 mm larger than the narrowest diameter of the PDA. Devices were

![Fig. 1. Study flow chart.](image_url)
deployed via venous approach in most patients, while arterial approach was reserved for difficult cases. Standard procedure was followed for loading and deploying the devices. The device was replaced by another device of different size if necessary. Descending aortogram was performed before and 10 min after device release to assess device position and residual shunt. At the end of the procedure, hemostasis at vascular access site was achieved by manual compression.

2.3. Device details

Devices used for occlusion were detachable coils (Cook Cardiology, Bloomington, Indiana, USA), vascular plugs (AGA Medical Corporation, Golden Valley, Minnesota, USA) or one of the following occluder devices: Amplatzer duct occluder (AGA Medical Corporation), Cardi-O-Fix Duct Occluder (Starway Medical Corporation, China), Heart and Cera Lifetech duct occluder (both ShenZhen Lifetech Scientific Inc., China).

2.4. Outcomes assessed

Outcomes measured include device success, immediate post-procedural residual shunt, complications including device embo-

2.5. Follow up

Follow up echocardiogram was performed on next day after the procedure to assess device position and residual shunt. Infective endocarditis prophylaxis and antiplatelets were recommended for 6 months, post-procedure. First clinical follow up and echocardiography were undertaken usually at 1–6 months after the procedure. Further follow ups were available at a range of 1–5 years.

2.6. Statistical methods

Data were summarized using mean ± standard deviation for continuous variables, and frequencies (percentages) for categorical variables. Median (interquartile range) was provided for continuous variables that had a skewed distribution. Continuous variables were compared using paired or independent samples t-test. Fisher’s exact or Chi square test was used for comparison of categorical variables. Pearson’s correlation was used to test the association between continuous variables. All statistical tests were two-sided with an alpha level set at 5%. All data were analyzed using SPSS software version 21.0 (IBM Corp., Armonk, NY, USA).

2.7. Ethics

This study was done in accordance with the ethical standards as laid down in the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. All patients gave informed consent prior to the procedure.

3. Results

3.1. Clinical characteristics

During the study period, a total of 70 patients (33 adolescents, 37 adults) underwent percutaneous PDA device closure (Fig. 1). The mean age of the study population was 23 years (range 10–58 years), and 71.4% of them were females. Twenty-six (37.1%) patients had associated PAH, and 15 (21.4%) had other cardiac lesions. Associated cardiac anomalies include: 4 atrial septal defects, 4 aortic stenosis with 2 bicuspid aortic valves, 3 mitral regurgitation, 1 coarctation of aorta, 1 pulmonary valvar stenosis, 1 ventricular septal defect, 1 interrupted inferior vena cava, 1 mitral valve prolapse, 1 bilateral superior vena cava and 1 congenital complete heart block. Fifty-eight (82.9%) were symptomatic: dyspnoea (67.1%) and palpitations (25.7%) were the most common presenting symptoms. Cardiomegaly was present in 52.9%. Normal electrocardiogram was noted in 34.3%. Left ventricular hypertrophy, biventricular hypertrophy and right ventricular hypertrophy were noted in 45.7%, 18.6% and 1.4%, respectively. All patients were in sinus rhythm. Four (5.7%) had left ventricular systolic dysfunction (Table 1). Apart from age and presence of diabetes and hypertension, there were no differences between adolescent and adult groups. The mean pulmonary artery and aortic pressures were higher in adults as compared to adolescents (Table 2).

3.2. PDA characteristics

According to the classification adopted by Krichenko et al,8 72.9% had type A PDA; 43.3% had type B; 8.6% had type C, 2.9% had type D and 5.7% were type E (Table 2). Two patients had morphological types which did not fit into any of the above categories, and morphological data was missing for 2. PDA was best visualised in right anterior oblique view in 17.1% of the patients. The median PDA size at the narrowest portion on angiography was 4.7 mm (range 1.5–16.5 mm). The median length of the PDA was 8.9 mm. Twenty-nine (41.4%) patients had a PDA size greater than 5 mm. The mean pulmonary artery pressure correlated

| Table 1 | Patient characteristics. |
|---------|--------------------------|
|         | Total (N = 70) | Adolescence (n = 33) | Adults (n = 37) |
| Age, years | 23 ± 11 | 14 ± 3 | 31 ± 10 |
| Female | 50 (71.4) | 20 (60.6) | 30 (81.1) |
| Systemic hypertension | 5 (7) | 0 | 5 (15.7) |
| Diabetes mellitus | 4 (5.6) | 0 | 4 (10.8) |
| Incidentally detected | 12 (17.1) | 9 (27.3) | 3 (8.1) |
| Symptomatic | 58 (82.9) | 24 (72.7) | 34 (91.9) |
| Associated cardiac lesions | 15 (21.1) | 5 (15.1) | 10 (27.0) |
| Left ventricular systolic dysfunction | 4 (5.6) | 1 (3.0) | 3 (8.1) |
| Hemoglobin, g/dl | 12.5 ± 1.4 | 12.5 ± 1.4 | 12.5 ± 1.4 |
| Serum creatinine, mg/dl | 0.7 ± 0.2 | 0.6 ± 0.2 | 0.8 ± 0.2 |

Data are expressed as mean ± standard deviation or as counts (percentages).
significantly with the PDA size (correlation coefficient, $r = 0.732$, $p < 0.001$). The mean PDA size was $4.5 \pm 2.2$ mm on echocardiography (Fig. 2).

### 3.3. Procedural details

Type and size of the devices used are presented in Table 2 and Fig. 3. Lifetech duct occluder device was the commonest device used. Coils were used in four patients. In most cases (90%), PDA was crossed anterogradely through the venous side. In remaining cases except 1 patient with interrupted inferior vena cava, the ductus was crossed retrogradely from the aortic side and the wire was snared and exteriorised at the femoral vein. Four devices (3 coils, 1 ADO II) were deployed retrogradely from the aortic side. One patient with type D ductus had kinking of the introducer sheath during device advancement. Device deployment was achieved by snaring the sheath from the aortic side and applying traction from both ends. Three patients had concomitant interventions for other

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**Table 2**

|                  | Total N = 70 | Adolescence N = 33 | Adults N = 37 | p value |
|------------------|--------------|--------------------|---------------|---------|
| PDA size, mm (Echocardiography) | $4.8 \pm 2.2$ | $4.6 \pm 2.4$ | $5.1 \pm 2.0$ | 0.33    |
| PDA type         |              |                    |               |         |
| A1               | 44 (62.9)    | 18 (54.5)          | 26 (70.3)     | 0.18    |
| A2               | 7 (10)       | 3 (9.1)            | 4 (10.8)      |         |
| B1               | 2 (2.9)      | 1 (3)              | 1 (2.7)       |         |
| B2               | 1 (1.4)      | 0                  | 1 (2.7)       |         |
| C                | 6 (8.6)      | 2 (6.1)            | 4 (10.8)      |         |
| D                | 2 (2.9)      | 2 (6.1)            | 0             |         |
| E                | 4 (5.7)      | 3 (9.1)            | 1 (2.7)       |         |
| Unclassified     | 4 (5.7)      | 4 (12.1)           | 0             |         |
| Minimum diameter of the ductus, mm | $4.7 (3.3–6.7)$ | $4.1 (2.4–5.5)$ | $4.9 (4–8.2)$ | 0.21    |
| Diameter at the aortic end, mm  | $10.8 (7.5–15.5)$ | $9.1 (7.4–14.4)$ | $11.2 (7.7–19.1)$ | 0.46    |
| PDA length, mm | $8.9 (5.1–13.4)$ | $8.9 (5–14.3)$ | $8.9 (5.2–12)$ | 0.97    |
| Mean PA pressure, mmHg | $23 (16–30)$ | $18 (14–27)$ | $26 (22–33)$ | 0.02    |
| Mean aortic pressure, mmHg | $84 \pm 19$ | $74 \pm 16$ | $93 \pm 18$ | <0.001  |
| Approach for crossing PDA |              |                    |               |         |
| Anterograde      | 63 (90)      | 29 (87.9)          | 34 (91.9)     | 0.58    |
| Retrograde       | 7 (10)       | 4 (12.1)           | 3 (8.1)       |         |
| Procedure time, min | $71 \pm 32$ | $74 \pm 37$ | $68 \pm 27$ | 0.41    |
| Type of device   |              |                    |               |         |
| Duct Occluder ADO I and II | 7 (10)   | 3 (9.1)            | 4 (10.8)      |         |
| Lifetech         | 56 (80)      | 24 (72.7)          | 32 (86.5)     |         |
| Cardiofix        | 1 (1.4)      | 1 (3)              | 0             |         |
| Vascular plug    | 1 (1.4)      | 1 (3)              | 0             |         |
| Muscular VSD device | 1 (1.4) | 1 (3)              | 0             |         |
| Coil             | 4 (5.7)      | 3 (9.1)            | 1 (2.7)       |         |
| Residual shunt   |              |                    |               |         |
| Immediate post-deployment (Aortogram) | 43 (61.4) | 19 (57.6) | 24 (64.8) | 0.53    |
| At 24 h (Echocardiography) | 3 (4.3)     | 0                  | 3 (8.1)       | 0.24    |

Data are expressed as mean ± standard deviation, median (interquartile range) or as counts (percentages). PDA—patent ductus arteriosus; ADO—Amplatzer duct occlude; VSD—ventricular septal defect.
cardiac lesions: 2 device closure of atrial septal defect, 1 balloon aortic valvuloplasty. Mean procedure time for all patients was 71 ± 32 min.

3.4. Outcomes

Device success was achieved with the first chosen device in all except 1 patient who needed a larger size device. Immediate complete occlusion was achieved in 38.6% on angiography. On echocardiography at 24 h, the occlusion rate was 95.7%. The remaining 4.3% (3 patients) achieved complete closure at 6-months echocardiographic follow up. These three patients had no residual shunt following the devices: ADOII (6/6), Cera occluder (18/16 and 12/10). There was no statistically significant difference between the Cera occluder and ADOII device with regard to immediate (62.5% versus 57.1%; p = 0.99) or 24-h post-procedure (3.6% versus 0; p = 0.99) residual shunt. Among the 29 large size PDAs, 20% had residual shunt immediate post-procedure. At 24-h post procedure, residual shunt was present in only 1 of them. In patients with severe PAH (mean pulmonary artery pressure >50 mmHg; n = 8), successful device deployment resulted in significant immediate reduction of the mean pulmonary artery pressures (77–33 mmHg; p = 0.014). There were no procedural or in-hospital deaths, device embolization, cardiac perforation, tamponade, post-procedural left ventricular systolic dysfunction or infection. Median (interquartile range) duration of hospital stay was 3 (3–4) days.

3.5. Follow up

Mean follow up duration was 531 days (range 11–2059 days). Fifty-five (79%) and 43 (61.4%) patients had more than 6 months clinical and echocardiographic follow up, respectively. Complete closure of the ductus and clinical improvement was documented in all patients who had follow up (Fig. 4). In patients who had baseline PAH, there was significant reduction of the peak tricuspid valve systolic gradient at follow up (33 ± 17–19 ± 7 mmHg; p = 0.03). No complications such as device migration, recanalization, hemolysis or endocarditis were encountered during follow up.

4. Discussion

Since the first percutaneous closure of PDA by Porstman in 1967, device technology has evolved and a variety of devices and techniques are currently available for catheter based treatment in children and adults. In current practice, while small to moderate size ductus are closed easily with various devices such as detachable coils, occluder devices and vascular plugs, surgery is mainly reserved for large complex ductus not amenable to transcatheter closure. Present study sought to provide contemporary data on the safety, efficacy, and follow up results of percutaneous device closure of PDA in adolescents and adults at a large referral center, spanning over a period of 6 years. Successful device deployment without immediate or long-term complications was achieved in all 70 study patients. All patients had complete occlusion of the ductus at follow up. Although the observed immediate complete occlusion rate on angiography was lower than those in previous reports, the 24-h post-procedure and follow up occlusion rates were comparable to previously reported data in adults. The benefits were valid across all device types and sizes.

Clinical manifestation of PDA in adults varies from asymptomatic (incidental diagnosis) to overt heart failure, severe PAH or Eisenmenger’s syndrome. In this adolescent and adult series, most patients were symptomatic; dyspnea and palpitations being their predominant symptoms. Indications for device closure in this series included audible small PDAs, PDAs with features of left ventricular volume overload, and severe PAH with demonstrated vasoreactivity or >20% drop in pulmonary artery systolic pressure with constant systemic pressure on balloon or device occlusion testing. PDA was not closed in 3 patients who had severe PAH and no significant drop in pulmonary artery systolic pressure on balloon/device occlusion testing. One patient who had bronchietasis and left segmental pulmonary artery aneurysm underwent left lower lobectomy and ligation of the PDA. Another patient with a very large ductus (>18 mm) was referred for surgery (Fig. 1).
Immediate and sustained drop in pulmonary artery pressures were observed post-procedure in patients with baseline reversible severe PAH. Similar findings were observed in previous studies of PDA device closure in adults with severe reversible PAH.\(^\text{13,14}\)

Several factors determine the success of percutaneous device closure of PDA including vascular accessibility, size and morphology of the ductus, and device selection. Retrograde arterial approach was used to cross the ductus in 7 patients; one had

Fig. 4. Pre- procedure and follow up chest radiograph and electrocardiograms.
Panel A: pre-procedure chest radiograph. Panel B: follow up chest radiograph. Panel C: pre-procedure electrocardiogram. Panel D: Follow up electrocardiogram.
interrupted inferior vena cava and other 6 had failed initial venous approach. ADO II devices\(^{15}\) and coils are the suitable devices for deployment by retrograde aortic approach. Small-sized PDAs are generally closed using coils, and occluders are recommended for moderate to large ones. In our series, coils were used for small PDAs (mean diameter of 2.2 mm). Vascular plug-4 was used for a type E PDA. While ADO device is available up to 16 × 14 mm in size, Cera occluder device that has a titanium nitride coating to effectively reduce nickel release and thrombosis, is available up to 26 × 24 mm in size and hence useful for large ducts. In our series, 9 patients had ductus sizes more than the largest available ADO device; the largest device used was a 24 × 22 mm Cera duct occluder. Device success was achieved without technical difficulties for each of these large size devices and only 1 of them had residual shunt 24-h post-procedure. Other options for defects larger than 14 mm include Cardi-O-Fix device, Cocoon device (Cocoon Vascular Innovation Nonthaburi, Thailand) and use of muscular septal defect occluder. Recently, a newer device (Occlutech occluder, Occlutech Germany) was introduced with designs to overcome some of the limitations of the ADO device.\(^{16–18}\)

This newer device has a core that is wider at the pulmonary end (to reduce risk of embolization), longer lengths throughout the ranges of sizes (better stability in longer ducts), prominent screw attachment at the pulmonary end (facilitates easy snaring) and absence of distal clamps at the aortic end (reduce risk of aortic obstruction). The device is available up to 24/18 mm (diameter) and 16 mm (length) in size. Most of the devices used in our series were Cera occluders mostly because of cost considerations and availability of wide range of sizes. Knowledge, expertise and availability of a wide range of devices are hence necessary for successful percutaneous management of adult PDA.

Kinking of long introducer sheath was encountered in 1 patient who had a D type ductus. Sheath kinking is one of the technical difficulties usually observed during PDA device closure in infants and occurs due to the presence of a sharp right ventricular outflow tract-pulmonary artery angle.\(^{19}\) Despite the availability of thinner and more flexible delivery cables, kinking of introducer sheaths can still occur at the curve of the right ventricular outflow tract during advancement of a constrained occluder device. In adults, this technical problem could occur in complex and unfavourable duct morphologies and can be overcome by either using a stiffer Cook sheath, for instance Ansel sheath (Flexor Ansel; Cook Medical, Bloomington, IN, USA) or by snaring the long sheath from the aortic side.

Severe complications have been described after percutaneous device closure of PDA that include device embolization, narrowing of the aortic isthmus and left pulmonary artery, hemolysis, device infection, post-procedure left ventricular systolic dysfunction and spontaneous recanalization.\(^{20–25}\) Certain patients are at high risk for transient left ventricular systolic dysfunction post PDA closure: large shunts, pre-procedure left ventricular systolic dysfunction, associated cardiac conditions such as mitral regurgitation and higher pulmonary artery pressure. Postulated mechanisms for deterioration of systolic function post-procedure include sudden reduction of preload in a previously overloaded left ventricle and increase in afterload. Although left pulmonary artery stenosis is one of the most important complications in the infant, it is not of concern in adults because of the large diameter of pulmonary artery branches. None of the above-mentioned complications were observed in our study.

4.1. Limitation

This was a retrospective single center study with a relatively smaller sample size. Selection of patients and devices were at the discretion of the operator. Ours being a large referral center, there is a possibility of referral bias. Six-months follow up echocardiography was not available for all patients. Nevertheless, complete occlusion of the ductus was achieved in all patients during course of their follow up.

5. Conclusions

Our data suggests that percutaneous closure of PDA with contemporary devices is safe and efficacious in adolescents and adults, including in those with large ductus and reversible severe PAH. Expertise and availability of a wide range of devices are the cornerstone of catheter based management of PDA in adult and adolescent population.

Conflicts of interest

None.

Funding

None.

Acknowledgements

None.

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