

Prospective evaluation of the feasibility, safety, and efficacy of Cocoon Duct Occluder for transcatheter closure of large patent ductus arteriosus: A single-center study with short- and medium-term follow-up results

Santosh Kumar Sinha, Mahmudula Razi, Rama Niwas Pandey, Prakash Kumar, Vinay Krishna, Mukesh Jitendra Jha, Vikas Mishra, Mohammad Asif, Nasar Abdali, Pradyot Tewari, Ramesh Thakur, Umeshwar Pandey, Chandra Mohan Varma

Department of Cardiology, LPS Institute of Cardiology, G.S.V.M. Medical College, Kanpur, Uttar Pradesh-India

ABSTRACT

Objective: To evaluate the feasibility, safety, and efficacy of a novel Cocoon Duct Occluder device for the transcatheter closure (TCC) of large patent ductus arteriosus (PDA).

Methods: In this prospective, non-randomized study, consecutive patients with large PDA (narrowest diameter: $\geq 3.5/4.0$ mm in symptomatic/asymptomatic patients, respectively), who underwent TCC with Cocoon Duct Occluder at our institute between November, 2012 and June, 2016 were examined. TCC was performed using the standard technique, and devices were antegradely delivered via 6–10F delivery sheaths. Device embolization, residual shunt, hemolysis, left pulmonary artery (LPA) stenosis, procedural and fluoroscopy time, and mortality were assessed. Patients were followed-up by transthoracic echocardiography with color Doppler imaging at 24 h (D1), 1 month (D30), and 6 months (D180) after implantation.

Results: A total of 57 patients (age: 11.7 ± 2.8 years; weight: 22.3 ± 3.5 kg) were enrolled. The mean narrowest diameter was 7.4 ± 0.7 mm. The PDA closure was successfully performed in each patient. Fluoroscopy and procedural time was 6.7 ± 3.2 min and 23.9 ± 2.7 min, respectively. Postprocedural angiography revealed that 49 (85.9%) patients had immediate and complete closure, whereas 8 (14.1%) had residual shunt. Color Doppler imaging at D1 revealed complete closure in 52 (91.3%) patients. At D30, complete closure was reported in all patients and was maintained at D180. Hemolysis, embolization, obstruction of LPA or descending aorta, and death were not reported till D180.

Conclusion: TCC using Cocoon Duct Occluder is feasible, safe, and effective in the management of patients with large PDA, with excellent results on short- and medium-term follow-up. (*Anatol J Cardiol* 2017; 18: 321-7)

Keywords: congenital heart disease, transcatheter closure, Cocoon Duct Occluder, large patent ductus arteriosus

Introduction

Patent ductus arteriosus (PDA), a persistent left-to-right shunt at the great arterial level, accounts up to 10% of all congenital heart disease (1). Natural history spans from being asymptomatic to pulmonary vascular disease, atrial fibrillation, dissection of the pulmonary artery, endocarditis, Eisenmenger's syndrome, congestive heart failure, and sudden death (2, 3). In the background of acquired cardiac disease, previously unnoticed ductus may become symptomatic. Therefore, all PDA with left atrial and/or left ventricular enlargement, pulmonary arterial hypertension, or symptoms should undergo either transcatheter closure (TCC) or surgical intervention as mortality rates may

reach 20% at third decade and increase by 4% per year if left untreated. Surgery is recommended when it is not amenable for device closure because of too large or distorted ductal anatomy (e.g., aneurysm or endarteritis). In adults, it may pose some additional problems due to the general tissue friability in the vicinity of ductus, the calcification of pulmonary artery and/or the ductus, atherosclerosis, the aneurysm formation, and the presence of other unrelated comorbid conditions which may adversely affect the operative outcomes (1). Since the first successful attempt of TCC in 1967 using an Ivalon plug, it has emerged as a valuable alternative to surgery because of its simplicity, high success rates, and lesser complications (e.g., device embolization and the protrusion of device into the left pulmonary artery

Address for correspondence: Dr. Santosh Kumar Sinha, MD, Department of Cardiology, LPS Institute of Cardiology
G.S.V.M. Medical College, 208002, Kanpur, Uttar Pradesh, India
Phone: +91 0512 255 61 99 Fax: +91 0512 255 65 21 E-mail: fionasan@rediffmail.com

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(LPA) and descending aorta) (4). In last three decade or more, a number of different devices have been developed and evaluated including Occlutech PDA Occluder (4), Rashkind umbrella device (5), Gianturco coils (6, 7), occluding spring coils (8), Amplatzer Duct Occluder (ADO; AGA Medical Corporation, Golden Valley, USA) (9), and Amplatzer muscular ventricular septal defect occluder (10), either by an antegrade approach from the femoral vein or a retrograde approach from the femoral artery. Currently, Nitinol-based, self-expanding occluder devices or coils are considered as the gold standard for TCC of PDAs and ADO is one of the most widely used devices (4). Although PDA anatomies vary in shape, the available devices are mainly suited for small and conically-shaped PDAs (i.e., Krichenko type A morphology) (4). In this regard, we conducted a prospective study to evaluate anatomic heterogeneities among patients with large PDA, technical considerations including challenges and complications, and short- and medium-term follow-up results with the Cocoon Duct Occluder device (Vascular innovations, Nathambury, Thailand).

Methods

Study design and patient population

In this prospective, single-center study, 57 consecutive patients with large PDA who underwent TCC at L.P.S. Institute of Cardiology, Kanpur, India between November, 2012 and June, 2016 were enrolled. Large PDA was characterized as the narrowest diameter of ≥ 3.5 mm in symptomatic or ≥ 4 mm in asymptomatic patients. The exclusion criteria were patients with weight < 5 kg, associated cardiac anomalies requiring corrective surgery, pulmonary vascular resistance > 8 Woods units/m², and bidirectional or right-to-left shunt. The protocol of the study was approved by institutional Ethics Committee. The study conformed to the principles of good clinical practice and the Declaration of Helsinki. Preprocedural written and informed consents were obtained from all the patients or their legally authorized guardian.

Device description

The Cocoon Duct Occluder is a permanent implant with low-profile intrinsic shape memory and is a platinum-coated, self-expanding and self-centering, mushroom-shaped device, made from 0.0004 to 0.0005 inch Nitinol wire mesh (Fig. 1a). It consists of a retention disk, which assures secure positioning at the distal end of the ductus, and a cylindrical main body, into which multiple poly propylene patches are securely sewn to the sides of the device to induce thrombosis thereby closing the ductus (Fig. 1b, c). The retention disk at the aortic end of the device is always 4 mm larger than the diameter of the quoted size (the first number denotes larger aortic end of device and the second number, which is always 2 mm smaller than the first, denotes the size of pulmonary end i.e., 12/10). Platinum improves radio-opacity, which enables easy positioning of the device. It is nano-coated over Nitinol wires by a process of plasma deposition, which prevents nickel release and the corrosion of Nitinol wire

frame in the long-run and has superior biocompatible properties compared with bare Nitinol after device implantation (Fig. 1a, d).

The delivery system consists of a delivery cable, loader, and a pin vise which helps in unscrewing and releasing the device. It requires sheath sizes varying 6–10F for delivery depending on the device size. In majority of the patients with conical PDAs, device size were 2 mm larger than the narrowest diameter of the ductus, but in patients with larger ductus, even bigger sizes were selected as the ratio of the retention disk diameter to the distal device diameter becomes increasingly smaller with increasing device size.

Procedural details

The procedures were performed under local anesthesia. The femoral artery and vein were accessed with 5F sheath using modified Seldinger's technique. Following sheath placement, routine right and left heart catheterization tests were performed in all patients to obtain the hemodynamics data. The descending aortogram was performed in anteroposterior projection (AP), right anterior oblique (RAO) 40° with 30° cranial angulation, and extreme lateral view to profile the ductus regarding its position, shape, and size and in both proximal and distal end by positioning the distal end of the pigtail catheter (Medtronic, USA) into the distal aortic arch (Fig. 2a, b). Each PDA was classified according to Krichenko (11) on angiogram. The contrast was injected using hand held syringe in pediatric patients and pressure injector in adult patients. With the help of a straight tip Terumo wire (Terumo Inc., Japan), 5F multipurpose catheter (MPA) was advanced from the venous side into PDA in RAO cranial view and sometimes, in AP view. Once reached into descending aorta, MPA was advanced till it reached the descending aorta and then Terumo wire was exchanged with a 0.035-inch J-tip super-stiff Amplatz wire, thereby establishing the femoral arteriovenous loop (Fig. 2c). MPA catheter was then

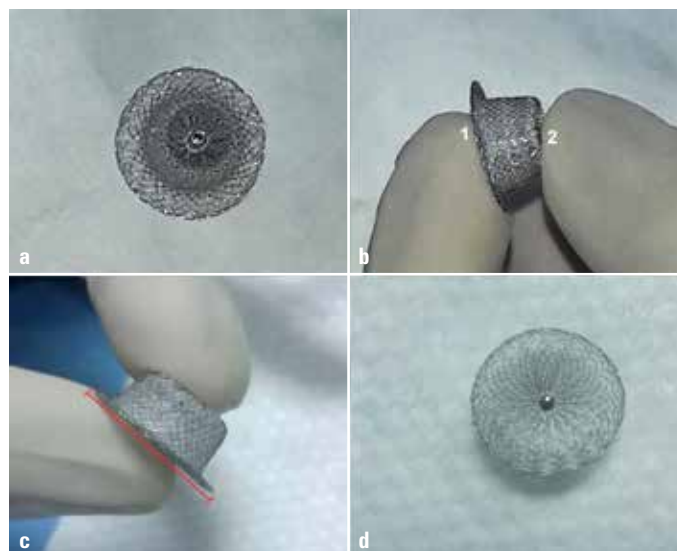


Figure 1. Cocoon Duct Occluder device morphology (B-1-distal diameter; 2-proximal diameter); C-red line indicates the retention disk diameter.

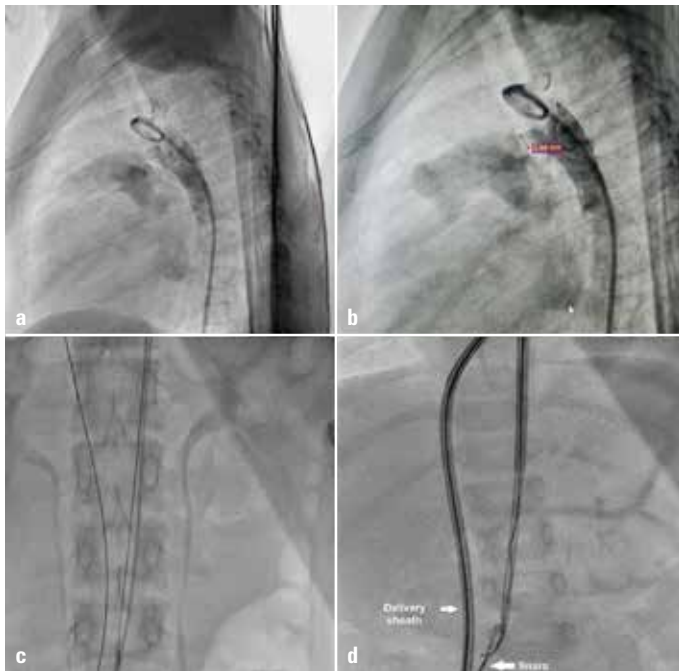


Figure 2. Descending aortic angiogram in lateral projection. Large type-A PDA measuring 5.09 mm in its narrowest diameter in a symptomatic 9-month old baby (a, b), Antegrade wiring forming an arteriovenous loop (c); Amplatz wire being snared by gooseneck snare (d)
PDA - patent ductus arteriosus

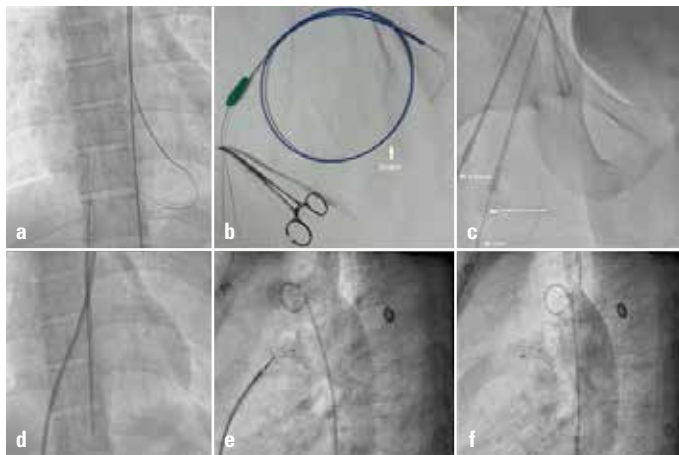


Figure 3. The soft tip of Terumo wire being caught by a customized snare in the right atrium (a), A customized snare prepared using an exchange length BMW wire by passing it through the Judkins right diagnostic catheter and proximal end caught by arterial forceps (b), Establishment of the arteriovenous loop (c), Delivery sheath in the descending aorta (d); Successful deployment of Cocoon Duct Occluder device (e), Post-procedural angiogram confirming the device position and complete occlusion of PDA (f)

exchanged with a long delivery sheath (size depending on the device selected). The dilator was removed, leaving the long venous sheath (delivery sheath: 6–10F) in the descending aorta. In some cases where the delivery sheath could not be advanced in the usual fashion due to tortuous anatomy and poor support by the Amplatz wire, we held the distal end of Amplatz wire by gooseneck snare (Microvena, MN, USA) or customized snare to

straighten it and then advanced the delivery sheath in the usual fashion (Fig. 2D). Then, the snare was removed and the pigtail catheter was re-introduced from the arterial side. A retrograde technique (i.e. from the descending aorta to the pulmonary artery) was used to establish a femoral arteriovenous loop when conventional antegrade technique failed in some patients with abnormal morphology, such as a smaller ostium of the side of the pulmonary artery compared with the side of the descending aorta, severe calcification, or tortuosity. Here, 5F MPA with long Terumo wire was advanced from the arterial side to the right atrium via PDA–MPA–right ventricle, where it was snared using the gooseneck snare and exteriorized from the venous end to establish the arteriovenous loop (Fig. 3a–c). Over this wire, the delivery sheath was advanced in the usual fashion (Fig. 3d, 4a). Subsequently, the delivery cable was passed through the loader and the appropriate device was screwed clockwise into its tip. The device and loader were immersed in a saline solution as the Cocoon Duct Occluder device was pulled into the loader to make it air-free. The loader was introduced into the delivery sheath, and the device was advanced into the descending aorta. The sheath was retracted enough to open the retention disk in the proximal descending aorta. The sheath, with the delivery cable in it, was pulled back as one unit until the retention disk was properly sitting against the aortic end of the ampulla. While maintaining the tension on the delivery cable, the sheath was further pulled into the pulmonary artery to deploy the tubular frame of the Cocoon Duct Occluder (Fig. 3e, 4b). With the device still attached to the cable, a descending aortogram was performed in the lateral and RAO cranial projections to confirm

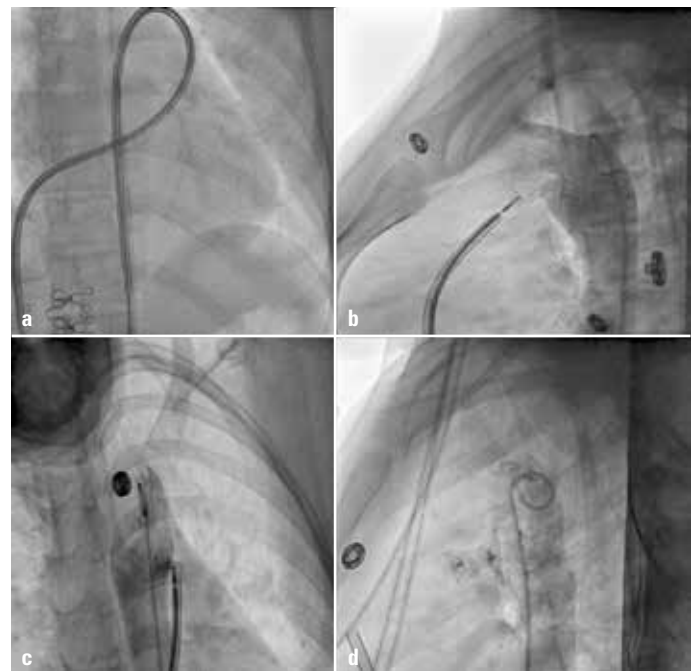


Figure 4. 11F Delivery sheath in the descending aorta (a), Fully opened PDA device attached with the delivery cable in lateral view (b) and in RAO cranial view (c), Well-deployed Cocoon Duct Occluder with no residual shunt in lateral view (d)

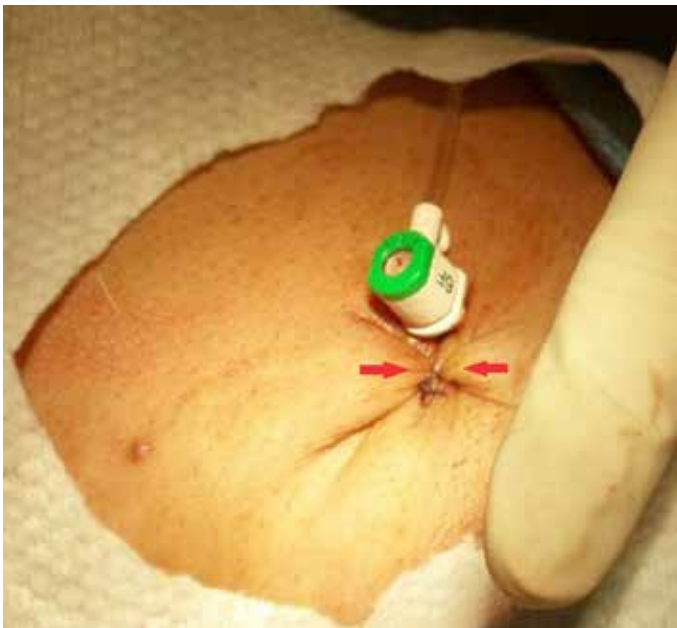


Figure 5. Z-suture around the venous entry site (red arrow)



Figure 6. Grade-3 shunt in lateral view immediately after the final deployment of disk

the device position (Fig. 3f, 4b–d). The device was recaptured and redeployed after upsizing if the device was not properly sitting across the defect prior to the release. Postimplantation angiogram was performed at 0 min and if device size was >10 mm, at 10 min. Once properly positioned, the device was released by turning the cable counter-clockwise using the pin vise. The arterial sheath was removed and local compression was applied with the help of a tight compression bandage and the venous sheath was removed and closed using the z-suture or figure of eight suture (Fig. 5).

Data collection and follow-up

At the time of enrolment, all patients were comprehensively assessed for clinical history, physical examination, routine haemogram, chest x-ray, and detailed transthoracic echocardiogram. Echocardiography was performed using Vivid 7TM (GE, USA) in parasternal long-axis and short-axis views for routine measurements and in high short-axis and suprasternal views for the sizing of PDA.

Postprocedural residual shunts on angiogram were labeled as: Grade 1- none; Grade 2- small (dye filling only proximal pul-

monary artery branches); Grade 3- moderate (dye filling the main pulmonary artery and extending to the distal branches); and Grade 4- significant (dye filling the main pulmonary artery and branches extending to the peripheral vessels with contrast return to the left atrium) (4). Procedural complications such as device embolization, hemolysis, need for blood transfusion, arrhythmia requiring major treatment, pericardial effusion with tamponade, pulmonary edema, LPA stenosis and death were assessed as major events and local site complications, arrhythmia requiring minor treatment, and extremity tingling/numbness as minor events.

Follow-up 2D-transthoracic echocardiogram including color Doppler imaging was performed at 24 h (D1), one month (D30), and the end of sixth month (D180) to assess the device position and residual shunts, and Doppler flow velocities of LPA and the descending aorta for any stenosis. Residual shunts on echocardiogram were labeled as: Grade 1- none; Grade 2- trivial (a small color Doppler jet limited to the device); Grade 3-moderate (Doppler jet beyond the device but no audible murmur); and Grade 4- significant shunt (large Doppler jet with an audible murmur and continuous Doppler flow) (4).

Table 1. Baseline characteristics of patients including their demographic, hemodynamic, and angiographic variables (n=57)

| Age, years | n (%) | Wt. kg±SD | PASP mm Hg±SD | Ao. Sys Pr mm Hg±SD | PVRI Woods U/m ² | Duct size mm±SD |
|---------------------------|------------|--------------|------------------|------------------------|--------------------------------|--------------------|
| Group A: Infant (<1 year) | 9 (15.8%) | 6.2±0.4 | 51.4±2.6 | 71±5.2 | 4.6±2.1 | 7.8±1.3 |
| Group B : 1-5 years | 11 (19.3%) | 13.3±1.7 | 65.3±7.4 | 91.5±10.7 | 3.9±1.3 | 8.2±1.4 |
| Group C: 6-18 years | 19 (33.3%) | 21.7±5.1 | 71.1±8.3 | 94.5± 9.1 | 4.4±1.2 | 10.3±2.3 |
| Group D : >18 years | 18 (31.6%) | 44.6±9.8 | 83.4±12.5 | 105.7±13.6 | 6.2±2.4 | 12.2±3.1 |

Ao Sys Pr- aortic systolic pressure; PASP- pulmonary artery systolic pressure; PVRI- pulmonary vascular resistance index; Wt-weight-woods U/m² = 79.92 dyn.s/cm⁵

Table 2. Procedural detail and outcome of patients (n=57)

| Variables | n (%) |
|---|----------------------|
| Age, years | Mean=11.7 (0.5-46) |
| Weight, kg | Mean=22.3 (5.8-61.1) |
| Associated defect | |
| a. ASD | 4 (7.1%) |
| b. VSD | 1 (1.7%) |
| c. Coarct | 2 (3.4%) |
| d. MR | 1 (1.7%) |
| PDA size, narrowest diameter-mm | Mean=7.4 (5-20) |
| Q _p :Q _s | Mean=2.4±0.3 |
| PDA morphology | |
| a. Type A (Conical) | 46 (80.7%) |
| b. Type B (Window) | 6 (10.6%) |
| c. Type C (Tubular) | 2 (3.5%) |
| d. Type E (Elongated) | 3 (5.2%) |
| Fluoroscopy time, min | 6.7±3.2 |
| Procedural time, min | 23.9 (15-39) |
| Radiation exposure, cGycm ² | 131.4 (97.3-198.4) |
| Antegrade wiring | 53 (92.9%) |
| Retrograde wiring + Antegrade snare | 4 (7.1%) |
| Antegrade wiring + Retrograde snare | 3 (5.2%) |
| Antegrade device deployment | 57 (100%) |
| Device, CDO | 57 (100%) |
| Residual shunt on angiogram | |
| a. Grade 1 | 49 (86%) |
| b. Grade 2 | 7 (12.3%) |
| c. Grade 3 | 1 (1.7%) |
| d. Grade 4 | 0 |
| Complications | |
| Major adverse events | |
| a. Death | 0 |
| b. Device embolization | 0 |
| c. Hemolysis | 0 |
| d. Requirement of blood transfusion | 0 |
| e. Arrhythmia requiring major treatment | 0 |
| f. Pericardial effusion with tamponade | 0 |
| g. Pulmonary edema | 0 |
| e. LPA stenosis | 0 |
| Minor adverse events | |
| a. Local site complication | 2 (3.5%) |
| b. Arrhythmia requiring minor treatment | 7 (12.3%) |
| c. Extremity tingling/numbness | 0 (0%) |

ASD- atrial septal defect; Coarct-coarctation; CDO-cocoon duct occluder; Kg-kilogram; LPA-left pulmonary artery; MR-mitral regurgitation; PDA- patent ductus arteriosus; Qp-qs-pulmonary-systemic flow ratio; VSD-ventricular septal defect

Statistical analysis

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS, Chicago, IL, USA) program, version 15.

Table 3. Residual shunt on echocardiogram and follow-up of patients (n = 57)

| Variable | D1 (n, %) | D30 (n, %) | D180 (n, %) |
|------------|------------|------------|-------------|
| a. Grade 1 | 52 (91.3%) | 0 (0%) | 0 (0%) |
| b. Grade 2 | 3 (5.2%) | 0 (0%) | 0 (0%) |
| c. Grade 3 | 2 (3.5%) | 0 (0%) | 0 (0%) |
| d. Grade 4 | 0 (0%) | 0 (0%) | 0 (0%) |

Categorical variables were expressed as frequency and percentages and continuous variables as mean ± standard deviation (SD).

Results

Baseline characteristics

A total of 57 patients (32 males, 25 females) were enrolled. The mean age was 11.7±2.8 years (range: 6 months–46 years), and the mean weight was 22.3±3.5 kg (range: 5.8–61.1 kg). All patients had continuous cardiac murmur on examination and 8 (14%) had a history of recurrent lower respiratory tract infection. Other baseline characteristics for overall patients and for patients stratified based on age (i.e. 1 year, 1–5 years, 6–18 years, >18 years) are described in Table 1. Clinical characteristics of patients, including presentation of other associated cardiac anomalies, and procedural details are given in Table 2. Of 57 the patients, 46 (80.7%) had type A, 6 (10.5%) had type B, 2 (3.5%) had type C, and 3 (5.2%) had type E PDAs. The mean PDA diameter on angiogram was 7.4 ± 2.9 mm.

Procedural outcomes

Successful PDA closure with the Cocoon Duct Occluder device was performed in all the patients without any major complications. Arrhythmias requiring minor treatment were noted in seven (12.3%) patients, of which, three had multiple atrial ectopics, one had atrial tachycardia, and three had ventricular ectopics. Vascular access complications in the form of local haematoma occurred in two (3.5%) patients, which were successfully and conservatively managed. Final postimplantation angiography showed complete closure in 49 (86%) patients, a small (Grade 2) shunt in seven (12.3%), and moderate (Grade 3) shunt in one (1.7%) (Table 3; Fig. 6).

Follow-up outcomes

All patients completed the echocardiographic follow-ups (i.e. at D1, D30, and D180). Color Doppler data at D1 showed that complete closure (no shunt, Grade 1) was achieved in 52 (91.3%) patients, trivial shunt (Grade 2) in three (5.2%), and moderate shunt in two (3.5%) with complete closure without any shunt at D30, which were consistent at D180 (Table 3). All the residual shunts required no specific treatment.

Discussion

In the present era, TCC has replaced surgical intervention as the first-choice management option. Despite its remarkable

safety, there is always a concern regarding complications, such as embolization and mild obstruction of LPA and descending aorta, particularly in infants with large PDA who require a relatively larger device (12, 13). Nevertheless, because of its design, the Cocoon Duct Occluder has made a cut through in the field of TCC and can be used for larger defects (up to 22 mm), with outcomes comparable to the ADO device (14). In addition, the retention disc on its distal aortic end which is 4 mm bigger than its size prevents its embolization to the pulmonary artery.

Our prospective, non-randomized study, showed 100% procedural success rate with the Cocoon Duct Occluder device in 57 patients with large PDAs. Further, the fluoroscopy and procedural times indicate that procedure with this novel device is feasible and simple with excellent safety profile without any incidence of embolization, haemolysis, or stenosis of adjacent structures, with excellent results on short- and medium-term follow-ups.

When larger devices were used ($\geq 18/16$) for larger PDAs (≥ 12 mm), they tended to have residual shunt at 10 min postimplantation and at 24 h on echocardiography. Although the incidence of residual shunt was slightly higher with the Cocoon Duct Occluder device (14% and 8.7% on angiogram and echocardiogram, respectively), all patients with a residual shunt achieved complete closure at 30 days without a need for special treatment, which indicates excellent efficacy of the device. Of note, ADO devices have certain limitations as they cannot be used to close a very large defect (≥ 11 -mm minimum diameter) (15). Also, the height of the waist of ADO is small, which makes it unsuitable for certain PDA morphologies as it cannot completely expand, resulting in residual shunt and hemolysis.

TCC of certain PDAs may be challenging due to the anatomy of PDA or the kinking of the delivery sheath from the antegrade route for establishing an arteriovenous loop. In such patients, a retrograde technique may be helpful, as previously reported by Hijazi et al. (7) and Hsin et al. (16). In our study, retrograde wiring was used in 7.1% patients, which was similar to 6.25% reported by Yang et al. (15). As the antegrade deployment of the delivery sheath may not be straight forward sometimes, we used the retrograde snare to facilitate its delivery, the technique also reported by Yan et al. (17).

Earlier, Spies et al. (18) had reported a case of successful closure of a large 22-mm PDA using an Amplatzer atrial septal occluder. Yan et al. (17) had reported that Amplatzer muscular ventricular septal defect occluder can be used for a large PDA of up to ≤ 14 mm. Bilkis et al. (9) examined 209 patients with PDA (size: 1.8–12.5 mm) who underwent TCC with ADO and reported success in 98% patients, with complete occlusion in 44% patients after the procedure, 66% at 24 h, and 97% at 1 month. On the contrary, our study with the Cocoon Duct Occluder demonstrated better outcomes with successful procedure in 100% patients, and complete occlusion in 86% patients after the procedure, 91.3% at 24 h, and 100% at 1 month. Similarly, Yang et al. (15) had examined 112 patients with complex PDA and reported procedural success in 93.8% patients, postprocedural residual

shunts in 8%, and residual shunts at 1-year follow-up in 1.8%, which was much higher than our study.

Device embolization was seen in 1.4% patients within 24 h of procedure, as reported by Bilkis et al. (9); however, it was not seen in our study. Furthermore, the incidence of hemolysis and vascular access complications was also significantly lower in our study, being 0% and 3.5% among patients respectively, as compared to 2.6% and 5.2% as reported by Yang et al. (15). Though rare, Simoes et al. (19) had reported a single procedure-related death with ADO due to mesenteric vascular complications and sepsis following embolization into the descending aorta in a study of 33 patients with PDA. In our series, the incidence of death was none. Therefore, an embolized device should always be retrieved from the aorta on emergency basis either by a transcatheter or surgical approach.

Study limitations

This was a small, non-randomized prospective study of patients with a great majority having type A morphology (80.7%). Therefore, a prospective study enrolling a higher number of patients with complex PDA morphology and longer follow-up may serve well to demonstrate the efficacy of Cocoon Duct Occluder devices.

Conclusion

The novel Cocoon Duct Occluder device is safe and effective for the closure of large type A PDAs with immediate closure and minimal residual shunt. Larger studies with long-term follow-ups are required to further establish its safety and efficacy, particularly for closure of less frequently seen non-type A PDAs.

Conflict of interest: None declared.

Peer-review: Externally peer-reviewed.

Authorship contributions: Concept – P.K., M.J.J., S.K.S.; Design – S.K.S.; Supervision – S.K.S., R.N.P.; Fundings – C.M.V., U.P., V.K.; Materials–S.K.S., M.R., R.N.P.; Data collection &/or processing – All Authors; Analysis &/or interpretation – P.K., P.T., R.T.; Literature search – V.M., N.A.; Writing – M.R., V.M., M.A.; Critical review – All Authors.

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Alper Elitok, from EFSAD's collections.