Cocoon devices for transcatheter closure of atrial septal defect and patent ductus arteriosus in children
Single center experience

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Abstract

Closure of the atrial septal defect (ASD) and patent ductus arteriosus (PDA) are among the most frequent cardiac interventional procedures. This was a prospective study, which started together with the implementation of a national program of pediatric interventional cardiology in Romania. We used Cocoon devices in 83 consecutive cases from 92 implantations for ASD and PDA. 27 cases were ASD closure and 56 cases PDA closure. Regarding the ASD closure, the median age was 8.5 years (range 3–25 years) and median weight 25 kg (range 11.5–63 kg). The mean follow-up was 17.4 ± 6.7 months (range 3–26 months). The mean ASD diameter by transesophageal echocardiography was 15.2 ± 4.1 mm (range 8–26 mm). The mean device diameter used was 17.3 ± 5.6 mm (range 8–32 mm). Regarding the PDA closure, the median age was 36 months (range 4–192 months) and median weight 14 kg (range 5–58 kg). The mean follow-up was 15 ± 8 months (range 3–28 months). The mean PDA minimum diameter was 2.5 ± 0.8 mm. The success implantation rate for both groups was 97.6% (2 cases of withdrawn for ASD and PDA), while the complication rate was 2.3% (including 2 ASD device embolization). In the first 24 hours, the closure rates were 96.3% for ASD, 98.2% for PDA, and 100% at 1-month follow-up for both procedures. On short and intermediate follow-up (3–28 months), no device-related complications were noted.

The Cocoon devices are safe for transcatheter closure of both ASD and PDA, and the initial experience with their use in our emerging center is encouraging.

Abbreviations: ASD = atrial septal defect, ASO = Amplatzer Septal Occluder, CDO = Cocoon Duct Occluder, CSO = Cocoon Septal Occluder, LAO = left anterior oblique, LSPV = left superior pulmonary vein, mPAP = mean pulmonary artery pressure, PDA patent ductus arteriosus, PS = pulmonary stenosis, RAO = right anterior oblique, TEE = transesophageal echocardiography, VSD = ventricular septal defect.

Keywords: atrial septal defect, cocoon occluder, congenital heart disease, patent ductus arteriosus, pediatric interventional cardiology

1. Introduction

Atrial septal defects (ASD) and patent ductus arteriosus (PDA) are among the most frequent cardiac defects. Interventional closure became the method of choice 40 years after the initial use for both ASD and PDA closure (King and Mills, in 1976[1,2] for ASD and Rashkind,[1] in 1979 for PDA). Still, the gold standard

for these defects, with negligible mortality and 100% success rate, is surgery.[3] These defects cover together 15% to 20% of all cardiac defects. The interventional closure is feasible for many of these defects, except for some situations: ostium primum, sinus venosus ASD and unroofed coronary sinus, the association of the secundum ASD with other cardiac defects which are inexorably surgical, or contraindications related to pulmonary hypertension with increased pulmonary vascular resistance.[1,3,4] Other situations of ASD associated with other interventional approachable malformations such as ventricular septal defect (VSD) or exclusion of other cardiac malformities are not a contraindication and are described in the literature as dual intervention usually in one procedure.[5–7] Coronary anomalies associated with ASD may be either a contraindication for interventional ASD closure or place the case in a high-risk group of interventions.[8]

The tremendous need for treating children in order to reduce morbidity and mortality in the pediatric population with congenital heart disease was the main purpose to start a new project of interventional cardiology in our country, our hospital being the first included on the base of an emerging national program. We started this program using the Cocoon devices (the providing company won the auction based on the cheapest product compared to similar products like Amplatzer and Occlutech occluders), which are known to be safe, certified in the European Economic Area, and to have a good reputation.[9,10]

Table 1

Descriptive characteristics and results of the studied group.

Characteristics	ASD	PDA
Number of patients	27	56
Age, years	8.5 (3-25)	3 (0.3–16)
Weight, kg	25 (11.5–63)	14 (5–58)
Mean diameter of the defect	15.2 ± 4.1	2.5 ± 0.8
Mean diameter of the device used	17.3 ± 5.6	—
Success rate	88.9%	98.2%
Complications	2	0
Embolization	2	0
Device withdrawn	1	1
Pericardial effusion	0	0
Stroke	0	0
Follow-up	17.4 ± 6.7 (3–26)	15 ± 8 (3–28)
Erosion	0	0
Fluoroscopy time, minutes	16.1	18.1

ASD = atrial septal defect, PDA = patent ductus arteriosus.

This is the initial experience of a single center, "Marie Curie" Emergency Children's Hospital, Bucharest, Romania, on the interventional closure of the ostium secundum ASD and PDA with Cocoon devices (Vascular Innovations Co., Nonthaburi, Thailand).

2. Materials and methods

A total number of 92 consecutive pediatric patients diagnosed with ASD and PDA were included in this prospective study between June 2015 and October 2017 in the Department of Interventional Cardiology of "Marie Curie" Emergency Children's Hospital, Bucharest, Romania. In 83 cases, we implanted Cocoon devices as follows: 27 cases were selected for ASD closure and 56 cases for PDA closure. For ASD, the median age was 8.5 years (range 3–25 years) and median weight 25 kg (range 11.5–63 kg). For PDA, the median age was 36 months (range 4–192 months) and median weight 14 kg (range 5–58 kg).

Patients were selected according to the clinical and imaging findings criteria for closure, following the indications of the American Heart Association.[1] All parents or custodians of the patients agreed to the procedure after having previously signed an informed consent regarding the procedure itself and its potential short and long-term risks. The descriptive analysis of the studied group is shown in Table 1.

The ASD device is a self-expandable double disk septal occluder, Cocoon Septal Occluder (CSO), which is made by a nitinol wire covered with platinum and filled with polypropylene fabric. The polypropylene fabric favors thrombogenicity.[4] The platinum coating provides at least 3 important advantages: better radiopacity, good bio-compatibility and prevents nickel allergy by stopping nickel leaking into the blood (Fig. 1). Other important characteristics of the CSO are smaller metal to septal ratio, MRI compatibility, ability to recapture and reposition.[9] The 2 disks are connected by a centered waist that starts at 8 mm length, and increases by 2 mm up to 40 mm.

The Cocoon Duct Occluder (CDO) is made of the same materials as CSO and has identical properties: biocompatibility, radiopacity, and thrombogenicity. Its design is almost similar to that of the Amplatzer Duct Occluder type I. The diameter of the pulmonary end starts at 4 mm (4/6 mm device), and increases by 2 mm up to 18 mm diameter of the pulmonary end (18/20 mm device). The aortic end is always 2 mm larger than the pulmonary end (Fig. 2).
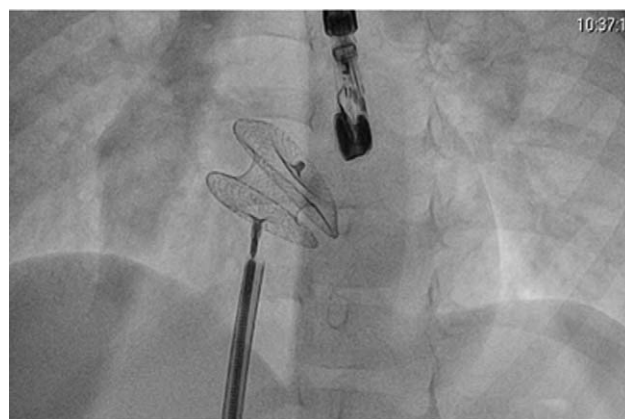
**Figure 1.** Cocoon Septal Occluder after implantation and before release.

The devices are produced by Vascular Innovations Co., Nonthaburi, Thailand, and they have European conformity certification and hence, a safety standard for products sold in the European Economic Area. Their external design is very similar to that of the Amplatzer occluders.

For the descriptive statistical analysis, we used the Excel Data Analysis Tool. We calculated the median, the mean value ± standard deviation.

3. Results

Regarding the evaluation of ASD, the patients were evaluated initially by transthoracic echocardiography, followed by transesophageal echocardiography (TEE). In cases with improper rims at TEE (soft or floppy), in 40.7% of the cases, for further evaluation, we used the balloon sizing technique. The mean ASD diameter by transesophageal echocardiography was 15.2 ± 4.1 mm (range 8–26 mm), and by balloon sizing 20.5 ± 5.2 mm (range 13.5–32 mm). The mean device diameter was 17.3 ± 5.6 mm (range 8–32 mm). The median device diameter was 16 mm. We used balloon sizing measurement in selected cases (40.7% of all cases), especially in those with soft or floppy rims. Patients with deficient inferior, superior or posterior rims were excluded, especially if also their aortic rim was deficient. We accepted all cases with a deficient aortic rim.

We started the procedure with a femoral vein access, and after exclusion of the abnormal partial pulmonary venous return by TEE and suspected pulmonary hypertension by right heart catheterization we continued with left superior pulmonary vein (LSPV) catheterization in order to obtain a stable position of the stiff guidewire AngioFlex (Kimal, UK). On the wire, we positioned the Cocoon Delivery Sheath (Vascular Innovations, Thailand) into the LSPV and then introduced the device into the sheath. Fluoroscopic guided we ascending the device up to the distal end of the sheath. By retrieving the sheath while pushing the device we released the left atrial disc into the left atrium, then position the left disc on the left side of the atrial septum and then releasing the right disc of the CSO into the right atrium. We performed the Minnesota maneuver to evaluate the stability of the device and after careful TEE evaluation for apposition, stability, residual shunts with released the device. In several cases with deficient aortic rim, a right superior pulmonary vein catheterization with deployment of the left disc coming from this direction was necessary. Also, another technique that we used was to deploy the left disc together with half of the right disc when approaching the
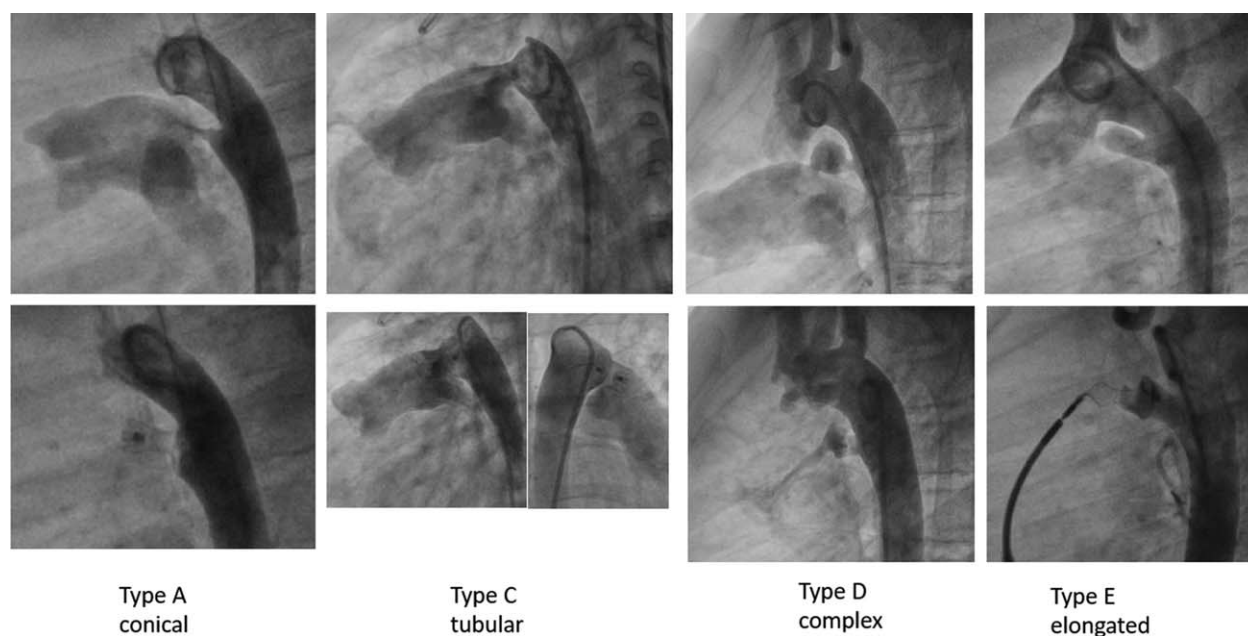
Figure 2. Different anatomical types of patent ductus arteriosus according to Kritchenco classification before and after Cocoon Duct Occluder implantation at check-up angiography.

atrial septum in order to obtain a good apposition and avoid the perpendicular position of the left atrial disc.

The success implantation rate was 96.3% (only in one case, the ASD could not be closed due to the deficient posterior rim in the presence of a good aortic rim), and the success rate of the procedure was 88.9% (including 2 cases of device embolization). The device embolization happened in the next 12 hours following the procedure and the cases were referred for surgical removal of the device and closure of the defect. The closure rate, which was free of an intradevice shunt, was 96.3% immediately after the procedure as well as in the first 24 hours. At the time of the procedure, all patients were on antiplatelet treatment with Aspirin, 3–5 mg/kg/day, started 24–48 hours previously and they followed this treatment for 6 months. No complications related to the antiplatelet treatment were reported.

Regarding the PDA, the minimum diameter of the defect was 2.5 ± 0.8 mm (range 1–5 mm). We used a 4/6 mm device in 51.8% of the cases (29 patients), 6/8 mm CDO in 46.4% (26 patients), and 8/10 mm and 10/12 mm CDO in 5.3% (3 patients) and 1.8% of the cases (one patient), respectively. We did not use devices $\geq$12/14 mm. In 3 cases (5.4%), we needed to exchange the initially selected device because of a great reactivity of the duct, which constricted at the moment of contrast injection and dilated at the moment of device implantation. We presume that this is also the explanation for the PDA, which initially measured 2.5 mm by transthoracic echocardiography, 1 mm minimum diameter at angiography, but we succeeded to implant a 4/6 mm device without problems. No difference in pressure gradient between ascending and descending aorta after implantation, except in the case of a 6-month-old female, 5.2 kg which developed a peak-to-peak gradient of 15 mm Hg after a 4/6 mm device positioning having a narrowed aorta. The device was withdrawn and the patient was operated with heart failure associated to PDA, bringing the success implantation rate at 98.2% for PDA closure. Regarding the Kritchenco classification of the PDA, we could use the CDO in all cases we had: 69.6% were type A, 8.9% type C,

8.9% type D, 12.5% type E. We did not find any Kritchenco B type for closure.

Around 25% of the PDA cases were done in children less than 1-year-old. A total of 12.6% of all PDA closures were performed in cases associated with pulmonary hypertension, with a mean pulmonary artery pressure (mPAP) of 35 mm Hg.

We started all cases with both arterial and venous access. Firstly, we performed an aortography in standard projections left anterior oblique and right anterior oblique (LAO90, RAO30) to evaluate the anatomy, dimensions and impact of the PDA. The device was selected according to the rule that the pulmonary end of the device should be 2 mm larger than the minimum diameter of the duct. After that, we performed a right heart catheterization with evaluation of the pulmonary pressure. We performed a pulmonary-aortic circuit, passing through the PDA with a standard guidewire and a multipurpose catheter MPA2 (Merit Medical, United States of America), and using a stiff guidewire we positioned the PDA Cocoon long sheath (Vascular Innovations, Thailand), and then ascending the device, followed by deployment.

The mean fluoroscopy time was 16.1 minutes for ASD closure, and 18.1 minutes for PDA closure. No complications were reported for PDA closure. In 3 cases, we exchanged the initial dimension of the device due to the lack of apposition to the aortic wall due to the great reactivity of the duct with good results.

For all cases, both ASD and PDA, the cardiac complication rate was 2.3% (including 2 ASD device embolization in patients with <5 mm deficient posterior rim). Neither arrhythmias nor heart conduction problems were registered. The local complication rate was 4.6%, with 2 cases of arteriovenous femoral fistula reported, which disappeared spontaneously in the next weeks, and 2 cases of small groin hematomas. No other complaints (headache, migraine, thoracic pain, palpitations, syncope, faint, dyspnoea, etc.) were noted.

A summary of the results, follow-up, and complications are presented in Table 1.

All patients were followed-up at 24 hours, 1 month and 3 months, and the majority of them have been also evaluated at 6 and 12 months after the procedure. Patients were checked by clinical examination, electrocardiography, bidimensional, and Doppler transthoracic echocardiography. Those with ASD who were subjected to ASD closure with CSO device were given a treatment with Aspirin (3–5 mg/kg/day, maximum 100 mg/day) for 6 months, which was started 24 hours before implantation.

For ASD, the mean follow-up was 17.4 ± 6.7 months (range 3–26 months), and the closure rate 100% at 1-month follow-up. For PDA, the mean follow-up was 15 ± 8 months (range 3–28 months), and the closure rate also 100% at 1-month follow-up. On short and intermediate follow-up (up to 28 months), no device-related complications were noted (nickel allergy, thrombosis with thrombus formation, endocarditis, hemolysis, migraine, and pericarditis).

4. Discussion

Closure of ostium secundum ASD and PDA with device became the method of choice for more than 40 years, and it was applied even in small infants and newborns with large PDA.[1]

In our pediatric hospital, we started an interventional cardiology program in 2013 and this was included in a national financed program in 2015. Our results of interventional ASD and PDA closure in a pediatric population by using Cocoon devices were good, with a 100% closure rate at 1-month follow-up for both groups. We had a success rate of implantation of 97.6%, and taking into account complications (the 2 ASD embolization cases), our final success rate was 95.2% for all 83 cases. The complications depend on several factors. Large ASD (larger than 30 mm for adults), misalign septum, multiple ASD, septal aneurysm, deficient or floppy appearance of the posterior rim associated or not to absent or deficient anterior rim, and associated lesions such as pulmonary stenosis (PS), VSD are factors that may increase the difficulty of the cases from a technical point of view and even decrease the final success rate.[3,11]

Comparing to the number of Amplatzer, Gore Occluder, or Occlutech device implantation, the number of Cocoon device implantation is smaller, and only a few reports are present in the literature, many of them have focused on case reports for difficult cases of ASD associated with coronary anomalies, off-label use of Cocoon duct occluder for ruptured sinus of Valsalva aneurysm, or use of 10/12 mm Cocoon ductal occluder for closure of an 8 mm PDA in a 1-year-old child weighing 3 kg.[8,12,13]

In our cohort, we did not have any complications related to the device. The mean follow-up period was around 15 to 17 months. We did not encounter any case of pericardial effusion, nickel allergy, unexplained headache, stroke or cardiac erosion. Amplatzer Septal Occluder (ASO), with more than 250,000 device implantations, has a risk of life-threatening cardiac erosions of 0.001%,[9] but cardiac erosion is described also for other septal occluders (Occlutech and Cardia), with a risk of 1–3 in 1000 implantations.[14] When evaluating the risk factors for aortic erosions in ASO implantation, deficient aortic rim, training of the operator and oversized devices were found to be significantly related to the risk of erosion. We did not estimate the risk of erosion for CSO, but to our knowledge, no cases have been reported in the literature to date, although it seems that more than 4000 Cocoon devices were implanted in eight Asian countries and 6 European countries.[4] This may be associated

with the softness of the device due to the removal of oxide from nitinol during its preparation.

The absence of nickel allergy was shown to be another good quality of the Cocoon device. Nickel allergy in population is estimated to 10%.[9,15] No case of nickel allergy related to the use of CSO for ASD closure has been reported up to now; more than that, in another study, Thanopoulos et al. reported that 6 patients known with nickel allergy prior to implantation accepted CSO implantation for ASD, and no allergic reaction was noticed afterwards.[9] Cocoon devices received the European certification for use in 2010, and since then, there have been no reported cases of nickel allergy related to their use. This may be due to the technologic processes by which nano-thin layers of platinum are deposited on the surface of nitinol wires to prevent nickel release into the blood once the device is implanted.[4]

Cocoon devices (especially CSO) were evaluated in other published studies, and the comparative results are summarized in Table 2.

Thanopoulos et al reported a multicenter European study on 92 consecutive patients, of which 50 were children, with a mean age of 10.5 years, a mean weight of 25 kg, with no-device related complications and 100% closure rate immediately or at one-month, which is similar with our findings.[9]

Promphan presented 148 ASD cases which were retrospectively reviewed with respect to the comparative safety and effectiveness of Amplatzer, Cocoon and Occlutech ASD devices. Among all patients, 52 had Cocoon ASD device implantation. The description of the studied group is presented in Table 2. There was one device embolization, one massive pericardial effusion for the Cocoon devices, and stroke at one month after implantation in a patient with previous atrial fibrillation.[4]

Lairakdomrong et al have also performed a study on ASD closure with Cocoon device in 2 groups (smaller and larger than 30 mm in diameter) on a total of 63 patients. Implanted device diameter influenced the success rate, which was 87.1% for the bigger diameters and 96.9% for the smaller ones.[11] Chamié et al. presented a study on 49 patients, mixing 2 groups using both Cera devices (45 subjects) and Cocoon devices (4 patients). The data cannot be conclusive for the use of Cocoon ASD device.[16] Like Chamié et al,[16] also Pillai et al[3] reported a mixt group of patients regarding the device used for closure [ASO (St. Jude), CSO (Vascular Innovations) and Heart R Septal Occluders (Lifetech)] on 75 complex ASD cases, with a success rate of 92%, but the results can not be extrapolated for CSO.

For PDA closure using the Cocoon devices, Lertsapcharoen et al[17] described the results on PDA closure in 60 patients with a mean age of 4 years (9 months–65 years) and a mean weight of 15.2 kg. The mean PDA diameter was 4.7 ± 2.2 mm (range 2.0–15.1 mm). The success rate was 100%, without any serious procedural complications. Difficulties and complications in PDA closure are usually related to small age and weight of the child. Food and Drug Administration originally limited Amplatzer Duct Occluder use in infants < 6 kg for the risk of iatrogenic obstruction of the descending aorta by the protrusion of the device, together with the risk for other vascular complications.[1,13]

In our cohort, in one ASD case, the procedure was not successful due to the deficient posterior and rim and was aborted. Two ASD device embolization cases are reported, both in children with a deficient posterior rim. The devices were surgically removed and the patients had their ASD surgically closed. The defect was completely closed in all patients at 1-month follow-up. On intermediate term, the device was not associated with nickel allergy or aortic erosions.

Table 2

Comparative data of our study with similar studies in the literature.

		No. of patients	Age, years	Weight, kg	Mean ASD diam (TEE)	Mean ASD device	Success (%)	Embo-lization	Withdrawn	Peric effusion	Stroke	Residual shunt in 24 h/at 1 month	Follow-up, months	Erosion
Thanopoulos et al (7)	ASD	92	10.5 (3–61)	25 (13–65)	21±7 (10–35)	24±8 (14–40)	100	0	N/A	0	0	4%/0%	3-12	0
Promphan (4)	ASD	52	40.9 ±13.4		23.5±4.3	27.6±7.8	100	1 (1.9%)	N/A	1 (1.9%)	1 (1.9%)	42.1%/ 0%	21.8±10.3	0
Mahmoud et al (our data)	ASD	27	8.5 (3–25)	25 (11.5–63)	15.2±4.1	17.3±5.6	88.9	2	1	0	0	3.7%/0%	17.4±6.7 (3–26)	0
Mahmoud et al (our data)	PDA	56	3 (0.3–16)	14 (5–58)	—	—	98.2	0	1	0	0	5.4%/0%	15±8 (3–28)	0

ASD = atrial septal defect, PDA = patent ductus arteriosus, TEE = transoesophageal echocardiography, N/A not available.

Our study has some limitations. Firstly, we report a monocentric experience in a developing center on a small number of cases. Secondly, the follow-up period is short (between 3 months and 28 months), because our medical center is under full development and our interventional cardiac activity started only 30 months ago. Thirdly, we do not have a controlled group for using other types of devices (Amplatzer, Occlutech) for the same technical experience of the center.

5. Conclusion

The experience with the Cocoon devices shows a good implantation rate for both ASD and PDA. No complications related to the use of the devices are reported. The complete occlusion rate for both ASD and PDA at 1-month follow-up was 100%. The embolization rate depends on the group selection and is directly related with a deficient posterior rim. They are safe and efficient in ASD and PDA closure, even in our emerging developing center. The short and intermediate results are very encouraging but long-term evaluation is also needed.

Author contributions

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Writing – review & editing: Eliza Elena Cinteza.

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