Duktus arteriyozus açıklığının perkütan yolla kapatılması: Kısa dönem sonuçlarımız

Percutaneous closure of patent ductus arteriosus: our short term results

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ÖZET

Amaç: Amplatzer Duct Occluder (ADO-1 ve ADO-2) ve Amplatzer septal tıkayıcı (AST) cihazı kullanarak perkütan yolla kapatma işlemi uygulanan çocuk ve erişkin yaş grubundaki duktus arteriyozus açıklığı (DAA) olgularının kısa dönem sonuçları değerlendirildi.

Çalışma planı: Çalışmaya 48 hasta (17 erkek, 31 kadın; dağılım 3-39 yıl) alındı. DAA'nın kapatılması öncesinde tüm hastalar transtorasik ekokardiyografi (TTE) ile değerlendirildi. İşlem floroskopi altında, öne doğru veya geriye doğru yaklaşımla yapıldı. Aortografi sonrası duktus arteriyozun çapı ve sınıflandırması yapıldı. İşlemden sonra duktusta kalan şant 10. dakikada aortografi ile, işlemden 24 saat ve üç ay sonra da TTE ile değerlendirildi.

Bulgular: Hastaların 25'inde ADO-1 (%52.1), 22'sinde ADO-2 (%45.8) ve birinde AST (%2,1) cihazı kullanıldı. Ortalama takip süresi 13.2 ay idi. İşlem 48 hastanın 47'sinde

ABSTRACT

Objectives: To evaluate short term results of percutaneous patent ductus arteriosus (PDA) closure in a cohort of pediatric and adult patients following closure with the Amplatzer Ductal Occluder (ADO-1 and ADO-2) and Amplatzer Septal Occluder (ASO) devices.

Study design: A total of 48 patients (17 males, and 31 females; range, 3- 39 years) were included in this study. All patients were evaluated with transthoracic echocardiography (TTE) before the intervention. Percutaneous closure was performed under fluoroscopy through anterograde or retrograde route. Aortography was performed to measure and classify the ductus arteriosus. Residual shunt through ductus was controlled by aortography at the tenth minute and by TTE 24 hours and three months after the procedure.

Conclusion: Transcatheter closure of PDA with ADO-1 and ADO-2 devices has low morbidity and mortality with high rates of success in selected patients.

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(%97,9) başarı ile uygulandı. İşlemin başarısız kabul edildiği bir hastada cihaz serbestleştirilirken emboli gelişti. Cihaz serbestleştirildikten sonra 10. dakikada yapılan aortografide 47 hastanın 38'inde DAA'nın tamamen kapandığı ve 24 saat sonra yapılan TTE'de iki hastada cihaz içinden eser miktarda, iki hastada da cihazın kenarında hafif derecede şantın devam ettiği gözlendi. Bu hastaların üç ay sonraki kontrollerinde cihaz içerisinden kaçak olan DAA'ların tamamen kapandığı, cihaz kenarından şantı olan iki olgudan birinde şantın devam ettiği tespit edildi.

Sonuç: Duktus arteriyoz açıklığının transkateter yolla kapatılmasında ADO-1 ve ADO-2 cihazlarının seçilmiş olgularda düşük morbidite ve mortalite ile yüksek bir başarı oranı ile uygulanabildiğini gözledik.

Results: The released device was ADO-1 in 25 patients (51.2%), ADO-2 in 22 patients (45.8%), and ASO in one patient. Mean follow-up period was 13.2 months. In 97.9% of the patients, the occluder was placed into the ductus without any complication. In one patient, the device embolized to the left pulmonary artery during implantation. Aortography performed ten minutes after the procedure showed complete closure in 38 patients without residual defect. TTE revealed trace amounts of residual shunt within the device in two patients, and flow around the device in two patients 24 hours after implantation, and residual shunt in only one patient three months after the intervention.

Abbreviations:

ADO Amplatzer Duct Occluder
ASO Amplatzer septal occluder
PDA Patent ductus arteriosus
EF Ejection fraction
PASP Pulmonary artery systolic
pressure
TTE Transthoracic
echocardiography

Ductus arteriosus is an intrauterine vessel connecting proximal pulmonary artery segment to the anterior descending aorta at the level where main pulmonary artery comes closer to the left pulmonary artery.[1-3] Normally, it closes spontaneously within the first 24-48 hours after birth as a result of muscular contractions. If ductus arteriosus fails to close physiologically after postnatal 2.nd months, it is termed patent ductus arteriosus (PDA).[3-6]

Based on the diameter of the defect, and timing of the treatment, circulatory, and respiratory system are exposed to excess overload leading to the development of many hemodynamic, and structural complications as congestive

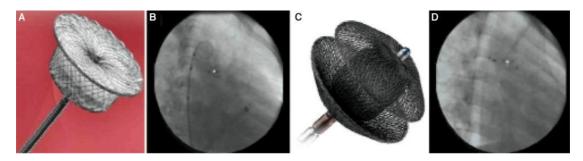
heart failure, pulmonary hypertension, growth retardation, and infective endocarditis. Fatal Eisenmenger syndrome might develop with time in patients with untreated larger size defects.[7] prevent occurrence of these complications, defect should be closed at an appropriate time. As treatment modalities surgical with staples, ligation, closure percutaneous transcatheter closure have been used.[8,9] Nowadays percutaneous transcatheter closure method has been used successfully in many centers of the world as in Turkey, [10-12] Nowadays, most frequently Amplatzer Duct Occluder (ADO)-1, and more innovative ADO-2 (Şekil 1) devices have been used together Gianturco-Grifka, Rashkind, with Buttoned. Botalloocluder. Swivel-disk occluders with residual shunt formation rates ranging between 3 and 38 percent.

In this study we evaluated clinical, and angiographic characteristics of our total of 48 pediatric, and adult cases, and also our experience, and short-term results with ADO-1, and ADO-2 occluders which we have been using for percutaneous transcatheter closure of defects.

PATIENTS AND METHOD

Among patients referred to our polyclinic from other centers located mainly in Eastern Anatolian cities between 2010 and 2012 with the diagnosis of PDA, cases with an indication of percutaneous transcatheter closure were enrolled in this prospective study. These patients had at least one of the indications for defect closure: symptoms, and signs of exertional dyspnea, and left heart failure. development of left ventricular dilation or dysfunction secondary to PDA, and pulmonary flow/ systemic flow ratio ((QP/QS)of \geq 1.5 as estimated angiographically.

Patients with irreversible pulmonary vessel disease (Eisenmenger syndrome) or those pulmonary/systemic pressure or resistance ratio above 2/3, and cases whose PDAs were evaluated as restrictive PDA were not scheduled for defect closure A total 48 patients were procedures. eligible for percutaneous closure, and they were included in the study after obtaining their approval. Diameters, and volumes of cardiac chambers, ejection fraction (EF), pulmonary artery systolic pressures (PASP), and Qp/Qs parametres of the patients were calculated as described previously.[17]



Şekil 1. Amplatzer ductal occluder (ADO) devices, and postimploantation angiographic images **(A)** Amplatzer ductal occluder-1 (ADO-1) device, and **(B)** postimplantation appearance of ADO-1 device through right anterior oblique cranial view The device is indicated with an (*); postimplantation appearance of **(C)** ADO-1, and **(D)** ADO-2 device through right anterior oblique cranial view. The device is indicated with a((†).

The patients were informed about the procedure, and its risks, and then their informed consents were obtained. A 4-6 F sheath was inserted into the right femoral artery. The caliber of the sheath was selected in consideration of height, and body weight of the patient. As a standard positioning, the patient was laid 90 degrees to his /her left side, and after injection of contrast agent at maximal doses of 1-1.5 mg/kg for children, and 30 ml for adults through pigtail catheters inserted beforehand, aortograms were

Demonstration of sustained obtained. passage of opaque material from aorta into artery through ductus pulmonary confirmed diagnosis of PDA. Ampulla, length, and the narrowest segment of the ductus were estimated from aortograms obtained, and classified according to the method recommended by Krichenko et al..[18] Patients deemed to be appropriate for defect closure, received 100 U/kg intravenous unfractionated heparin, and antibacterial prophylaxis with 500-1000

mg IV sefazolin sodium during the procedure

ADO-1 (AGA Medical, Golden Valley, MN, USA) and ADO-2 (AGA Medical, Golden Valley, MN, USA) occluders were selected in consideration of length, narrowest segment of the ductus, and diameter of the ampullar segment of the ductus on the side of the aorta. For cases with ductal diameters over 5 mm, ADO-1 device was preferred. For transcatheter closure procedure, either tranvenous (antegrade) or transarterial (retrograde) approach was used. Arteriovenous ring was constructed in 4 cases who had undergone antegrade procedures

In the antegrade approach, following application of regional anesthesia on the right inguinal region, sheaths were inserted into right femoral vein, and artery. Then a multipurpose and/or diagnostic right coronary catheter with mounted 150 cm guide wire with a caliber of 0.045 inch was negotiated through inferior vena cava, right atrium, right ventricle, and pulmonary artery, and ductus, and advanced into descending aorta. This guide wire was replaced by a new 260 cm guide wire with a 0.035 inch. Under the guidance of this new guide wire, ADO delivery system was advanced through PDA into descending aorta. Firstly disk of the device was opened in the aorta, and then disk in the pulmonary artery was engaged.

In the retrograde approach, sheath was deployed in only right femoral artery. A 150 cm- guide wire with a caliber of 0.035 inch, a multipurpose catheter or right coronary diagnostic catheter were advanced through descending aorta into ductus, and placed in the main pulmonary artery. Guide wire was replaced by a 260 cm long guide wire with 0.035 inch caliber. Under the guidance of this new

guide wire, ADO delivery system was advanced through PDA into the main pulmonary artery. Firstly, disk of the device was opened in the pulmonary artery and then disk in the descending aorta was engaged

Contrast material was administered manually and/or with the aid of a pump, and then position of the device, engagement of the disks, and condition of the residual shunt were controlled, and the device was released from the delivery system, and deployed in the ductus. To determine the presence of a residual shunt (if any), aortography was performed using a pigtail catheter while the patient was lying in the left lateral position.

The patients were followed up till 24 hours after the operation. Then their clinical tests laboratory analyses and transthoracic echocardiographic (TTE) examinations were performed before discharge. As a prophylactic measure 100-300 mg acetylsalicyllic acid was initiated. Three months later TTE was repeated. The study was approved by the local ethics committee.

Statistical analysis

All data were evaluated using "SPSS for Windows 17.0" (IBM Inc., Armonk, USA) program. Categorical data were expressed percentages. as Continuous variables were indicated as mean ± standard deviation, and in distribution ranges. Assumption normality of distribution was evaluated by one-way Kolmogorov-Smirnov test. In cases where differences between pre-, and postprocedural data had a normal distribution pattern, dependent variables –t test was used. However, for data with nonnormal distribution Wilcoxon test was employed. All data with a p value below 0.05 were considered statistically significant. For both comparisons precise *p*-values were provided.

RESULTS

Demographic, echocardiographic, and laboratory data of the cases are summarized in Table 1. The patients had complaints of exertional dyspnea (70.8 %), chest pain (47.9 %), and palpitations (31.3 %). Cardiac murmurs were heard in all patients except one (97.8%). Patients (14.6 had also symptoms of left heart %) patients failure. Female (n=31)constituted 14.6 % of the study population with a mean age of 11.5 ± 9 years. All patients had normal sinus rhythm, and preprocedural **ECGs** of patients demonstrated signs of left ventricular volume overload (n=14; 29 %), and left ventricular hypertrophy (n=8; 17 %). Preprocedural EF value estimated by TTE was 0.69±0.06, while it was 0.71±0.05 at 3^{rd} postoperative months (p=0.01). Preprocedural Qp/Qs ratio was measured as 1.90±0.25, while it was estimated to be 1.24±0.16 at postoperative 3rd month (p<0.001). Preprocedural PASP 35.11±10.76 mmHg, while it was calculated as 24.26±6.91 mmHg at 3rd (p<0.001). postoperative months Preprocedural, and control hemoglobin values were 13.83±1.60 mg/dL, and 13.54 ± 1.22 mg/dL, respectively. (p=0.16). Preprocedural, and postoperative control creatinine values were measured as 0.62 ± 0.23 mg/dL, and 0.59 ± 0.22 mg/dL, respectively (p=0.62).

Table 1. Demographic, echocardiographic, and laboratory data of the patients

Patients(n=48)		Before closure	3 months after the closure	р
,	n (%)	Mean ± SD	Mean ± SD	
Age (yrs)		11.5±9		
Female gender	31 (64.6)			
Height(cm)		129.62±28.20		
Body weight(kg)		30.4±17.5		
Echocardiographic findings				
Qp/Qs		1.90±0.25	1.24±0.16	<0.001
LVEDd		3.98±0.87	3.59±0.90	<0.001
LVESd		2.46±0.58	2.15±0.52	<0.001
LAd		2.67±0.66	2.48±0.64	<0.001
LVEDv		74.07±37.65	59.16±34.66	<0.001
LVESv		23.50±13.13	16.92±0.84	<0.001
Ejection fraction		0.69±0.06	0.71±0.05	0.01
Pulmonary artery pressure (mmHg)		35.11±10.76	24.26±6.91	<0.001
Laboratory findings				
Hemoglobin (g/dL)		13.83±1.60	13.54±1.22	0.16
Creatinin e(mg/dL)		0.62±0.23	0.59±0.22	0.62

SD: Standard sapma; Qp/Qs: Pulmonary flow /systemic flow; LVEDd: Left ventricular end-diastolic diameter; LVESd: Left ventricular end-systolic diameter; LAd: Left atrial anteroposterior diameter i; LVEDv: Left ventricular end-diastolic volume; LVESv: Left ventricular end-systolic volume.

Based on Krichenko classification, a total of 48 PDA patients were categorized as type A (n=27; 56.2 %), B (n=8; 16.7 %), C (n=7; 14.6 %), and D (n=6; 12.5 %) PDA. We hadn't any type E PDA patient. The mean diameter of the narrowest segment of the ductus was 5.38±3.50 mm (range 2-21 mm) which was observedly larger than the mean values reported in case reports cited in the literature. Transcatheter closure procedure was performed via antegrade (transvenous) (n=31; 64.6 %) or retrograde (transarterial) (n= 17; 35.4 %) routes. Angiographic data, and the followup information of the patient are indicated in Table 2. In the antegrade approach, in four cases, passage from pulmonary artery into descending aorta failed which necessitated creation of an arteriovenous ring.

Defects were closed with ADO-1 (n=25; 52.1 %), ADO-2 (n=22; 45.8 %), and Amplatzer septal occluder (n=1; 2.1 %). Ductal defect in one patient whose PDA had been closed with ADO-2 device with a resultant distinct residual shunt was closed completely with an appropriate- sized ADO-1 device. However in one patient, was recommended surgical closure because of relatively larger (21 mm) ductal defect The patient declined surgical intervention, so ductal defect was occluded with a ASO-22 mm device which was successful in 47 (97.9 %) of 48 patients. In the remaining one patient device embolization occurred in the pulmonary artery soon after release of retrogradely implanted ADO-2 device. Device in the pulmonary artery which led to formation of pulmonary embolism was snatched with a snare, and retracted into femoral vein. From there, the device was pulled outside through a small incision, and the procedure was terminated. Finally, surgical closure was recommended for the patient. Mean fluoroscopy, and procedural

times were 13.57±4.70 mins (range, 7-34 mins), and 52.96±15.88 mins (range, 31-123 mins), respectively. Aortographic examinations performed 10 minutes after the procedure revealed complete closure in 38 (81 %) of 47, trace amounts of intradevice residual shunt in 7 (15 %), and small amount of flow around the device in 2 (4.2 %) patients, respectively. In 47 (8.5 %) of the patients with residual shunts ADO-1 was implanted. TTE performed after 24 hours detected persistence of intradevice leakage in 2 (4.2) %) of 7 patients. In both of two (4.2 %) patients leakage around the edges of the device also persisted. ADO-1, and ADO-2 devices were used equally (50 %, and 50 respectively) in patients who demonstrated leakage around occluders on the first postoperative days. Echocardiographic controls performed 3 months later, and ADO-2 was implanted in only one patient with persistent minimal shunt. Excluding one case, in none of the patients, complications such as bleeding requiring transfusion, aorta dissection, cardiac tamponade, infective endocarditis, arterial or venous aneurysms, and fistula were observed.

DISCUSSION

Patent ductus arteriosus is a congenital heart disease which can be seen in adults, but more frequently observed in premature infants.[4,6,19] Early diagnosis, and treatment are extremely important in PDA, and if left untreated it can cause serious morbidity, and mortality with its early, and late-term complications. Among causes of morbidity, and mortality heart failure, pulmonary vascular hypertension, infective endocarditis, aneurysm of ductus arteriosus, and related rupture, pulmonary or systemic embolism, laryngeal nerve paralysis, and aortic dissection can be enumerated.[4,6,20,21]

Table 2. Angiographic data, and follow-up information of the patients who had undergone PDA closure procedures*

Hastalar (n=48)	n	%	Meanate SD
DAA tipi			
Туре А	27	56.2	
ТуреВ	8	16.7	
Type C	7	14.6	
TypeD	6	12.5	
Type E	0	0	
DPA (diameter of the most stenotic segment (mm)			5.83±1.34
DPA length (mm)			12.46±2.86
Diameter of the defect facing aorta *			6.73±2.43
Diameter of the defect facing pulmonary artery*			5.38±3.50
Device used			
ADO-1	25	52.1	
ADO-2	22	45.8	
AST	1	2.1	
Selection of device based on the type of the defect			
PDA Type A			
ADO-1	25 / 27	92.6	
ADO-2	1 / 27	3.7	
AST	1 / 27	3.7	
PDA Type B			
ADO-2	8/8	100	
PDA Tip C			
ADO-2	7 / 7	100	
PDA Type D			
ADO-2	6/6	100	
Dimensions of the device used			
ADO-1 (Mean diameter of the aortic disc/			11.08±2.80 / 4.41±2.74
mean diameter of the pulmonary disc) (mm)			
ADO-2 (the narrowest caliber of the device / Length of the device)			5.09±2.20 / 9.12±2.71
ASO (the narrowest caliber of the device) (mm)	21		
Approach			
Antegrade	31	64.6	
Retrograde	17	35.4	
Procedural time min)			52.96±15.88
Fluoroscopy time (min)			13.57±4.70
Follow-up period (mos)			13.23±6.28
Complication	1	2.1	
Number of monitorized patients (n=47)			
Residual shunt			
Postoperative 10. minute	9	19.1	
Postoperative 1. day	4	8.5	
Postoperative 3. month	1	2.1	

Diameter of the defect facing aorta and Ddameter of the defect facing pulmonary artery is less stenotic

SD: Standard deviation; PDA, patent ductus arteriosus; ADO: Amplatzer duct occluder; ASO: Amplatzer septal occluder

In the surgical management of PDA, ligation, isolation or both have been applied for the closure of PDA for 50 years with success rates. ranging between nearly 94 and 100 percent. However, their morbidity, and mortality rates were higher than those of transcatheter PDA closure procedures .[22,23] Firstly, in 1967, Porstmann et al[24] demonstrated transcatheter closure of PDA using Ivalog plug in a 17-year-old male patient. Efficacy of this method which is performed using various devices, and coils has been confirmed in pediatric, and adult patients, also closure with device has been firstly recommended in current guidelines especially for cases with isolated PDA..[25-28] In European guidelines PDA which cause left ventricular overload or in cases with persistent auscultated cardiac murmurs, closure of PDA has been recommended, while in silent PDAs or Eisenmenger syndrome defect should not be closed.[28]

In many studies, transcatheter closure procedures reportedly have been performed with higher success rates both in children, and adults. Thanopoulos et al.[27] reported success rates of 95, and 98 %, soon after, and one month after device implantation in patients with a mean age of 3.6 years. In another study, a ductal occluder (ADO in 25 patients, and another brand occluder in the remaining 1 patient), was used and complete closure was achieved in 73.1, 84.6, and 96.1 % of the patients immediately, 24 hours, and 3 months after the procedure.[29] In a large scale study which included both pediatric, and adult patients, ADO-1 device had been successfully implanted in 435 of 439 patients, and success rates of 70, and 99.7 % were reported immediately, and within one year after the procedure.[30] In our study which enrolled patients aged between 2, and 39 years, in 47 of 48 cases ADO-1, ADO-2, and ASO were implanted with a highly success rates (97.9%). Aortograms obtained 10 minutes after the procedure demonstrated complete closure (n= 38; 81 %), trace amounts of leakage through the device (n=7; 15 %), and a small shunt around the edges of the device (n=2:4.2 %). Echocardiographic examinations performed 3 months later revealed that trace amount of residual shunt detected within the device on the first postprocedural day, disappeared completely, while in one of 2 cases with small amounts of leakage around the edges of the device, residual shunt persisted. In our study using ADO-1, ADO-2, and in one case ASO devices, we achieved complete closure at the end of 3 months, in 46 of 48 cases (95.8%).

Embolization during release of the device is one of the important complications of the procedure. Embolization can occur in systemic, and generally in pulmonary artery. In their published series of 27 cases, Forsey et al [31] reported displacement of the device (n=1), and embolization (n=1)They development attributed of these complications to underestimation of ductal diameter secondary to spasm of the ductus arteriosus induced by catheterization with resultant implantation of a smaller device. However in another study, development of device embolization was reported in 3 of 209 patients which was associated with catheter manipulation performed after deployment device in one, and spontaneous occurrence in 2 patients, respectively.[32] In our study, as a procedural complication only device embolization was observed in one patient.

In one of our cases, 3 years after the implantation of the first device (ADO-2) blood flow through the device was observed which necessitated closure of the residual defect with another device (ADO-

1) (Figure 2). Even though closure of the ductal defect was reported in the literature previously,[33] as far as we know implantation of more than one device in the same patient has not been reported so far. In this patient, ductal defect was successfully closed using a second device, and any residual shunt was not detected. In one of our case extremely enlarged ductal defect (22 mm) was closed using an ASO device, and any complication did not develop during follow-up period. In the literature, closure of PDA with the same device has been reported only once, and any study related to this subject is lacking. [34] However we think that in selected cases with elongated, and enlarged PDA, closure of defect with ASO device is an alternative approach.

ADO devices have been designed to facilitate management of PDA using

percutaneous transcatheter approach, and also reduce relevant complication rates The capability of the originally developed ADO device (ADO-1) to close all PDA defects with a wide range of diameters has been shown in various studies.[26] Besides, in a study conducted using this device, serious complication rate was reported to be only 2.3 percent. Especially in infants weighing less than 5 kg, ADO-1 device can demonstrate obstructive lesions within the pulmonary artery or aorta.[35] ADO-2 device has been designed more recently, and it can be especially used safely in small children, and infants. .[12,36] Besides, design of the device allows for both antegrade, and retrograde deployments. [12] However, for larger defects use of ADO-1 device has been found to be more appropriate.[37]

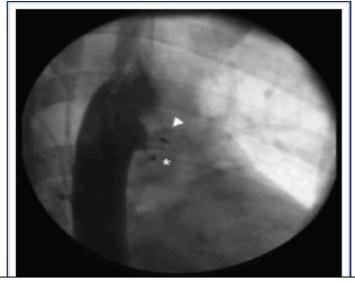


Figure 2. aortographic right anterior oblique cranial view of the ADO-2 device implanted in the patient for a residual defect developed after ADO-1 device implantation performed 2 years ago. Any postimplantation leakage of blood flow is not seen. ADO-2, and ADO-1 devices are indicate with (*), and arrowhead,

Patients within a wider age range were included in our study. We have demonstrated that percutaneous treatment can be realized with lower complication, and residual shunt rates. Nowadays,

thanks to advances in diagnostic, and therapeutic modalities, diagnosis, and treatment of DPA can be accomplished at a relatively early age. However, especially in patients with a lower socioeconomic status, diagnosis, and treatment can be delayed because of difficulties experienced in affording healthcare expenses. The most important distinction between ours and other patient groups is that mean age at diagnosis was greater in our study group because of particularities of the region which we provide medical coverage. This phenomenon changes patient profile, and creates differences in the devices used. We think that our outcomes will have favourable for regions implications the with comparable patient profile.

In conclusion, percutaneous transcatheter closure of PDA using ADO-1, and ADO-2 occluders can be performed safely, and effectively for patients within a wider age range with lower complication rates. In some cases, closure of the residual defects with another ADO device or in larger defects closure with an ASO device can be considered as alternative procedures. However lack of adequate evidence precludes making conclusive recommendations on this issue.

Limitations of the study

Our study is a single centered case series. This study design prevents making clear-cut recommendations about ADO devices. Since it reflects experiences of a single center, it is not appropriate, and proper to make generalizations for all centers. On the other hand, our results are in line with previously performed studies, and support the opinion favouring safety of PDA closure using ADO.

In our study an ADO-1 occluder was implanted in a patient with residual shunt who had been implanted an ADO-2 occluder, previously. Another patient underwent an ASO implantation with the indication of a larger PDA. Even though both procedures were successful without any complication, based on the results of this study it will not be accurate to say that

both procedures are safe. However we think that both procedures are viable alternatives in appropriate cases.

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Conflict of Interest: None declared REFERENCES

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Anahtar sözcükler: Amplatzer tıkayıcı cihaz; duktus arteriyozus, açıklık/tedavi;

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Key words: Amplatzer occluder device; ductus arteriosus, patent/therapy; echocardiography; heart catheterization; septal occluder device.