DOI: 10.4274/jbuch.galenos.2024.08634
J Dr Behcet Uz Child Hosp 2024;14(2):71-80

Original Article

Percutaneous Closure of Patent Ductus Arteriosus in Children Using ADO I and ADO II Devices: A Thirteen Year Single Centre Experience

Çocuklarda Perkütan Yöntemle ADO I ve ADO II Cihazları Kullanılarak Patent Duktus Arteriosus Kapatılması: On Üç Yıllık Tek Merkez Deneyimi

Mustafa Mertkan Bilen[1], Murat Muhtar Yılmazer[1], Gamze Vuran[1], Mehmet Murat[2], Ceren Karahan[3], Cem Doğan[1], Yusuf İlker Dur[1], Timur Meşe[1]

[1]University of Health Sciences Turkey, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital, Clinic of Pediatric Cardiology, İzmir, Turkey
[2]University of Health Sciences Turkey, Gazi Yaşargil Training and Research Hospital, Clinic of Pediatric Cardiology, Diyarbakır, Turkey
[3]Dr. İsmail Fehmi Cumalıoğlu City Hospital, Clinic of Pediatric Cardiology, Tekirdağ, Turkey

ABSTRACT

Objective: Transcatheter closure of patent ductus arteriosus (PDA) has taken its place as the first choice in the treatment of PDA thanks to the development of new devices and techniques. In this study, we present our cases with PDA closed with Amplatzer duct occluder I (ADO I), Amplatzer duct occluder II (ADO II) and discuss the efficacy and safety of transcatheter PDA closure with these devices in children.

Method: Between January 2010 and January 2023, a total of 373 patients underwent PDA closures using ADO I (n=40), and ADO II (n=333) devices in the Pediatric Cardiology Clinic of our hospital and PDA closure was successfully performed in 370 patients. These cases were analysed retrospectively.

Results: The mean age of our patients was 3 (0.2-17) years. The mean narrowest diameter of the PDA was 2.48±0.80 mm. Median procedure and fluoroscopy times were 55, and 11 minutes, respectively. The procedure was successful in 99.1% of the cases. PDA was successfully treated in 387 patients using ADO I (n=39), ADO II (n=331) devices. Minimal residual shunt was detected as a minor complication only in 7 patients in the acute phase. In 4 of these 7 patients, residual shunt disappeared completely in the follow-up period, but it persisted in 3 patients. Major complications in our study were device embolisation in 2 patients who underwent ADO I and infective endocarditis that developed in 1 patient 2 weeks after the procedure. In our patient with device embolisation, the device was tried to be removed with the help of a snare, but it failed, so it was surgically removed and the PDA was closed surgically. In our case with infective endocarditis, the device was surgically removed and the PDA was surgically closed. In one patient, the mean pulmonary artery pressure measured during the procedure was found to be high with 29 mmHg, but the procedure was continued because the pulmonary vasoreactivity test was positive. In the procedure performed with ADO I device, the PDA was closed by opening the first disc without releasing the device, but the procedure was not continued because the patient developed desaturation.

Conclusion: Transcatheter PDA closure can now be successfully performed in many centres. In this study, we evaluated the cases of PDA closure performed with ADO I and ADO II devices, in the last 13 years. As a result of our study, in accordance with the literature data, we have shown that transcatheter PDA closure using ADO I, ADO II devices is an effective and safe method with low complication rates in children.

Keywords: Patent ductus arteriosus, Amplatzer duct occluder, percutaneous closure, pediatric

ÖZ

Amaç: Transkateter yöntemle patent ductus arteriosus (PDA) kapatılması yeni cihaz ve tekniklerin gelişimi ile birlikte tedavide ilk seçenek olarak yerini almıştır. Bu çalışmada Amplatzer dukt okluder (ADO) ve Amplatzer dukt okluder II (ADO II) kullanılarak kapatılmış olgularımız sunulmuş, çocuklarda bu cihazlarla PDA kapamanın etkinlik ve güvenilirliği tartışılmıştır.

Yöntem: Hastanemizçocuk kardiyoloji kliniğinde Ocak 2010-Ocak 2023 tarihleri arasında toplam 373 hastaya (40 ADO, 333 ADO II) cihazı uygulanmış, 370 hastada PDA kapama başarıyla yapılmıştır. Bu olgular retrospektif olarak incelenmiştir.

Bulgular: Hastalarımızın ortanca yaşı 4,3 yıl (2 ay-17 yaş) idi. PDA en dar çapı ortalama 2,45±0,80 mm idi. Ortalama işlem ve floroskopi süreleri sırasıyla 55 ve 11 dakika idi. Olguların %99,1'inde işlem başarılı olmuştur. Başarılı olunan 370 hastanın 39'unda ADO, 331'inde ADO II cihazı kullanılmıştır. Minör komplikasyon olarak yalnızca 7 hastada akut dönemde minimal rezidüel şant saptanmıştır. Bu 7 hastanın 4'ünde takipte rezidüel şant tamamen kaybolmuş 3'ünde ise minimal düzeyde devam etmiştir. Çalışmamızda majör komplikasyonlar ADO II uygulanan 2 hastada görülen cihaz embolizasyonu ve 1 hastamızda işlemden 2 hafta sonra gelişen enfektif endokardit idi

Received: 23.01.2024
Accepted: 14.03.2024

Corresponding Author
Mustafa Mertkan Bilen,
University of Health Sciences Turkey, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital, Clinic of Pediatric Cardiology, İzmir, Turkey
bilen.uygar@gmail.com
ORCID: 0000-0002-8906-5075

Cite as: Bilen MM, Yılmazer MM, Vuran G, Murat M, Karahan C, Doğan C, Dur Yİ, Meşe T. Percutaneous Closure of Patent Ductus Arteriosus in Children Using ADO I and ADO II Devices: A Thirteen Year Single Centre Experience. J Behcet Uz Child Hosp. 2024;14(2):71-80

Cihaz embolizasyonu gelişen olgumuzda cihaz snare yardımıyla çıkarılmaya çalışılmış ancak başarısız olunması üzerine cerrahi olarak çıkartılmış ve PDA cerrahi yöntemle kapatılmıştır. Enfektif endokardit olan olgumuzun cihazı cerrahi olarak çıkarılmış ve PDA cerrahi olarak kapatılmıştır. İşlem sırasında bir hastada ortalama pulmoner arter basıncı yüksek (29 mmHg) ölçülmüş, ancak pulmoner vazoreaktivite testi pozitif olduğu için işleme devam edilmiştir. ADO I ile uygulanan işlemde cihazı çıkartmadan önce ilk disk açılarak PDA kapatılmış, ancak hastada desatürasyon geliştiğinden işleme devam edilmemiştir.

Sonuç: Transkateter PDA kapatma artık birçok merkezde başarıyla uygulanabilmektedir. Biz de bu çalışmada son 13 yılda ADO I, ADO II cihazlarıyla gerçekleştirdiğimiz PDA kapatma olgularını değerlendirdik. Çalışmamızın sonucunda literatürle de uyumlu olarak, çocuklarda transkateter yöntemle ADO I, ADO II embolizasyon cihazları kullanılarak yapılan PDA kapamanın düşük komplikasyon oranıyla etkili ve güvenli bir yöntem olduğunu göstermiş olduk.

Anahtar kelimeler: Patent duktus arteriosus, Amplatzer dukt okluder, perkütan kapatma, pediatrik

INTRODUCTION

Patent ductus arteriosus (PDA) is located between the left pulmonary artery and the anterior descending aorta in the intrauterine period and its presence is necessary to receive oxygen from the placenta during the fetal period. After birth, as the infant's respiratory system is activated, the ductus arteriosus is expected to close, first functionally and then anatomically with fibrous replacement of the ductal tissue[1]. When the PDA does not close, an open connection remains between the left pulmonary artery and the anterior descending aorta with resultant increase in the left ventricular workload and the risk of heart failure[2]. In addition, pulmonary hypertension may develop with an increased risk of mortality and morbidity in the long term[3]. Transcatheter closure of PDA is an interventional procedure that does not require surgical intervention and is currently the firstly preferred treatment option. PDA closure was first performed by Porstmann et al.[4] in a 17 year-old female patient using an Ivalon plug. In the following years, Rashkind and Cuaso[5] used a polyurethane foam-coated disc umbrella, and in our country, treatment with the Rashkind umbrella was initiated in the early 1990s, and then oscillation-controlled coils were used for the occlusion of PDA. While a controlled oscillation coil can be used for a small diameter PDA, devices such as the Amplatzer duct occluder I (ADO I) and Amplatzer duct occluder II (ADO II) may be preferred for the management of a PDA with a larger diameter. ADO I and II are preferred devices because of their ease of surgical application, repositioning and low migration rate[6].

In this study, we aimed to observe our mid-to long-term clinical experience with transcatheter PDA closure using ADO I and ADO II devices and to evaluate the efficacy and safety of transcatheter PDA closure with these two devices.

MATERIALS and METHODS

A retrospective evaluation of 373 patients with PDA hospitalised in our clinic between 2010 and 2023, and underwent transcatheter closure of PDA. The procedure details of these patients were obtained from the hospital archives. The written consent was obtained from the families of the patients included in the study.

The study was conducted in accordance with the Helsinki Declaration's standards and was approved by University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital's Ethics Committee (decision number: 2023/514/258/26, date: 27.09.2023).

Using transthoracic echocardiography, the defect was evaluated in detail through the parasternal short axis and suprasternal windows and its morphology and dimensions were determined. Patients with irreversible pulmonary vascular disease (Eisenmenger syndrome) or high pulmonary/systemic pressure and resistance ratios did not undergo closure and were excluded from the study.

Devices

The ADO I and II devices (AGA Medical Corporation, Golden Valley, Minnesota, USA) are low-profile, self-expanding occluders consisting of a mushroom-shaped 0.0004-0.0005 inch nitinol wire mesh. They consist of a metal rigid disc on the outside and a cylindrical main body containing polyester fibrils inside. The cylindrical body is asymmetrical and the proximal part is smaller (Figure 1). The ADO I device is a low-profile device consisting of a mushroom-shaped nitinol wire mesh. It consists of a distal retention disc that can self-expand and attach to the ampulla and tubular parts that occlude the ductus proximally. The body length of the device varies between 5-8 mm. The diameter of the retention disc is 4 mm larger than the body diameter[7]. The ADO II device, which was developed later, consists of two equal sized discs and a thin waist in the middle. This device has a waist diameter of 3-6 mm and a length of 4-6 mm and is designed for closure of ducts with a diameter smaller than 6 mm (Figure 2). Since the ADO II device does not contain filler, it can be placed with smaller diameter delivery catheters[8,9]. ADO I and ADO II devices are very suitable for the closure of conical shaped ducts.

The PDA can be closed by antegrade (arterial) or retrograde (venous) approach. In the retrograde

approach, it is necessary to insert a second arterial catheter for angiographic control after placement of the device. The advantage of the antegrade approach is that every stage of the procedure can be controlled by injections through the arterial catheter. While the ADO II device can be applied using both venous and arterial access, the ADO I device can only be applied through the antegrade approach[10].

In our study, our choice of venous or arterial approach was based on the echocardiographic and angiographic shape of the PDA, the patient's age, weight and the diameter of the descending aorta.

Catheterisation

All patients received prophylaxis for infective endocarditis and dissociative anaesthesia with midazolam and ketamine before the procedure. Local anaesthesia was also applied to the puncture site. Firstly, cardiac catheterisation was performed to determine haemodynamic variables. Depending on the height and weight of the patient, 4F, 5F and/or 6F sheaths were inserted into the right femoral vein and/or artery using Seldinger percutaneous technique[10]. After administration of heparin at a dose of 50-100 U/kg for heparinisation, systolic, diastolic and mean arterial pressures were measured with a multipurpose catheter and blood gases were obtained from the superior vena cava and pulmonary artery. Blood gases obtained from pulmonary artery and right ventricle were analysed for patients to be intervened by retrograde route. Pulmonary blood flow/systemic blood flow (Qp/Qs) ratio was determined according to Fick's principle of cardiac output measurement[11]. As a standard procedure, cardiac catheterisation was performed with the patient lying in 90 degrees left lateral decubitus position and right anterior oblique position. Aortography was performed with a non-ionic opaque substance at a dose of 1-1.5 mL/kg (maximum 30 mL) using a pigtail catheter and the ampulla, narrowest point and length of the ductus were measured and typing of PDA was performed according to the angiographic method proposed by Krichenko et al.[12] (Figure 3).

Figure 1. Amplatzer duct occluder I

Figure 2. Amplatzer duct occluder II

Percutaneous Closure Procedure

Two different devices, ADO I, and II were used for percutaneous closure. The choice of the device was based on factors such as the width of the ampulla on the aortic side of the duct on aortography, its narrowest diameter and length.

The closure procedure was performed under sedation. General anaesthesia was not preferred except

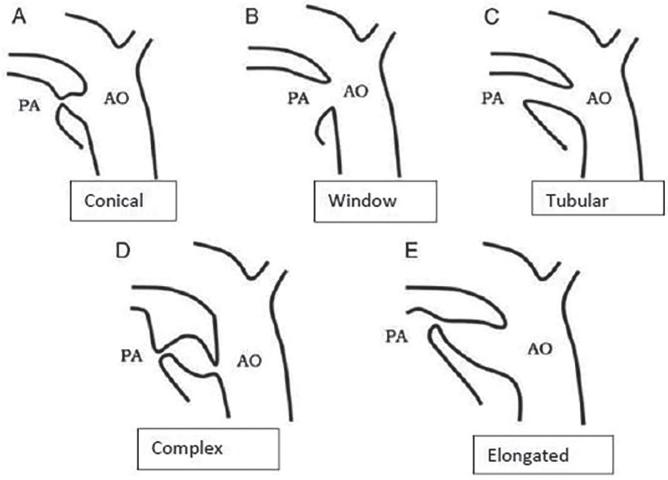

Figure 3. Angiographic classification of patent ductus arteriosus

in rare cases where the patient was resistant to medical anaesthetic drugs used for sedation and was mobile enough to threaten the safety of the procedure[13]. Intravenous heparin at a dose of 50-100 units/kg was given to all patients during the procedure.

There are no hard and fast rules for which patients ADO II or ADO I devices should be preferred[14]. However, we decided on the device to be used by measuring the diameter and length of the ductus, the width of the bulb, and the diameter of the descending aorta. For example, in patients with large PDA, if the PDA was conical and not very long, ADO I device was preferred. In patients with smaller PDA, ADO II device was preferred if the diameter of the descending aorta was appropriate (so that the device would not cause stenosis). In addition, ADO II device can also be implanted via the retrograde route, in cases where the pulmonary artery does not pass through the PDA to the aorta allowing the implantation of this device via the retrograde route. Therefore, we primarily preferred the ADO II device in small or medium-sized defects or in cases where antegrade passage could not be achieved.

In the transvenous approach, a multipurpose catheter with a sheath was inserted percutaneously through the right femoral vein and artery and a 150 cm-0.035 inch guidewire was then advanced percutaneously by way of the ductus through the inferior vena cava, right atrium, right ventricle and pulmonary artery to the descending aorta. The guidewire was then replaced with a new 260 cm-0.035 inch guidewire and the Amplatzer TorqVue LP delivery system was guided from the ductus to the descending aorta. Firstly, the disc on the aortic side of the device and then the disc on the pulmonary artery side were opened. In the transarterial approach, only the sheath was placed in the right femoral artery. Using a 150 cm-0.035 inch guidewire, the ductus was passed through the descending aorta with the Judkins right catheter and the main pulmonary artery was reached. The guidewire was replaced with a 260 cm-0.035 inch guidewire and under the guidance of this wire, the Amplatzer TorqVue LP delivery system was passed from the ductus to the main pulmonary artery. Firstly, the disc of the device on the pulmonary artery side and then on the descending aorta side were opened. Control aortography and transthoracic echocardiography were performed to check the location of the device, the opening status of the discs and the residual shunt. Control angiography was performed using a separate catheter passed through the aorta in cases with antegrade closure, whereas in retrograde cases, it was performed using the loading catheter of the device. Afterwards, if the device was in the appropriate position, it was released from the delivery system, inserted into the ductus and the procedure was terminated. Then, the patients were taken to the ward and monitored and the puncture sites were checked. Control echocardiography was performed one day later. Two-dimensional and colour Doppler echocardiograms were obtained to evaluate residual shunt, right-left pulmonary artery and stenosis of the descending aorta, ventricular function, and valvular regurgitation. Patients with no complications were discharged. Patients were evaluated clinically and echocardiographically at the 1st, 3rd, 6th, and 12th months within the first year after percutaneous closure, then followed up annually.

Statistical Analysis

Statistical analysis of the data was performed using "SPSS 18.0" statistical software. Kolmogorov-Smirnov test was performed to check for the normal distribution of the numerical data. Since all of the data in our study did not fit the normal distribution, non-parametric tests (Mann-Whitney U) were preferred. In addition, chi-square analysis was used to compare categorical data. The level of statistical significance was determined as $p<0.05$. The results obtained by these analyses were evaluated and statistically significant differences and correlations were determined.

RESULTS

In the last 13 years, transcatheter closure of PDA was attempted in a total of 373 patients using ADO I and ADO II devices in our clinic. The procedure was successful in 371 (99.5%) of these patients. In 2 patients in whom ADO I was used, the device embolized to the aorta in one patient and to the femoral artery in the other when the device was released. In the patient with device embolisation in the femoral artery, the narrowest part of the PDA was measured to be 3.9 mm and a 3x4 mm ADO I device was selected for this patient. The device embolized the right femoral artery, then it was trapped in the iliac artery bifurcation, but it was successfully removed from the body using a snare catheter. The PDA of this patient was subsequently closed surgically. In the patient with device embolisation of the aorta, the narrowest part of the PDA was measured as 2.5 mm and a 3x4 mm ADO I device was selected. The device was tried to be removed using a snare catheter but the procedure failed. The embolized device was surgically removed and the PDA was surgically closed simultaneously.

Five patients (1.3%) had previously undergone surgical PDA ligation but had residual PDA. Since an atrial septal defect of more than 8 mm was detected in the transthoracic echocardiographic evaluation of 4 patients whose PDA was closed with ADO II, simultaneous atrial septal defect device embolisation together with atrial septal defect closure was performed in these patients. In 3 patients whose PDA was closed with ADO II, mild stenosis was detected in the left pulmonary artery on transthoracic echocardiographic evaluation. In the follow-up of these patients, the stenosis completely resolved within the first 6 months. The median age of the patients was 3 (0.2-17) years and the median PDA diameter was 2.4 mm (1.1-6.5). The average follow-up period was 5 (0.5-13) years. Our study population consisted of 145 (38.8%) male and 228 (61.2%) female patients with a female/male ratio of 1.57. The median pulmonary artery pressure was 16 (13-29) mmHg. Our study patients had conical (n=259; 69.4%), tubular (n=108; 29%), window-shaped and/or elongated ductus, (n=6; 1.6%), and PDA was closed using ADO I device in 40 (10.7%) and ADO II device in 333 (89.3%) patients. The mean duration of fluoroscopy was 8.8 (4.8-26.7) minutes. The median (range) values for Qp (6.9:3.6-34.9), Qs (4.3:1.2-20.9), Qp/Qs (1.5:0.81-6), pulmonary vascular resistance (PVR)/systemic vascular resistance (SVR) (0.08:0.01-2.15), while median (range) PVR (1.5:0.2-8.8 Wood units), SVR (16.5:2.78-63.9 Wood units) were as indicated.

Minimal residual shunt was present in 7 (1.8%) patients in the early postoperative period. However, minimal residual shunt persisted in only 3 (0.08%) of these patients and the shunt disappeared in the remaining 4 (0.1%) patients.

When comparing patients in terms of the devices used, the average PDA diameter of patients who had ADO I device was statistically significantly longer than those who had ADO II device (median values of 3.2 mm and 2.2 mm, respectively; p<0.001). However, any significant intergoup differences were not observed in terms of age, weight, PVR/SVR ratio, Qp/Qs ratio, mean pulmonary artery pressures, fluoroscopy time, and duration of the procedure among patients using different devices (p>0.05). Transcatheter closure was performed using the antegrade route (venous) in 103 and the retrograde route (arterial) in 270 patients. The demographic and procedural data of the patients is summarized in Table 1.

Thrombosis developed at the access site in 6 patients. In only 1 of these 6 patients, thrombosis did not regress despite heparin treatment and recombinant tissue plasminogen activator treatment was required. Thrombosis completely regressed in this patient after treatment. All patients who developed thrombosis were patients who underwent arterial intervention.

In one male patient, 2 weeks after the procedure was successfully performed, high fever and deterioration in general condition were observed. Transthoracic echocardiography revealed an increase in echogenicity of the device which had not been seen before, and device-related infective endocarditis was considered and antibiotherapy was started. However, despite

Table 1. Demographic and procedure information

n	373
Success rate	371/373 (99.5%)
Age, median	3 (3.5 months-17 years)
Gender (male/female)	145/228 (1.57)
Follow-up duration, median	5 (5 months-13 years)
PDA narrowest diameter, median	2.4 (1.1-6.5 millimeters)
ADO I device, n (%)	40 (10.7%)
ADO II device, n (%)	333 (89.3%)
Fluoroscopy duration, median	8.8 (4.8-26.7 minutes)
Qp/Qs, median	1.5 (0.81-6)
PVR/SVR, median	0.08 (0.01-2.15)
ADO I vs ADO II PDA diameter, median	3.2 vs. 2.2 millimeters, p<0.001
Mean pulmonary pressure, median	16 (13-29 mmHg)
Antegrade approach, n (%)	103 (27.6%)
Retrograde approach, n (%)	270 (72.4%)

n: number, PDA: Patent ductus arteriosus, ADO I: Amplatzer duct occluder I, ADO II: Amplatzer duct occluder II, Qp: Pulmonary flow, Qs: Systemic flow, PVR: Pulmonary vascular resistence, SVR: Systemic vascular resistance

intensive treatment, the patient's febrile episodes did not regress and his general condition deteriorated, so surgical removal of the device was decided. After the device was surgically removed and the defect was closed, the patient's fever decreased and his general condition improved.

DISCUSSION

Complications such as neurodevelopmental adverse effects, pneumothorax secondary to surgery, development of hemorrhagic complications and infection observed after surgical closure of the PDA have led clinicians to search for alternative treatment methods, and transcatheter closure of PDA has taken the first place among treatment options as a minimally invasive procedure[15]. Closure of all haemodynamically significant PDA has been recommended[16]. Percutaneous transcatheter closure is recommended as the first-line treatment most suitably for the conical type PDA.

Over time, simplification of percutaneous transcatheter closure system, delivery of small-caliber PDA occluders and the development of innovative systems that allow repeated trials before the device is released have popularized the transcatheter method of duct closure. In our study, ducts were closed with 99.5% success by transcatheter method. PDA closure with the ADO was firstly introduced in 1997. The main criterion for device selection is the diameter and morphology of the ductus. ADO I and ADO II devices are very suitable for closure of conical and some tubular shaped ducts.

In a study evaluating 389 patients for transcatheter closure of the PDA without using arterial access, Cook® detachable coil was used in 288 and ADO I in 101 patients and patients were followed up for an average of 1 year after the closure[17]. In the ADO I group, venous access had been successful in 82% of these patients. Reintervention was necessary in two patients due to device embolisation. Ductal closure with ADO I was performed in 2 patients who developed embolisation. Unlike this study, which included a similar number of patients as our study, we preferred both antegrade and retrograde access. Our choice of venous or arterial approach was based on the echocardiographic and angiographic morphology of the duct.

As a major complication, the authors reported device embolisation in a comparable number of cases as in our study and the patients who underwent closure with ADO I developed embolisation as in our study[17]. Since arterial intervention was not performed in the above-mentioned study, thrombosis was not detected unlike our study. Since it is difficult to perform a control angiography by placing another catheter in the artery in cases where the retrograde route is used and because of the risk of embolisation, it is more preferable to use the antegrade route in eligible patients.

In a study from Italy, ADO I and II devices were used in the patient group with a mean PDA diameter of 3.2±1.2 mm (1.8-9 mm)[18]. Complete occlusion was achieved at a rate of 77.8% at 24 hours, 92.6% at 1 month and 94.4% at 23±12 months. It was reported that PDA morphology and Qp/Qs ratio did not affect the development of residual shunt or complete closure success rates. Long-term follow-up showed a higher occlusion rate in the ADO group[19]. When compared with our study, demographic characteristics and mean PDA diameters of the patients were similar in both studies. Similar to the Italian study, ductus morphology and Qp/Qs ratios had no effect on achievement of complete occlusion in our study.

In the follow-up of percutaneously closed PDAs, residual shunts may sometimes be observed and interventional treatment may be required for these residual shunts. In cases with a clinically significant residual shunt, a second closure with a coil or another device may be required which may increase the complication rates[20,21]. It should be considered that the anatomy and shape of the ductus may have altered in previously operated patients, so current attempts to close PDA should be performed accordingly. In our 3 patients with residual shunt, since the amount of residual shunt was found to be very small and haemodynamically insignificant based on the results of clinical and transthoracic echocardiographic evaluation, any re-interventional procedures were not performed and the patients were continued to be followed up clinically.

In our patients, our procedure and fluoroscopy times were similar to the literature, but we achieved higher mean occlusion rate (99.5%) using ADO I and ADO II devices. However, we prefer ADO II device in PDAs with a diameter <2.5 mm, provided that it does not cause stenosis in the descending aorta or pulmonary artery. Compared to the ADO I, the ADO II device has been used more frequently because it has a lower risk of aortic protrusion, ensures closure of almost all PDA types, and it can be used with a smaller delivery sheath as in most of our cases where ductal diameter was <5 mm. In recent years, the ADO Piccolo device, which has

flatter retention discs and a thicker waist compared to currently used occluders has been produced for the management of much smaller PDAs[22]. It can be safely applied in small PDAs with insufficient ampullas[23]. In our study, patients whose PDAs were closed with the ADO Piccolo device were not included in our study because data entry was performed afterwards. The ductuses of these patients were successfully closed and no complications developed during the procedure.

Although transcatheter closure of PDA is safe and effective, various complications such as haemolysis[24], embolisation[25], infective endocarditis[26] and narrowing of adjacent vessels may occur. In patients whose PDAs were closed by transcatheter method using different devices, major complications (significant haemolysis, infective endocarditis, device embolisation) and minor complications (mild narrowing of the descending aorta, mild narrowing of the origin of the left pulmonary artery) may be observed[27]. In a multicentre study conducted by Pass et al.[28] in the USA, PDAs of 484 patients with a mean age of 1.8 years were closed with ADO I and II devices. The major complication rate was found to be 2.3% at one year follow-up. Eighteen out of 484 (0.3%) patients had vascular complications and/or blood loss requiring transfusion. In 2 patients in our series, the ADO II device embolised to the descending aorta and femoral artery immediately after the procedure. Pulmonary artery pressure was not very high in these patients. Therefore, we thought that embolisation was related to the small diameter of the defect. In one of our patients, febrile episodes and deterioration of general health condition developed 2 weeks after the procedure, and device-associated infective endocarditis was diagnosed after transthoracic echocardiographic evaluation of the patient revealed an increase in device echogenicity that had not been previously present. In this patient, we perfectly applied prophylactic measures against the development of infective endocarditis and sterile techniques during procedures. Therefore, we found no etiology to explain the development of infective endocarditis.

In the study conducted by Gruenstein et al.[29] in 2017 with 436 patients in which they experienced PDA closure with ADO II, patients aged between 6 months and 18 years, and those with a ductal diameter <5.5 mm were included in the study. The gender (Male: 120-63%, Female: 72-38%), and mean age (2.5±4.5 years) of the patients, type of PDA (conical 73-48%, tubular 31-16%) were similar to our study. Unlike our study, the rate of elongated type PDA was close to 20% (n=38). Antegrade access had been performed in 62% (n=128) of the patients and a significant decrease in fluoroscopy time was detected in the use of retrograde access (11.6 66.3 min. vs. 15.2 69.1, min. p=0.0001). Device embolisation developed in one patient and the device was removed by snare method. In 9 patients, the procedure was not continued because of protrusion into the left pulmonary artery or aorta before the device was left *in situ*. In two patients, residual shunt persisted during the post-procedural follow-up period. Residual shunt of their patients had been closed at follow-up, while the PDA of the other patient was closed again with coil embolisation in the first year of follow-up and the shunt was repaired. In our study, we observed that mild stenosis of the left pulmonary artery detected in post-procedural transthoracic echocardiography in three patients and continuous-wave Doppler ultrasound measurement of Δ17 mmHg in the arcus aorta after transcatheter closure in one patient were completely normalised during follow-up.

In the year 2013 Liddy et al.[30] performed a PDA closure study using Amplatzer duct occluders ADO I and ADO II on 177 patients with a mean age of 3.3 years and the mean PDA diameter of 2.5 mm. One hundred and twelve patients (63.3%) with conical type ductuses underwent PDA closure using ADO I (n=89; 50.9%), or ADO II (n=59; 33.3%) devices. Residual shunt was observed in 2 patients in the first 48 hours after the procedure. The residual shunts of these 2 patients disappeared completely in 6 month follow-up. Retrograde approach was used in 60% of the patients who underwent the procedure using ADO II device. Fluoroscopy time was shorter in patients who had undergone the procedure using the retrograde approach (3.7 vs. 5.0 min., p=0.0068). Protrusion developed in 7 (3.9%) patients using ADO II and in 10 (5.6%) patients using ADO I. Device embolisation developed in two patients. There was no difference in the rates of embolisation, residual shunt and protrusion in patients who had undergone PDA closure using retrograde or antegrade route. Compared to the study performed by Liddy et al.[30], post-procedural residual shunt was seen more frequently (n=8) during early postoperative period, but it was similarly observed in only three patients during the follow-up period since the residual shunts in our study were not found to be haemodynamically significant, any re-intervention was not performed. The types of PDA repaired, retrograde approach, and embolisation rates, fluoroscopy times were comparable to those reported by Liddy et al.[30].

In a study conducted by Baykan et al.[31] in Erciyes University, 379 patients, with a mean age of 18 months

(6 months-6 years) had conical (n=182), tubular (n=174), elongated (n=2), window-type (n=21) PDAs For the PDA closure, ADO I (n=149), ADO II (n=149) devices and Cook® coils (n=179) had been used in respective number of patients. Arterial route was used in 257 and venous route in 122 patients. Device embolisation developed as a major complication in only 5 patients. The patients who had developed device embolisation weighed less than 2000 grams. Our study was demographically different from the study of Baykan et al.[31] and compatible with the literature. Although it was similar to our study in that mostly arterial interventions had been performed, the rate of major complications was lower in our study.

Eight years ago Yılmazer et al.[32] used different occluder types in 82 patients in our centre, and PDAs of 291 new patients were closed during this period. Despite a significant increase in the number of patients treated, only one patient had device embolisation as a major complication during this period and the device was surgically removed. It is remarkable that as experience gained by the clinical team, minor complications were not seen except for 2 new patients with haemodynamically insignificant shunts.

Our results have shown that transcatheter PDA closure is an effective and safe method with low complication rates in children. In our study, the procedure was performed in a total of 370 patients with a success rate of 99.1 percent. Device embolisation occurred in only two patients and surgical intervention was required in these patients. Embolisations were observed in patients in whom the ADO I device was used. The ADO II device allows the closure of more challenging anatomical structures due to its advantages of using the retrograde route. Careful patient selection and meticulous planning of the procedure is important in patients at risk of embolisation.

Very scarce number of (1.8%) patients had minimal residual shunts in the acute period after closure. Except for a few patients, almost all of the residual shunts in the acute period were closed. These results support the efficacy and success of transcatheter PDA closure. Major complications such as device embolisation and infective endocarditis were rarely seen (0.8%). The case of infective endocarditis was treated by surgical removal of the device. Such rare complications emphasize the importance of performing transcatheter PDA closure carefully and in expert hands. In our study, demographic and clinical characteristics of the patients in whom different devices were used were also analysed. It was found that PDA diameters were smaller in patients whose PDAs were closed with ADO II device rather than ADO I device. This result shows that the choice of occluder should be based on the size and anatomical features of the ductus. The device that should be preferred should be determined depending on the type, diameter and anatomical features of patient's PDA.

Study Limitations

The data was collected from a single centre, which may limit the generalizability of the results. Multi-center studies could provide more generalized outcomes. While the follow-up period averaged 5 years, longer-term follow-up would be beneficial to fully assess the sustainability of the procedure and the long-term outcomes and potential late complications.

CONCLUSION

In conclusion, our study provides important data supporting the efficacy and safety of transcatheter PDA closure in children. As a minimally invasive procedure, transcatheter PDA closure carries a lower risk of complications compared to surgical intervention and accelerates the recovery process of patients. When performed in expert hands for eligible patients, transcatheter PDA closure should be considered as the first treatment alternative in cases with PDA.

Ethics

Ethics Committee Approval: The study was conducted in accordance with the Helsinki Declaration's standards and was approved by University of Health Sciences Turkey, Kartal Dr. Lütfi Kırdar City Hospital's Ethics Committee (decision number: 2023/514/258/26, date: 27.09.2023).

Informed Consent: The written consent was obtained from the families of the patients included in the study.

Author Contributions

Surgical and Medical Practices: M.M.B., Concept: M.M.Y., Design: T.M., C.K., Data Collection and Processing: C.D., Y.İ.D., Analysis and Interpretation: M.M.B., G.V., Literature Search: M.M., C.D., Writing: M.M.B.

Conflict of Interest: The authors have no conflict of interest to declare.

Financial Disclosure: The authors declared that this study has received no financial support.

REFERENCES

1. Shen J, Benson W. Aortopulmonary shunts: Patent ductus arteriosus, aortopulmonary window, aortic origin of a pulmonary artery. Moller JH, Hoffman JIE, editors Pediatric cardiovascular medicine 2nd Ed, UK, Blackwell publishing ltd. 2012:343-53. doi: 10.1002/9781444398786.ch24
2. Bernstein D. Acyanotic congenital heart disease: Left-to-right shunt lesions. Kliegman RM, Stanton BF, St. Geme JW, Schor NF, editors Nelson textbook of pediatrics 20th Ed, volume 2, Philadelphia, Elsevier Inc. 2015:2197-8https://scholar. google.com /scholar_lookup?title= Nelson+Textbook+of+Pediatrics.&author= RM+Kliegman&autho=BF+Stanton&author =JW+ Geme&publication_year=2016&
3. Ekström, G. (1959). Patent Ductus Arteriosus. In: Derra, E. (eds) Encyclopedia of Thoracic Surgery/Handbuch Der Thoraxchirurgie. Springer, Berlin, Heidelberg. doi: 10.1007/978-3-642-94757-5_8.
4. Porstmann W, Wierny L, Warnke H. Closure of persistent ductus arteriosus without thoracotomy. Ger Med Mon. 1967;12(6):259-61. https://pubmed.ncbi.nlm.nih.gov/6045537/
5. Rashkind WJ, Cuaso CC. Transcatheter closure of patent ductus arteriosus. Pediatr Cardiol. 1979;1:3-7. doi: 10.1007/BF02307335
6. Hsin HT, Lin LC, Hwang JJ, Ho SG, Tseng CD, Chiang FT. Retrograde wire-assisted percutaneous transcatheter closure of persistent ductus arteriosus with Amplatzer duct occluder in the elderly: A new application. Catheter Cardiovasc Interv. 2004;61(2):264-7. doi: 10.1002/ccd.10762
7. Masura J, Walsh KP, Thanopoulous B, Chan C, Bass J, Goussous Y, et al. Catheter closure of moderate- to large-sized patent ductus arteriosus using the new Amplatzer duct occluder: immediate and short-term results. J Am Coll Cardiol. 1998;31(4):878-82. doi: 10.1016/s0735-1097(98)00013-8
8. Agnoletti G, Marini D, Villar AM, Bordese R, Gabbarini F. Closure of the patent ductus arteriosus with the new duct occluder II additional sizes device. Catheter Cardiovasc Interv. 2012;79(7):1169-74. doi: 10.1002/ccd.23477
9. Bilkis AA, Alwi M, Hasri S, Haifa AL, Geetha K, Rehman MA, et al. The Amplatzer duct occluder: experience in 209 patients. J Am Coll Cardiol. 2001;37(1):258-61. doi: 10.1016/s0735-1097(00)01094-9
10. Higgs ZC, Macafee DA, Braithwaite BD, Maxwell-Armstrong CA. The Seldinger technique: 50 years on. Lancet. 2005;366(9494):1407-9. doi: 10.1016/S0140-6736(05)66878-X
11. Sigurdsson TS, Lindberg L. Indirect calorimetry overestimates oxygen consumption in young children: caution is advised using direct fick method as a reference method in cardiac output comparison studies. Pediatr Cardiol. 2020;41(1):149-54. doi: 10.1007/s00246-019-02238-5
12. Krichenko A, Benson LN, Burrows P, Möes CA, McLaughlin P, Freedom RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. Am J Cardiol. 1989;63(12):877-80. doi: 10.1016/0002-9149(89)90064-7
13. Benson L, Macpherson B. Operator-directed sedation in the pediatric cardiac catheterisation laboratory: "The Wheel Has Come Full Circle". J Am Coll Cardiol Intv. 2021;14(4):414-6. doi: 10.1016/j.jcin.2020.11.023. PMID: 33602438.
14. Yıldız K Sr, Kir M, Prencuva P, Genc HZ, Celiktepe V, Bozyer HE, et al. Transcatheter patent ductus arteriosus closure in children with different devices and long-term results. Cureus. 2023;15(10):e46504. doi: 10.7759/cureus.46504
15. Teixeira LS, Shivananda SP, Stephens D, Van Arsdell G, McNamara PJ. Postoperative cardiorespiratory instability following ligation of the preterm ductus arteriosus is related to early need for intervention. J Perinatol. 2008;28(12):803-10. doi: 10.1038/jp.2008.101
16. Fortescue EB, Lock JE, Galvin T, McElhinney DB. To close or not to close: the very small patent ductus arteriosus. Congenit Heart Dis. 2010;5(4):354-65. doi: 10.1111/j.1747-0803.2010.00435.x
17. Willcoxson FE, Viswanathan S, Thomson JD, Gibbs JL. Transcatheter closure of the arterial duct without arterial access. Cardiol Young. 2010;20(1):39-43. doi: 10.1017/S104795110999103X
18. Wang JK, Wu MH, Lin MT, Chiu SN, Chen CA, Chiu HH. Transcatheter closure of moderate-to-large patent ductus arteriosus in infants using Amplatzer duct occluder. Circ J. 2010;74(2):361-4. doi: 10.1253/circj.cj-09-0473
19. Santoro G, Bigazzi MC, Carrozza M, Palladino MT, Sarubbi B, Scarpati C, et al. Percutaneous treatment of moderate-to-large patent ductus arteriosus with different devices: early and mid-term results. Ital Heart J. 2005;6(5):396-400. https://pubmed.ncbi.nlm.nih.gov/15934412/
20. Kusa J, Szkutnik M, Baranowski J, Adams E, Karwot B, Rycaj J, et al. Percutaneous closure of recanalised ductus arteriosus--a single-centre experience. Kardiol Pol. 2007;65(2):125-9. https://pubmed.ncbi.nlm.nih.gov/17366356/
21. Wang LH, Wang JK, Mullins CE. Eradicating acute hemolysis following transcatheter closure of ductus arteriosus by immediate deployment of a second device. Cathet Cardiovasc Diagn. 1998;43(3):295-7. doi: 10.1002/(sici)1097-0304(199803)43:3<295::aid-ccd11>3.0.co;2-l
22. Sathanandam S, Gutfinger D, Morray B, Berman D, Gillespie M, Forbes T, et al. Consensus guidelines for the prevention and management of periprocedural complications of transcatheter patent ductus arteriosus closure with the Amplatzer piccolo occluder in extremely low birth weight infants. Pediatr Cardiol. 2021;42(6):1258-74. doi: 10.1007/s00246-021-02665-3
23. Nagasawa K, Muneuchi J, Sugitani Y, Ezaki H, Doi H, Furuta T, et al. Distensibility of the ductus arteriosus in neonates and young infants undergoing transcatheter closure. Heart Vessels. 2022;37(3):513-6. doi: 10.1007/s00380-021-01925-9
24. Rashid A, Lone A, Rather H, Hafeez I. Management of PDA device closure complicated by severe hemolysis by transcatheter retrieval and deployment of new device. Egypt Heart J. 2023;75(1):17. doi: 10.1186/s43044-023-00343-8
25. Salustri A, Anilkumar S, Ghareep AN, Alkuwari M, Hijazi ZM. Late complication after transcatheter closure of patent ductus arteriosus. JACC Case Rep. 2019;1(3):433-5. https://doi.org/10.1016/j.jaccas.2019.07.029
26. Mahmood UF, Durairaj S. Patent ductus arteriosus-related endocarditis: not just a theoretical risk. BMJ Case Rep. 2021;14(6):e241201. doi: 10.1136/bcr-2020-241201
27. Jang GY, Son CS, Lee JW, Lee JY, Kim SJ. Complications after transcatheter closure of patent ductus arteriosus. J Korean Med Sci. 2007;22(3):484-90. doi: 10.3346/jkms.2007.22.3.484
28. Pass RH, Hijazi Z, Hsu DT, Lewis V, Hellenbrand WE. Multicenter USA Amplatzer patent ductus arteriosus occlusion device trial: initial and one-year results. J Am Coll Cardiol. 2004;44(3):513-9. doi: 10.1016/j.jacc.2004.03.074
29. Gruenstein DH, Ebeid M, Radtke W, Moore P, Holzer R, Justino H. Transcatheter closure of patent ductus arteriosus using the

AMPLATZER™ duct occluder II (ADO II). Catheter Cardiovasc Interv. 2017;89(6):1118-28. doi: 10.1002/ccd.26968

30. Liddy S, Oslizlok P, Walsh KP. Comparison of the results of transcatheter closure of patent ductus arteriosus with newer Amplatzer devices. Catheter Cardiovasc Interv. 2013;82(2):253-9. doi: 10.1002/ccd.24768
31. Baykan A, Narin N, Pamukçu Ö, Korkut S, Argun M, Özyurt A, et al. Seventeen years experience of a single center in percutaneus PDA closure in children. Türk Pediatri Kardiyoloji Derneği Kayseri. 2015;2:20-5. doi: 10.1016/j.amjcard.2015.01.096
32. Yılmazer MM, Özdemir R, Meşe T, Demirpençe S, Güven B, Öner T, et al. Transcatheter closure of patent ductus arteriosus using ADO and ADO II devices in children: A single center experience. J Dr Behcet Uz Child Hosp. 2015;5:177-83. doi: 10.5222/buchd.2015.177