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Transcatheter Closure of Patent Ductus Arteriosus in Infants Between 2-10 Kg

Patent Duktus Arteriozus'un Transkateter Kapatılması; 2-10 Kg Arası Bebeklerde

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ABSTRACT

Objective: The aim of this study was to present our experiences on transcatheter patent ductus arteriosus (PDA) closure with different devices, mostly the Amplatzer Piccolo Occluder, in infants weighing between 2-10 kg.

Material and Methods: In this study, the files of 31 patients who underwent transcatheter PDA closure between December 2019 and August 2022 were reviewed retrospectively.

Results: Transcatheter PDA closure was performed on 31(14 female) infants weighing between 2-10 kg. The mean age of patients was 10.7±6.7 months (2-28), and the mean weight was 6.6±2 kg (3-9.9). The median narrowest diameter of the ductus was 2.2 mm (IQR 2-3) and the median ductus length was 6 mm (IQR 4.75-8). The procedural success rate of all interventional procedures was 88% (30 of 34). Complications occurred in a total of four patients including failure of device implantation in one patient, post-procedural device embolization in 2 patients, and the significant residual shunt in one patient. None of the patients required surgery. In 34 interventional procedures, 3 of which were reintervention, 34 devices were used. Twenty-seven (79%) of them were Amplatzer Piccolo Occluder. The median fluoroscopy and procedural times were 10.5 minutes (IQR 7.25-18.5) and 40 minutes (IQR 35-57.5) respectively. The mean duration of follow-up was 10.3±8.8 months (1-32 months).

Conclusion: In our experience, transcatheter treatment of PDA with the Amplatzer Piccolo Occluder device which was our first choice for appropriate duct anatomy and size in infants weighing between 2-10 kg, is safe and effective.

Key Words: Amplatzer occluder device, Patent ductus arteriosus, Premature infant

ÖZ

Amaç: Bu çalışmanın amacı, 2-10 kg arası bebeklerde çoğunlukla Amplatzer Piccolo Occluder olmak üzere farklı cihazlarla transkateter patent duktus arteriyozus (PDA) kapatma konusundaki deneyimlerimizi sunmaktır.

Gereç ve Yöntemler: Bu çalışmada Aralık 2019-Ağustos 2022 tarihleri arasında transkateter PDA kapatılan 31 hastanın dosyaları geriye dönük olarak incelendi.

Bulgular: Toplam 31(14 kadın), 2-10 kg ağırlığındaki, bebeğe transkateter PDA kapaması yapıldı. Hastaların yaş ortalaması 10.7±6.7 ay (2-28) ve ortalama ağırlık 6.6±2 kg (3-9.9)'du. Duktusun en dar ortanca çapı 2.2 mm (IQR 2-3)

0000-0002-9756-4616 : KAVURT AV
0000-0001-6581-6121 : SAYIN S
0000-0002-9107-4894 : GUZELCE B
0000-0003-0375-1726 : BAGRUL D
0000-0002-0707-2678 : GURSU HA
0000-0002-3657-2209 : ECE I
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Ethics Committee Approval / *Etik Kurul Onayı*: This study was conducted in accordance with the Helsinki Declaration Principles. Approval for this study was obtained from the Ankara City Hospital Ethics Committee 2 and the Ministry of Health (07/09/2022 decision number E2-22-2324).

Contribution of the Authors / Yazarların katkısı*: *KAVURT AV: Constructing the hypothesis or idea of research and/or article, planning methodology to reach the conclusions, taking responsibility in logical interpretation and conclusion of the results. taking responsibility in the writing of the whole or important parts of the study. ***SAYIN S:*** Taking responsibility in patient follow-up, data management and reporting, taking responsibility in logical interpretation and conclusion of the results. ***OZELCE B:*** Taking responsibility in patient follow-up, data management and reporting, taking responsibility in logical interpretation and conclusion of the results. ***BAGRUL D:*** Organizing, supervising the course of progress and taking the responsibility of the research/study, taking responsibility in necessary literature review for the study. ***GURSU HA:*** Organizing, supervising the course of progress and taking the responsibility of the research/study, taking responsibility in necessary literature review for the study. ***ECE I:*** Planning methodology to reach the conclusions, taking responsibility in logical interpretation and conclusion of the results, taking responsibility in necessary literature review for the study, reviewing the article before submission scientifically besides spelling and grammar. ***CETIN II:*** Planning methodology to reach the conclusions, taking responsibility in logical interpretation and conclusion of the results, taking responsibility in necessary literature review for the study, reviewing the article before submission scientifically besides spelling and grammar.

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ve ortanca duktus uzunluğu 6 mm (IQR 4.75-8)'di. Tüm girişimsel prosedürlerin prosedürel başarı oranı %88'di (30/34). Bir hastada cihaz implantasyonu başarısızlığı, 2 hastada işlem sonrası cihaz embolizasyonu ve bir hastada önemli rezidüel şant olmak üzere toplam dört hastada komplikasyon meydana geldi. Hiçbir hastada ameliyat gerekmedi. Üçü yeniden müdahale olmak üzere 34 girişimsel işlemde 34 cihaz kullanıldı. Bunların 27'si (%79) Amplatzer Piccolo Occluder'dı. Ortanca floroskopi ve prosedür süreleri sırasıyla 10.5 dakika (IQR 7.25-18.5) ve 40 dakika (IQR 35-57.5)'dı. Hastaların ortalama takip süresi 10.3±8.8 ay (1-32 ay)'dı.

Sonuç: Deneyimlerimize göre 2-10 kg arası bebeklerde uygun duktus anatomisi ve boyutu için ilk tercihimiz olan Amplatzer Piccolo Occluder cihazı ile PDA'nın transkateter tedavisi güvenli ve etkilidir.

Anahtar Sözcükler: Amplatzer tıkayıcı cihaz, Patent duktus arteriozus, Prematüre bebek

INTRODUCTION

Transcatheter device closure of patent ductus arteriosus (PDA) is the standard of care in infants, children, and adults in the last few decades (1). In recent years, transcatheter PDA closure in small babies and premature infants with new devices is a candidate to be the standard treatment. The AmplatzerTM Piccolo Occluder (Abbott Structural Heart, Plymouth, MN), previously called the AmplatzerTM Duct Occluder II Additional Sizes (ADO II AS) obtained CE-Mark in Europe in 2011 for PDA closure in patients ≥6 kg. United States Food and Drug Administration (FDA) approval of the Amplatzer Piccolo Occluder for use in premature infants ≥700 g was obtained on January 11, 2019 (2). ADO-II AS has been used with high procedural success in transcatheter PDA closure in larger, small babies, and premature infants in many centers in the United States and Europe (3-12). After the FDA approval of The Amplatzer Piccolo Occluder in premature infants ≥700 g, it has been widely used as a good alternative to surgery in premature PDA that does not respond to conservative and medical treatments (13,14). Today, transcatheter PDA closure is performed in babies with different devices such as AmplatzerTM Duct Occluder I or II (ADO; AGA Medical Corporation, Golden Valley, MN, USA), KONAR-Multifunctional™ Occluder (MFO) (Lifetech, Shenzhen, China) (15,16). However, it is mostly preferred in patients whose duct size or anatomy is not suitable for transcatheter PDA closure with Amplatzer Piccolo Occluder.

Here, we present our findings on transcatheter PDA closure with different devices, mostly the Amplatzer Piccolo Occluder, in infants weighing between 2 and 10 kg.

MATERIALS and METHODS

Study population

This was a retrospective study including infants weighing between 2 and 10 kg who underwent transcatheter PDA closure in the pediatric cardiology department of Ankara City Hospital, University of Health Sciences between December 2019 and August 2022. This study was conducted in accordance with the Helsinki Declaration Principles. Approval for this study was obtained from the Ankara City Hospital Ethics Committee 2 and the Ministry of Health (07/09/2022 decision number E2-22-2324).

Patient records were reviewed for demographic data also including previous echocardiograms and catheterization reports and angiograms. Patients' age, weight, height, narrowest diameter of the ductus, ductus length, type of ductus, vascular access, femoral sheath size used, device implantation approach, type and diameter of device procedure, and fluoroscopy time, length of follow-up were all recorded.

Procedural and follow-up complications including device implantation failure, post-procedure or intra-procedural device embolization, aortic or pulmonary artery occlusion due to device protrusion, residual shunt, device-induced endocarditis and hemolysis, large blood loss, transient weak arterial pulse were recorded.

Pre-interventional evaluation with transthoracic echocardiography

Cardiac and ductal anatomy were evaluated by two dimensional transthoracic echocardiography (2D-TTE) using a Vivid-S60N machine (General Electric, Norway) before the procedure in all patients. PDA measurements and additional cardiac defects were noted.

Infants weighing ≤ 2 kg or ≥10 kg who underwent transcatheter PDA closure were excluded in this study.

The interventional procedure

Duct morphology was determined according to the classification used in investigational device exemption (IDE) and the continued access protocol (CAP) studies (2). This classification was created by adding fetal-type ductal morphology (17) to the Krichenko classification (18) (Figure 1).

Informed consent was obtained from the parents of all infants before transcatheter PDA closure.

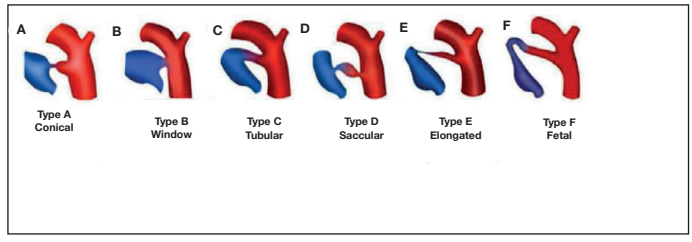

Figure 1: Six morphologic types of Patent Ductus Arteriosus. This classification has been used in the investigational device exemption (IDE) and the continued access protocol (CAP) studies (2). It was created by adding fetal-type ductal morphology (17) to the Krichenko classification (18). [Color figure can be viewed at wileyonlinelibrary.com]

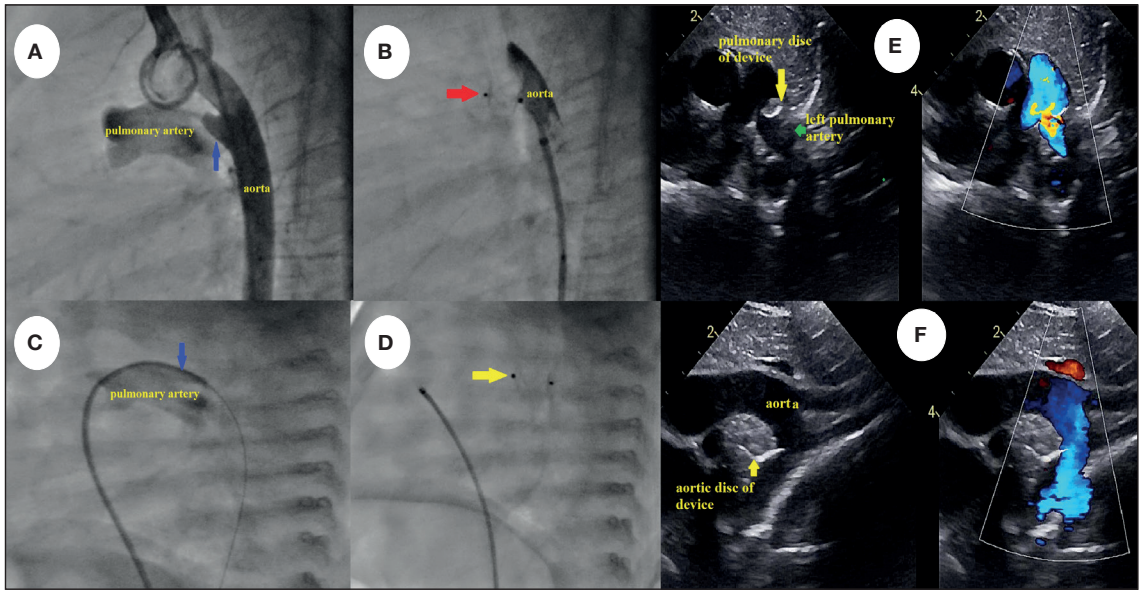

Figure 2: Transcatheter Patent Ductus Arteriosus (PDA) closure by retrograde transarterial approach; aortography in left lateral view shows conical type (Type-A) of PDA (**A**). Aortography in the left lateral view shows the implanted Amplatzer Piccolo Occluder 4/4 mm which is in the proper position within the duct and extraductal disc placement with no residual shunt and no protrusion into the aorta (**B**). Transcatheter PDA closure by anterograde transvenous approach and only by femoral vein access; a straight lateral image; while manually injecting the contrast, the catheter is withdrawn and the central diameter and length of the PDA [fetal type (Type-F)] are determined (**C**). The left lateral view shows the implanted Amplatzer Piccolo Occluder 5/4 mm in the proper position within the duct and extra ductal disc placement (**D**). The control echocardiography during the procedure revealed that the device did not protrude into the descending aorta or pulmonary artery (**E,F**). On all fluoroscopy images, the red arrowhead points to Amplatzer Piccolo Occluder 4/4 device, the yellow arrowhead points to Amplatzer Piccolo Occluder 5/4 mm device, and the blue arrowhead points to PDA.

The Vivid-7 machine (General Electric, Norway) was used for TTE assessment during the procedure in all patients.

Prophylactic antibiotics were administered. Cardiac catheterization was performed under deep sedation or general anesthesia. The Seldinger technique was used for vascular access. The 4F and 5F sheaths were placed arterial only, venous only, or both. Then, heparin sulfate (100 IU/kg) was administered.

Oximetric and some hemodynamic studies (eg pulmonary to systemic flow ratio or pulmonary vascular resistance) were performed only if there was an additional cardiac anomaly detected or suspected in echocardiography or when moderate or significant pulmonary hypertension is detected by invasive measurements.

Transcatheter PDA closure was performed by anterograde transvenous or retrograde transarterial approach.

Retrograde transarterial approach

The ductus was visualized with contrast injections to the descending aorta at the lateral and right oblique positions with a 4-5f pigtail catheter or Amplatzer TorqVue LP catheter (Abbott Structural Heart, Plymouth, MN). From the aorta the 0.014-inch coronary wire was gently advanced into the pulmonary artery through the PDA; a 4F Judkins catheter or 4F Amplatzer TorqVue LP catheter were then slid over the guide wire and advanced to the pulmonary artery. Devices were delivered through a 4 F or 5F Amplatzer TorqVue LP catheter (Abbott Structural Heart, Plymouth, MN). This system was connected to a Y-connector, and the position of the implanted device was verified by injecting the contrast material with hand. After confirming that the device was in the proper position, it was released under fluoroscopy. Then, the position of the device in the duct and the presence of residual shunt were checked with contrast injection into the descending aorta (Figure 2 a,b).

Anterograde transvenous approach

A 4F Judkins catheter was advanced into the right atrium and its tip was turned toward the tricuspid valve. The hydrophilic guide wire (Terumo Medical Corporation, Somerset, NJ, USA) or 0.014-inch coronary wire inside the catheter was advanced into the right ventricle and the pulmonary artery. From the pulmonary artery, the hydrophilic wire was gently advanced into the aorta through the PDA; the catheter was then slid over the guide wire and advanced to the aorta. If there is an arterial sheath, the duct was visualized as described in the retrograde transarterial approach. If there is a venous sheath, this system was connected to a Y-connector and the catheter was withdrawn while injecting the contrast material by hand, the central diameter and length of the PDA were determined at the left anterior oblique view with slight caudal angulation (15 LAO-15 CAU), and straight lateral positions. After determining the appropriate device to use based on the PDA measures, the device was implanted into the duct with an Amplatzer TorqVue LP catheter (Figure 2c, d). The location of the device and whether it protruded into the aorta/ the pulmonary artery

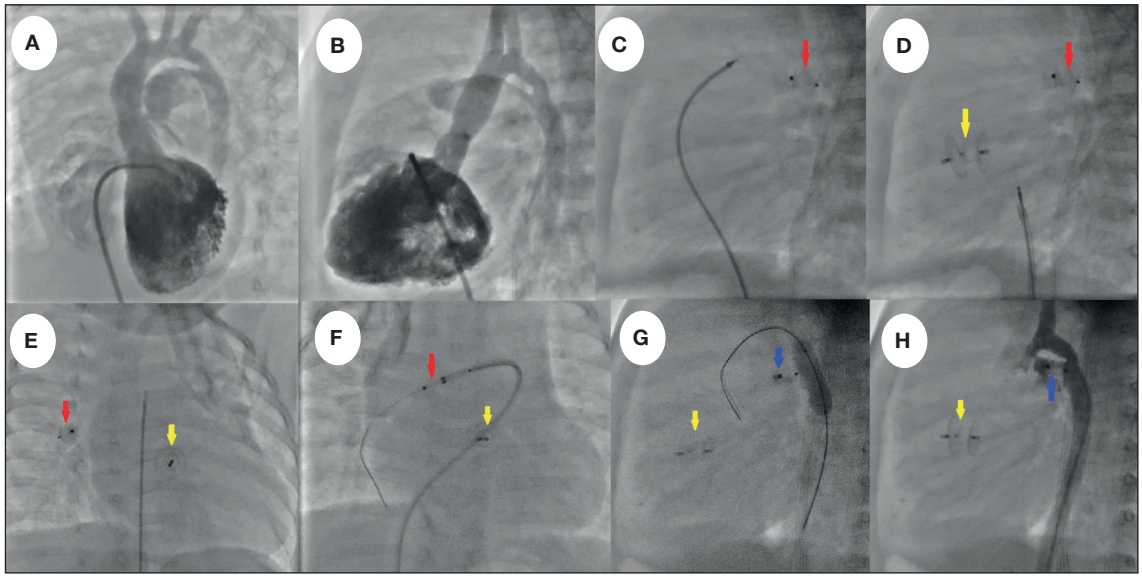

Figure 3: Left lateral and frontal views of Patent Ductus Arteriosus (PDA) and Ventricular Septal Defect (VSD) by left ventricular contrast agent injection (**A,B**). Left lateral views of the Amplatzer™ Piccolo Occluder 5/4 device in the duct, and the KONAR-Multifunctional™ VSD Occluder (MFO) implanted into the VSD anterogradely (**C,D**). Frontal views of the embolized Amplatzer™ Piccolo Occluder into the right pulmonary artery (**E**), and retrieval into the 5F long sheat with gooseneck snare (**F**). Left lateral views of the Amplatzer Duct Occluder-I (ADO-I)6/4 device in the duct, and balloon angioplasty with Tyshak balloon catheter 7/20 mm (**G**). The final position of ADO-I 6/4 device in lateral view with aortogram (**H**). In all images, the red arrowhead points to Amplatzer Piccolo Occluder 5/4 device, the yellow arrowhead points to the KONAR MFO device, and the blue arrowhead points to ADO I 6/4 device

were determined by transthoracic echocardiography using a high parasternal short axis and suprasternal windows (Figure 2 e,f). If there is an arterial sheath, the position of the device in the duct and the presence of residual shunt were checked with contrast injection into the descending aorta.

Procedural success

Procedural success was defined as the presence of all three following criteria: successful device implantation, no major complications and requiring no reintervention during follow-up.

Device Specifications

In this study, devices whose technical specifications are described below were used for transcatheter PDA closure.

The Amplatzer Piccolo Occluder device

The Amplatzer Piccolo™ Occluder is a self-expandable, nitinol mesh device with a central cylindrical waist and low-profile retention discs that are marginally larger than the waist, resulting in a nearly isodiametric device. The device comes pre-loaded on a delivery wire, which has a soft floppy distal end with a microscrew attachment at the tip. It can be delivered through a 4 F Amplatzer TorqVue LP catheter. The Amplatzer Piccolo Occluder is available in nine sizes comprised of three waist diameters (3, 4, and 5 mm) and three lengths (2, 4, and 6 mm). This device is not recommended for PDA >4mm in diameter or <3mm in length.

The Amplatzer Piccolo Occluder can be delivered either antegrade via the femoral vein or retrograde via the femoral artery because of the symmetrical configuration. In infants ≤2 kg, special procedural modifications were utilized to avoid the need for vascular access into the femoral artery in order to maximize safety and avoid complications. Both retention discs can be completely implanted into the canal (intraductal placement) or the central waist can span the entire length of the duct with retention discs placed just outside the canal (extraductal disc placement) (2).

The Amplatzer duct occluder-I device

The ADO-I is a mushroom-shaped device made of 0.004-inch nitinol wire mesh. A 2-mm retention skirt extends radially around the distal part of the device, assuring secure fixation in the mouth of the PDA. Prostheses are available in five different sizes (5/4, 6/4, 8/6, 10/8, and 12/10). The largest measurement is at the aortic site and the narrowest is at the pulmonary end. The device is attached by a recessed microscrew to a 0.038-inch delivery cable made of stainless steel; it is delivered through a 5F to 7F long sheath with anterograde transvenous route (19).

The Amplatzer duct occluder-II device

The ADO-II is a self-expanding nitinol device with a central waist and two symmetrical retention discs (both 6 mm larger than the central waist). The central waist is designed to fill the defect, and the two retention discs are designed to be deployed on the aortic and pulmonary sides of the defect. The occluder has a multilayered, multisegmented design creating six potential planes of occlusion with no central fabric. This design decreases the profile of the occluder and is deliverable with either a 4F or 5F delivery system. The ADO II is available in two lengths (4 and 6 mm) and four waist diameters (3, 4, 5, and

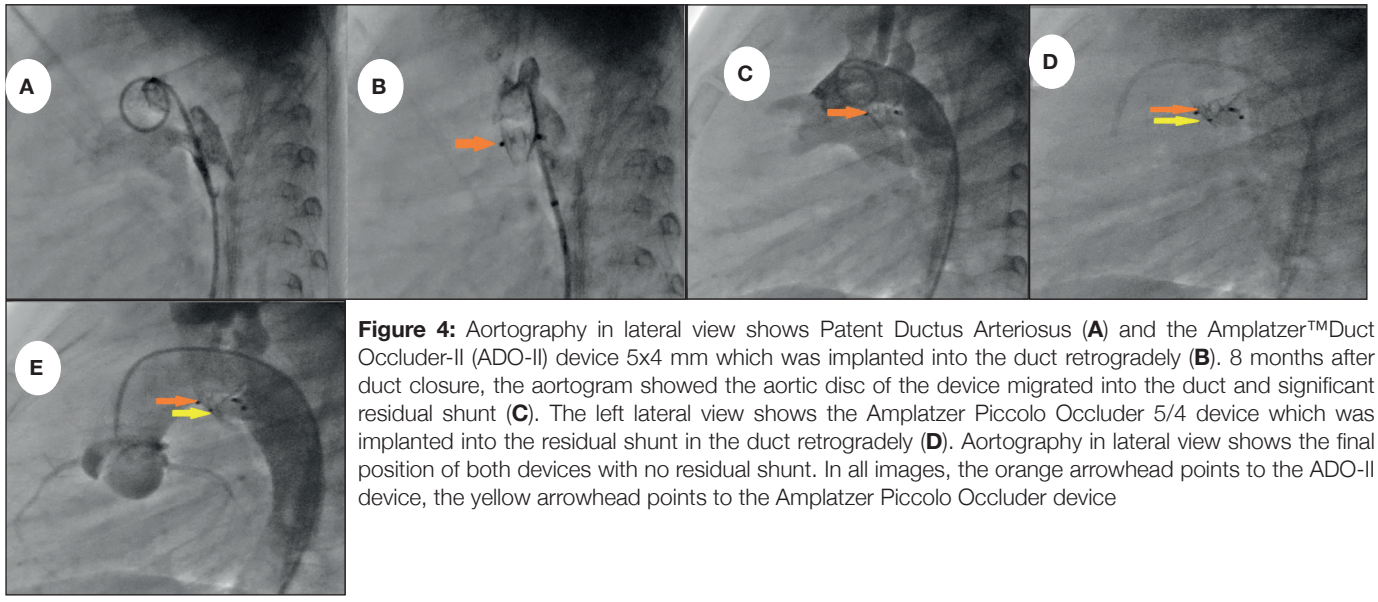

Figure 4: Aortography in lateral view shows Patent Ductus Arteriosus (**A**) and the Amplatzer™Duct Occluder-II (ADO-II) device 5x4 mm which was implanted into the duct retrogradely (**B**). 8 months after duct closure, the aortogram showed the aortic disc of the device migrated into the duct and significant residual shunt (**C**). The left lateral view shows the Amplatzer Piccolo Occluder 5/4 device which was implanted into the residual shunt in the duct retrogradely (**D**). Aortography in lateral view shows the final position of both devices with no residual shunt. In all images, the orange arrowhead points to the ADO-II device, the yellow arrowhead points to the Amplatzer Piccolo Occluder device

6 mm). This occluder has a screw attachment for a delivery wire and radiopaque markers. The ADO-II device can be implanted either the anterograde transvenous route or the retrograde transarterial route (19).

The Lifetech Konar-MF device

The KONAR- MFO device is a self-expandable, double-disc device made from double nitinol wire mesh layers with 144 threads of nitinol wires. It is designed as a hybrid of single-disc and double-disc PDA devices. Two discs are linked together by a cone-shaped waist and there are two screws on the left and right disc. It can be screwed together at both sides and therefore its placement can be anterograde transvenous route or the retrograde transarterial route. Device sizes are given as LV waist diameter and then RV waist diameter. The sizes start from 5/3 mm and up to 14/12 mm, the length in total being 4 mm without stretching. In total, eight sizes are available. The waist of the four largest models is sewn with PTFE membranes, whereas the four smaller models have no membrane. The device is used through a 4–7 F sheath (20). This device was used off-label in one patient.

Follow-up

Transthoracic echocardiography was performed immediately after the procedure, at the 24th hour, and 1, 3, and 6 months after the procedure in all patients to evaluate the therapeutic effects and complications of transcatheter PDA closure. A residual shunt was considered if Doppler color flow mapping showed an aorta-to-pulmonary shunt across the ductus.

Complications

Major and minor complications at the peri-procedural period or during follow-up were recorded for all patients. Major complications included death, cardiac arrest, device embolization, failure of device implantation, significant residual shunt, device-related endocarditis, significant obstruction of the aorta or the pulmonary artery due to device protrusion, massive blood loss, device-related hemolysis; minor complications included mild narrowing of the left pulmonary artery or descending aorta due to device protrusion, transient weak arterial pulse.

Statistical analysis

Statistical Package for the Social Science (SPSS_17.0.1 for Windows; SPSS Inc) was used for statistical analysis. The normal distribution test of continuous variables was performed by using the Shapiro-Wilk test. Normally distributed continuous data were presented as mean ± standard deviation (SD) (minimum-maximum) and the nonnormally distributed continuous data were reported as median {interquartile range (IQR)}. Categorical data are presented as numbers (n) and percentages (%). Statistical signifcance was defined as a two-tailed p value of<0.05.0

RESULTS

Transcatheter PDA closure was performed on 31(14 female) infants weighing 2-10 kg between December 2019 and August 2022. The mean age of patients was 10.7±6.7 months (2-28), and the mean weight was 6.6±2 kg (3-9.9). The median narrowest diameter of the ductus was 2.2 mm (IQR 2-3) and the median ductus length was 6 mm (IQR 4.75-8). A conical PDA (type A) was observed in 64% of patients (Figure 1a), while a fetal, tubular, and elongated PDA (type F, C, or E) were observed in 16%, 13%, 6.5% of patients respectively (Figure 1f, c, e). The demographic and ductus characteristics of the patients are given in table I.

Procedural characteristics and outcomes are shown in table II. Thirty-four interventional procedures, 3 of which were reintervention, were performed on 31 patients and 34 devices

Table I: General characteristics of the patients and ductal morphology

	Patients (n=31)
Age (months)	10.7 ± 6.7 (2-28)
Gender (female), n (%)	14 (45)
Body weight (kg)	6.6 ± 2 kg (3-9.9)
Narrowest diameter of the ductus (mm)	2.2 (2-3)
Ductus Length (mm)	6 (4.75-8)
Type of ductus * n (%)	Type A (n=19) (64) Type B (n=1) (0) Type C (n=4) (13) Type D (n=0) (0) Type E (n=2) (6.5) Type F (n=5) (16)

Values are presented as mean ± SD (minimum-maximum) or median (interquartile range). ***** *This classification has been used in the US IDE and the CAP studies (2). It was created by adding fetal-type ductal morphology to the Krichenko classification (17,18).*

Table II: Procedural characteristics and outcomes

	Patients (31), Procedure (34)*
Procedural success, n (%)	30 (88)
Access	Only venous in 3, only arterial in 24, and both in 7
Device implantation approach	Retrograde (n=27) Anterograde (n=7)
Sheath size used	4F (n=23, arterial 19 vein 4) 5F (n=18, arterial 12 vein 6)
Fluoro time (min)	10.5 (7.25-18.5)
Procedure time (min)	40 (35-57.5)
Length of follow-up (months)	10.3 ± 8.8 (1-32)

Values are presented as mean ± SD (minimum-maximum) or median (interquartile range). ***34 interventional procedures were performed on 31 patients and 34 devices were used.*

were used. None of the patients required surgery. Failure of device implantation occurred in one patient. In this patient, the ductus closed spontaneously after the interventional procedure. The rate of procedural success was 88% (30 of 34). An antegrade and a retrograde implant approach were used in 7 and 27 procedures respectively. The median fluoroscopy and procedural times were 10.5 minutes (IQR 7.25-18.5) and 40 minutes (IQR 35-57.5) respectively. The mean duration of follow-up for our patients was 10.3±8.8 months (1-32 months).

In addition to transcatheter PDA closure, transcatheter ventricular septal defect (VSD) closure was performed in one patient in the same session.

Specifications of the devices used and the procedural characteristics of device types are shown in table III. When comparing the device types, the use of the Amplatzer Piccolo Occluder was significantly higher than the other device types ($p< 0.001$). Twenty-seven (79%) Amplatzer Piccolo Occluder was used. Of the patients who underwent transcatheter PDA closure with the Amplatzer Piccolo Occluder device, 8 were ≤ 6 kg, and 19 were >6 kg. The most preferred implantation approach in this device was retrograde route (n= 23, 85%). The most frequently used sizes of Amplatzer Piccolo Occluder were 4/4 mm (37%) and 5/4 mm (37%). Post-procedural device embolization occurred in two patients. Therefore, the success of the procedure was 89%. The procedural success was 87.5% in infants ≤ 6 kg and 90% in infants > 6 kg. The MFO occluder device was used off-label in one patient.

Procedural and follow-up complications are shown in table IV. One patient had an unsuccessful implant. After the Amplatzer Piccolo Occluder 4/4 device was released, it was found to protrude into the descending aorta and create a 20 mmHg gradient. The device was retrieved with a gooseneck snare and successfully removed from the body. Control angiography showed that the duct was restricted. Then the procedure was postponed to a future date. In this patient, the ductus closed spontaneously during follow-up.

Post-procedural device embolization occurred in two patients. In the first patient weighing 5.6 kg, transcatheter VSD and PDA closures were performed in the same session using only the venous route. The duct was visualized by left ventricular contrast injection (Figure 3a, b). Transcatheter PDA closure was performed with the Amplatzer Piccolo Occluder 5/4 mm device with an antegrade transvenous route (Figure 3 c, d). At 12 hours after the procedure, it was observed that the device was embolized into the right pulmonary artery. We thought that embolization was due to the underestimation of ductal dimension due to incomplete visualization of the ductus. The device was retrieved with a gooseneck snare into the 5F long-sheath placed in the main pulmonary artery and was successfully removed from the body (Figure 3e, f). Then, transcatheter PDA closure was performed with ADO1 6/4 device. After the procedure, a peak-to-peak 15 mmHg gradient was obtained in the aortic isthmus, which was also present before the procedure. Balloon angioplasty was performed with a Tyshak balloon catheter 7/20 mm covering the aortic isthmus and the aortic disc of the device. After balloon angioplasty, the peak-to-peak gradient decreased to 8 mmHg (Figure 3 g, h). Also, the control echocardiogram revealed a mean Doppler gradient of 10 mmHg in the aortic isthmus without a diastolic tail. No Doppler gradient showing significant aortic stenosis was obtained during follow-up echocardiograms. In the second patient weighing 6.1kg, transcatheter PDA closure was performed with the Amplatzer Piccolo Occluder 4/2 device. On the 1st post-procedure day, it was observed that the device was embolized to the left pulmonary artery. We speculate that the device embolization is due to the fact that the implanted device is too small for the encountered anatomy. The device was retrieved with a gooseneck micro snare into the 5F long-sheath placed in the main pulmonary artery and was successfully removed from the body. Then, transcatheter PDA closure was performed with Amplatzer Piccolo Occluder 5/4 device. After

Table III: Specifications of the devices used and procedural characteristics

Devices*	Amplatzer Piccolo Occluder (n=27)† (79)	ADO II (n=4) (12)	ADO I (n=2) (6)	LT-MFO (n=1) (3)‡
Device diameter (mm), n(%)	4/2 (n=2) (7) 5/2 (n=1) (3) 4/4 (n=10) (37) 5/4 (n=10) (37) 4/6 (n=1) (3) 5/6 (n=4) (15)	3/4 (n=1) 6/6 (n=1) 5/4 (n=2)	8/6 (n=1) 6/4 (n=1)	6/8 (n=1)
Sheath size used	4F (n=19), 5F (n=11)	4F (n=2), 5F (n=3)	4F (n=2), 5F (n=2)	5F (n=2)
Device implantation approach	Retrograde (n=23) (85) Anterograde (n=4) (15)	Retrograde (n=4)	Anterograde (n=2)	Anterograde (n=1)
Access	Only venous in 3, only arterial in 21, and both in 3 (two are retrograde)	Only arterial in 3, venous and arterial in 1	Venous and arterial in 2	Venous and arterial
Major Complication	Device embolization (n=2) Failure of device implantation (n=1)	Significant residual shunt (n=1)		

Thirty four interventional procedures were performed in 31 patients and 34 devices were used. †The use of the Amplatzer Piccolo Occluder was statistically significantly higher than other device types (p< 0.001). ‡The LifeTech™ multifunctional occluder device was used off-label in one patient.* ***ADO:* *Amplatzer™ duct occluder,* ***LT-MFO:*** *LifeTech™ multifunctional occluder device.*

Table IV: Procedural and Follow-up complications

	Patients (n=31)
Major complications, n(%)	
Failure of device implantation	1 (3.2)
Post-procedure device embolization	2 (6.5) *
Significant residual shunt	1 (3.2) †
Device -related endocarditis	0 (0)
Significant obstruction of the aorta or the pulmonary artery due to device protrusion,	0 (0)
Massive blood loss	0 (0)
Device -related hemolysis	0 (0)
Total events	4 (13)
Minor complications, n(%)	
Mild narrowing of the left pulmonary artery due to device protrusion	0 (0)
Mild narrowing of descending aorta due to device protrusion	1 (3.2)
Transient weak arterial pulse	0 (0)
Total events	1 (3.2)

**Two Amplatzer Piccolo Occluder devices were replaced with the ADO-I device and the larger Amplatzer Piccolo Occluder device. †The residual shunt was closed by implanting a second device (Amplatzer Piccolo Occluder) during follow-up.*

the second procedure, no complications were observed during the follow-up.

In another patient who underwent transcatheter PDA closure, second device implantation was performed due to progressively increasing residual shunt during follow-up. In this patient weighing 6 kg, transcatheter PDA closure was performed with an ADO-II device at the age of 5.5 months(Figure 4 a, b). Eight months after the first procedure, the patient was taken to the catheter room because of a moderate-to-significant residual shunt that gradually increased on echocardiography. In aortography, it was observed that the aortic disc of the device migrated into the duct in an inappropriate position and there was a significant residual shunt at the edge of the device (Figure 3c). We thought that device malposition developed due to a mismatch of the implanted device with the shape of the ductus. Then a transcatheter Amplatzer Piccolo Occluder 5/4 device was successfully implanted by retrograde route into the residual duct (Figure 3d, e). After the second procedure, no complications were observed during the follow-up.

DISCUSSION

Transcatheter closure of the PDA has been the mainstay of treatment in infants, children, and adults. In addition, as a result of the developments in the industry, the widespread use of Amplatzer Piccolo Occluder in premature babies and its equivalence with surgical ligation are the subject of debate today (12,14,21,25).

The most common type of ductus was conic PDA in our study, consistent with the literature (2, 19).

Sathanandam SK et al. (2) reported a 92% success of implant for the Amplatzer Piccolo Occluder over 2 kg infants. Similarly, in our study, transcatheter PDA closure was performed with a procedural success rate of 88% in infants weighing between 2 and 10 kg. According to data obtained from 277 patients receiving ADO II AS in 10 European medical centers, the successful implantation rate was reported as 93.2% in infants 2-6 kg and 100% in infants >6 kg. In our study, the rate of procedural success with the Amplatzer Piccolo Occluder device was 87.5% in infants ≤ 6 kg and 90% in infants with >6 kg, these results are comparable to the results of the European medical centers, considering the learning curve and the number of patients (3-12).

In our study, a retrograde device implantation approach was preferred in 27 (70%) procedures. Amplatzer Piccolo Occluder device was implanted in 23(85%) of these procedures and the ADO-II device was implanted in 4 (15%) of them. In addition, 24 of these procedures had only a femoral arterial sheath. 5F arterial sheaths were not used in any infant weighing less than 6 kg. The smallest infant who underwent the transcatheter PDA closure using a 4f femoral arterial sheath weighed 4 kg. Moreover, all sizes of the Amplatzer Piccolo Occluder device are delivered through a 4 F Amplatzer TorqVue LP catheter. In the study of Sathanandam SK et al. (2) transcatheter PDA closure was performed with a retrograde approach in 26% of patients > 2 kg (but, femoral arterial access was used in 48%). In the same study, it has been stated that femoral artery access must be avoided in preterm infants <2 kg. In another study, 89% of transcatheter PDA closures with the ADO-II AS device were performed by retrograde arterial route in infants >6 kg (10).

The use of the retrograde arterial routes shortens the procedure and fluoroscopy times, provides better visualization of the duct angiographically, allows to perform aortography to check the placement of the device in the duct, and also avoids cardiac injury and tricuspid valve regurgitation. However, it can cause femoral artery injuries. In our comment absence of vascular complications in this study was due to not using femoral artery sheaths in infants weighing less than 4 kg. Nevertheless, in our opinion, the anterograde route under transthoracic echocardiography guidance should be preferred without using a femoral arterial sheath, especially in small infants.

The procedure and fluoro times in our study (median 40 and 10.5 min respectively) were comparable with the procedure time and fluoro time of transcatheter PDA closure in the study of Sathanandam SK et al. (2) (mean 57.1 and 10.1 min respectively) and in the study of Park YA et al (22) (mean 48.6 and 13.4 min respectively).

Sathanandam SK et al. (2) reported that the intra-procedural device embolization rate was 3% and the post-procedure device migration rate was 1% in patients >2 kg in whom the Amplatzer Piccolo Occluder device was implanted. On the other hand, Baspinar et al reported one major complication (device embolization) in a group of 53 patients who were under 6 kg (8). Also, a large meta-analysis of ductus arteriosus occlusion reported adverse event rate of 10% (23). Similarly, in our study, post-procedure device embolization occurred in 2(7.4%) of 27 procedures in which the Amplatzer Piccolo Occluder device was implanted, and failure of device implantation occurred in one (3.7%) patient. Méot M et al. (22) reported that in the case of transcatheter PDA failure, mechanically induced spontaneous closure may occur early after the procedure. They also suggested that surgical ligation should be postponed when clinically tolerated (24). In our study, during the follow-up the patient who had failed device implantation, the duct closed spontaneously.

CONCLUSION

In our study, the Amplatzer Piccolo Occluder device has been our first choice in properly sized ducts because it requires a smaller delivery sheath, can be implanted with antegrade and retrograde approaches, is a nearly isodiametric device, and complications can be managed more easily. In our experience, the transcatheter treatment of PDA with Amplatzer Piccolo Occluder is safe and effective in appropriate anatomy and size in infants with 2 -10 kg.

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