



ORIGINAL ARTICLE / ОРИГИНАЛНИ РАД

Transcatheter closure of patent ductus arteriosus using Flipper coil and Amplatzer Duct Occluder – Ten-year experience from a single center

Milan Đukić^{1,2}, Vojislav Parezanović^{1,2}, Stefan A. Đorđević^{1,2}, Igor Stefanović^{1,2}, Vesna Miranović³, Slobodan Ilić^{1,4}, Ida Jovanović^{1,2}

¹University of Belgrade, School of Medicine, Belgrade, Serbia;

²University Children's Hospital, Department of Cardiology, Belgrade, Serbia;

³Institute for Children's Diseases, Clinical Center of Montenegro, Podgorica, Montenegro;

⁴University Children's Hospital, Department of Cardiac Surgery, Belgrade, Serbia

SUMMARY

Introduction/Objective Transcatheter closure is a well-established procedure for treatment of patent ductus arteriosus (PDA).

We aimed to make a comparison between transcatheter PDA occlusion with Flipper coil and Amplatzer Duct Occluder (ADO) and to determine the incidence and significance of procedural complications.

Methods Between November 2004 and October 2014, 148 patients were eligible for transcatheter PDA closure at the University Children's Hospital in Belgrade, Serbia. The median age was 5.9 years (the range of 0.9 years to 17.3 years) and the median weight was 21 kg (the range of 8.8 kg to 94 kg). Follow-up evaluations with Doppler echocardiogram were performed at one day, three months, and one and two years after the PDA occlusion.

Results Median narrowest PDA diameter was 1.5 mm (the range of 0.5 mm to 5.6 mm). Flipper coil was used for PDA closure in 84 (59.2%) and ADO in 58 patients (40.8%). There was no significant difference in the rate of immediate complete closure between the coil and the ADO group (86.9% vs. 75.9%, $p = 0.089$), but a significantly higher rate of complete closure was achieved with ADO at one day (83.3% vs. 98.3%, $p = 0.004$), three months (85.7% vs. 100%, $p = 0.002$), and both one and two years after the implantation (91.7% vs. 100%, $p = 0.041$). In total, 12 complications occurred during the procedure, seven of which with coil and five with ADO occlusion of PDA.

Conclusion Transcatheter closure of PDA using both coils and ADOs is a very safe and effective procedure. ADO proved superior to coil in terms of complete closure rate as early as one day after the procedure.

Keywords: cardiac catheterization; prostheses and implants; child; adult

INTRODUCTION

Ductus arteriosus is a blood vessel connecting the aortic isthmus with the pulmonary artery in utero. If it fails to close after birth, it is called a patent ductus arteriosus (PDA) and is considered a congenital heart disease. PDA accounts for about 5–10% of all congenital heart diseases, and is an especially common and significant problem in preterm infants [1].

Persistent aortopulmonary flow through the PDA leads to pulmonary overcirculation and volume overload of the left heart. The amount of ductal shunting mainly depends on the size and morphology of the PDA and the level of pulmonary vascular resistance. PDAs vary from extremely small and hemodynamically insignificant (the so-called “clinically silent” PDAs) to large ones leading rapidly to pulmonary hypertension (the so-called “window-like” PDAs). Dilation and dysfunction of the left heart, pulmonary hypertension, or rarely even infectious endocarditis may occur as late complications. Therefore, it is advisable to close PDA unless it is too small and hemodynamically insignificant.

Nonsteroidal anti-inflammatory drugs such as indomethacin or ibuprofen can be used for PDA closure in neonates [2, 3]. Surgical ligation is usually reserved for patients with very large PDAs, unfavorable ductal anatomy (mostly Krichenko type B), associated cardiovascular anomalies, and for infants weighing less than 8 kg [4, 5]. However, transcatheter closure of PDA has now become the treatment of choice for patients after early infancy. The most commonly used devices for transcatheter closure of PDA are spiral-shaped coils and plug-shaped Amplatzer Duct Occluders (ADOs). Flipper coils are one of the most frequently used coils. The results of transcatheter PDA closure are excellent with a high complete closure rate, minimal complications, and virtually no mortality.

This study aimed to compare the safety and efficacy of transcatheter PDA occlusion using Flipper coil and ADO and to determine the incidence and significance of procedural complications.

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Correspondence to:

Stefan ĐORĐEVIĆ
University Children's Hospital
10 Tiršova Street
Belgrade 11000, Serbia
stf.djordjevic@gmail.com

METHODS

Study population

Between November 2004 and October 2014, 148 patients were eligible for transcatheter closure of PDA at the University Children's Hospital in Belgrade. All of them had echocardiographic evidence of a PDA and met the criteria for transcatheter PDA closure established by manufacturers of the occlusion devices [6, 7]. Two patients had a residual PDA after attempted surgical ligation.

The great majority of patients (134) were asymptomatic. Four patients failed to thrive, six patients complained of fatigue with exertion, and three patients experienced palpitations. In addition, one patient with associated pulmonary hypertension and a small interatrial communication within the oval fossa was mildly cyanosed.

A written informed consent was obtained from all patients and/or their parents prior to the procedure.

Description of the procedure

Catheterizations were carried out under general anesthesia using Axiom Artis angiography system (Siemens, Erlangen, Germany). For transcatheter PDA closure we used Flipper coils (Cook medical, Inc., Bloomington, IN, USA) and Amplatzer Duct Occluders (St. Jude Medical, Inc., MN, USA).

After femoral artery access, left heart catheterization was performed with the measurement of aortic pressures. Then, an aortogram was taken in the lateral and occasionally right anterior oblique projection to determine the morphology of the PDA based on the Krichenko classification [4]. Furthermore, PDA diameters at the aortic and

pulmonary end and their lengths were measured on the aortogram.

The decision whether to use Flipper coil or ADO for PDA closure and the choice of the optimal size of the device were based on the morphology and the narrowest diameter of the PDA (Figures 1 and 2) [8]. Coils were used for smaller PDAs with the narrowest diameter smaller than or equal to 2.5 mm, while ADOs were mostly employed for larger PDAs greater than 2 mm in the narrowest diameter (Figure 2).

If Flipper coil was chosen for the occlusion of PDA, a 4-Fr end-hole catheter was passed through the aorta and the PDA to the pulmonary artery. Then, pulmonary artery pressures were obtained and the coil of the appropriate size was introduced through the catheter and carefully placed in the PDA, avoiding protrusion into the aorta or left pulmonary artery. After the assessment of adequate positioning, the coil was finally released (Figure 3).

When ADO was used for PDA closure, aortography was followed by femoral vein puncture and right heart catheterization with pressure measurements in the right heart and the pulmonary artery. If increased pulmonary artery pressure (mean pressure > 25 mmHg) was recorded, flows and resistances in the pulmonary and systemic circulations were calculated. Pulmonary vascular reactivity was assessed as needed, using vasodilating agents (nitric oxide and 100% oxygen) and by temporary test occlusion of the PDA with a sizing balloon [9]. Next, a catheter was introduced through the femoral vein and passed through the pulmonary artery and PDA to the descending aorta and then exchanged over a guidewire for a long sheath of adequate size. Afterwards, ADO of appropriate size was introduced through the long sheath and advanced to the descending aorta. Initially, only the retention disk was opened and then the remainder of the

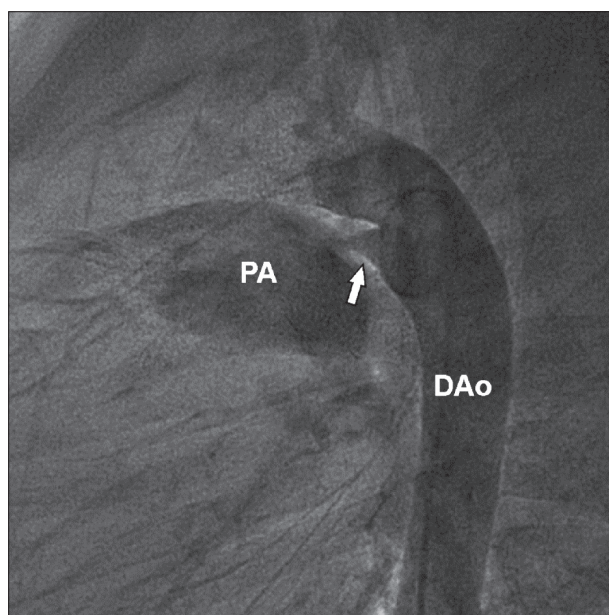


Figure 1. An aortogram in lateral projection showing a smaller patent ductus arteriosus (PDA) type A (arrow); there is a prominent ductal ampulla (the widened aortic end of the PDA); the narrowest PDA diameter is at the pulmonary end; PA – pulmonary artery; DAo – descending aorta

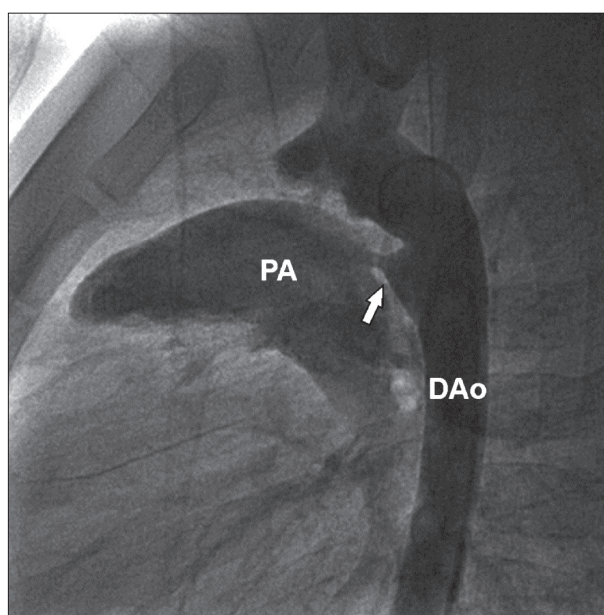


Figure 2. This aortogram in lateral projection shows a larger patent ductus arteriosus (PDA) type A (arrow) with a well-defined ductal ampulla; the PDA is the narrowest at the pulmonary end; there is a marked opacification of the pulmonary artery from the PDA, suggesting a significant aortopulmonary shunt; PA – pulmonary artery; DAo – descending aorta



Figure 3. An aortogram of the same patient as in Figure 1 demonstrates complete closure of the patent ductus arteriosus (PDA) after coil placement (arrow)



Figure 4. An aortogram of the same patient as in Figure 2 reveals an Amplatzer Duct Occluder (ADO) implanted in the patent ductus arteriosus (PDA) (arrow); there is no residual shunt

device was embedded into the ductal ampulla. After being carefully placed and in stable position, ADO was released from the delivery cable. The mean diameter of the ADO occluder was at least 2 mm larger than the narrowest diameter of the duct. A repeat angiogram was performed 10 minutes after the implantation of occluder in order to assess the position of the device, its relationship to adjacent structures, and the presence of the residual shunt (Figure 4).

Following removal of catheters and vascular introducers, digital compression, and after checking the pulses, the patients were transferred to the ward for close observation. All the patients received antibiotic prophylaxis prior to the procedure. Intravenous heparin was reserved for prolonged procedures or absence of pulses immediately after the catheterization.

Follow-up Doppler echocardiograms were performed at one day (pre-discharge), three months, one and two years after closing the PDA to evaluate the presence of the residual shunt and device protrusion into the aorta or the pulmonary artery.

Statistical analysis

Continuous variables were summarized using descriptive statistics. Parametric data were expressed as mean and standard deviation, while non-parametric data were given as median and range between minimum and maximum values. Mann–Whitney U-test (two-tailed) was applied for comparison of two independent groups of nonparametric data. Independent-samples t-test was used to examine the difference between two groups of data that follow a normal distribution. Fisher's exact test and χ^2 test were used to analyze the difference between categorical variables. A p -value < 0.05 was considered statistically significant. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 20.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Of 148 patients eligible for transcatheter PDA closure, the procedure was abandoned in four patients. Three of them had extremely small angiographic PDA diameter at the pulmonary end (< 0.5 mm) and one patient had unfavorable morphology and size of the PDA (closure was possible only with ADO, but we assumed it would cause considerable protrusion into the pulmonary artery). Furthermore, spontaneous occlusion of very small PDAs occurred following the placement of the guide wire in two patients.

Thus, a total of 142 patients underwent coil or ADO occlusion for PDA, of which 56 males and 86 females. The median age of the patients was 5.9 years (range of 0.9–17.3 years), weight 21 kg (range of 8.8–94 kg), and body surface area 0.8 m² (range of 0.4–2.2 m²). Median narrowest PDA diameter was 1.5 mm (range of 0.5–5.6 mm). Coil was used for PDA closure in 84 (59.2%) and ADO in 58 (40.8%) patients. Baseline demographic data and PDA characteristics, as well as hemodynamic data for both the coil and the ADO group are given in Table 1. The narrowest diameter of the PDA was significantly larger in the ADO group ($p = 0.000$). PDA type B was more prevalent in the ADO group ($p = 0.042$), and type C in the coil group ($p = 0.001$). Mean pulmonary artery pressures were significantly higher in patients who underwent ADO than coil closure of PDA ($p = 0.030$). Furthermore, a total of eight patients had mean pulmonary artery pressure > 25 mmHg (two in the coil group, and the rest in the ADO group).

The various sizes of coils and ADOs used during the procedure are shown in Table 2 and Table 3, respectively. One patient needed the placement of two coils. In five patients a larger coil was deployed since the smaller one was not appropriately positioned. In nine patients, ADO was placed after initial unsuccessful coil implantation (five coils were unstable and four coils embolized). In two

Table 1. Comparison of baseline demographic data, PDA characteristics, and hemodynamic parameters between the coil and the ADO group

Type of device	Coil	ADO	p-value
Demographic data			
Age (yrs)	6.1 (1.1–17.3)	4.8 (0.9–17.2)	0.094
Male to female ratio	38 : 46	18 : 40	0.089
Weight (kg)	24 (10–94)	18.8 (8.8–78)	0.075
Body surface area (m ²)	0.9 (0.5–2.2)	0.8 (0.4–2.0)	0.135
PDA characteristics			
Narrowest PDA diameter (mm)	1.1 (0.5–2)	2.3 (1.3–5.6)	0.000
PDA length (mm)	7.5 (3.3–22)	7.8 (5–18)	0.334
PDA type:			
A	35 (41.7%)	26 (44.8%)	0.708
B	1 (1.2%)	5 (8.6%)	0.042
C	24 (28.6%)	4 (6.9%)	0.001
D	13 (15.5%)	14 (24.1%)	0.196
E	11 (13.1%)	9 (15.5%)	0.683
Hemodynamic parameters prior to procedure			
Mean aortic pressure	82.8 ± 15.5	82.3 ± 12.7	0.855
Mean pulmonary artery pressure	17.5 (7–26)	20 (11–46)	0.030
Mean pulmonary-to-systemic arterial pressure ratio	0.22 (0.09–0.44)	0.23 (0.14–0.53)	0.062

PDA – patent ductus arteriosus; ADO – Amplatzer Duct Occluder

patients, the PDA was closed with ADO after failed surgical ligation.

Repeat angiogram showed complete occlusion of PDA in 117 (82.4%) patients, while trace residual shunting was found in 25 (17.6%) patients. Residual ductal shunting on angiogram was present in 11 out of 84 (13.1%) patients in the coil group, compared to 14 out of 58 (24.1%) in the ADO group. There was no statistically significant difference in the rate of immediate complete closure of PDA with coil or ADO (86.9% vs. 75.9%, $p = 0.089$). Follow-up Doppler echocardiography at one day, three months, and both one and two years showed only a trace residual shunt in 15 (10.6%), 12 (8.4%), and seven (4.9%) patients, respectively. There was a significant difference in complete closure rate between the coil and the ADO group at one day (83.3% vs. 98.3%, $p = 0.004$), three months (85.7% vs. 100%, $p = 0.002$), and both one and two years (91.7% vs. 100%, $p = 0.041$).

Elevated pulmonary artery pressures returned to normal levels in both patients in the coil group, and in almost all patients in the ADO group, except in one with pulmonary hypertension documented prior to procedure.

In total, 12 complications occurred during the procedure, seven of which with coil and five with ADO closure of the PDA (Table 4).

Coil embolization occurred in five patients. Coils migrated towards the pulmonary artery in four patients, and to the common hepatic artery in one case. All embolized coils were successfully retrieved and replaced with a larger coil (one patient), or ADO (four patients) during the same procedure. One of the patients with coil embolized to the pulmonary artery required a red blood cell transfusion due to the prolonged attempts to retrieve the coil. ADO embolization happened in a three-year-old girl weighing 14 kg.

Table 2. The size and number of coils deployed

Coil sizes (mm)	Number
8 × 5	2
6.5 × 4	1
5 × 5	8
5 × 4	12
5 × 3	13
3 × 5	4
3 × 4	16
3 × 3	29
Total	85

Table 3. The size and number of ADOs deployed

ADO sizes	Number
5/4	32
6/4	20
8/6	4
10/8	2
Total	58

ADO – Amplatzer Duct Occluder

Table 4. The type and number of procedural complications encountered during coil and ADO closure of PDA

Complications	Coil group		ADO group	
	Major complications	Device embolization	4	Device embolization
Device embolization and red blood cell transfusion		1		
Minor complications	Mild device protrusion into the aorta	2	Mild device protrusion into the left pulmonary artery	3
			Arrhythmia requiring medication	1

ADO – Amplatzer Duct Occluder; PDA – patent ductus arteriosus

Namely, ADO was released too early during the procedure and it lodged in the abdominal aorta. The embolized device was successfully retrieved, using a snare catheter and long sheaths of a large diameter, and subsequently implanted in the PDA during the same procedure. Coil embolizations were associated with Krichenko type A (2), and C (3) PDAs, and ADO embolized in a patient with PDA type A.

In two patients, coil was not appropriately positioned at the aortic end. In one of them, the last coil loop was placed along the wall of the distal aortic arch, while in the other the distal end of the coil protruded about 3 mm into the aorta. Both complications occurred in the setting of PDA type C. In three patients, ADO protruded into the left pulmonary artery without causing significant flow disturbance (Doppler echocardiographic flow velocity of 1.8 m/s). All these patients were asymptomatic and there was no progression of obstruction or need for additional procedures during follow-up. ADO protrusion was associated with PDA type A (1), B (1), and E (1).

A 3.5-year-old girl developed supraventricular tachycardia during the placement of the long sheath through the right heart. Tachycardia was rapidly terminated by intravenous amiodarone, and an ADO was successfully implanted.

DISCUSSION

In the period from 1939 to the mid-1990s, surgical ligation of PDA was considered the gold standard for managing PDAs. Mavroudis et al. [10] reported that ligation of PDA, performed on 1,108 patients older than 30 days with isolated PDA, was successful in 100% of cases. In addition, mortality was zero and morbidity as low as 4.4% [10].

In the past few decades, numerous new cardiac catheterization procedures for correction of congenital heart diseases have been developed to avoid the disadvantages of surgical procedures. Portsmann was the first to attempt to perform a non-surgical closure of PDA with the so-called “plug” in the 1970s. However, this method was not widely accepted because of the large dimensions of the device and catheter through which it was passed. Later on, Gianturco embolization coil was introduced into the clinical practice and was followed by the Rashkind double-umbrella device. At the beginning, the use of nondetachable Gianturco coils frequently led to device embolization to the pulmonary artery and the aorta. Afterwards, the original Gianturco coil was redesigned into the so-called “detachable” coil, which was attached to a cable, thus allowing full control during the placement and release of the coil with the possibility of easy repositioning and retrieval when necessary. A major advance in transcatheter closure of larger PDAs occurred with the advent of ADO in 1998 [11].

Currently available devices designed for PDA occlusion are very efficient, but have some shortcomings [12, 13, 14]. The limitations of transcatheter closure of PDA include the failure of the procedure, the presence of residual shunt with or without hemolysis, device embolization and other cardiovascular complications, device protrusion into surrounding vasculature, and exposure to radiation. As previously mentioned, coils are used for closure of smaller PDAs with the narrowest diameter being smaller than or equal to 2.5 mm, while ADOs are usually reserved for larger PDAs, greater than 2 mm in diameter. In our study, the median narrowest PDA diameter was 1.1 mm (range of 0.5–2 mm) in the coil group and 2.3 mm (range of 1.3–5.6 mm) in the ADO group, and was significantly larger in the latter group. We achieved a high complete closure rate regardless of the device employed. In total, 25 (17.6%) patients had a trace residual shunt at the end of the procedure and only seven (4.9%) at both one and two years after the procedure. Furthermore, complete closure of PDA at both one and two years was achieved in 91.7% and 100% of cases in the coil and the ADO group, respectively.

Studies analyzing the efficiency of coil occlusion of PDA reported that complete closure rate varied from 63.4 to 96.6% at the end of the procedure, and from 80.5% to 96.2%, at one year [15–19]. When present, the residual ductal shunt was almost invariably hemodynamically insignificant. However, in some patients with residual ductal shunting after coil placement, acute hemolysis occurred because of mechanical destruction of erythrocytes after their contact with the metal structure of the coil. In our study, out of seven patients with residual ductal flow none had hemolytic anemia. According to the literature, the rate of complete closure of the PDA using ADO varied from 56.6% to 100% immediately after the procedure, and from 99.7% to 100% at one year [17–23]. The studies of PDA closure with ADO showed that, if present, there was only a small residual shunt after the procedure comparable to that seen with coil placement.

The mortality rate for transcatheter PDA occlusion is nearly zero (0–0.9%). Procedure-related major and minor

complications are rare, ranging 0–9.1% and 0–16.2%, respectively [17–27]. Similarly, our results showed zero mortality rate and the equal occurrence of major and minor complications (4.2%).

The single most common procedural complication is probably device embolization (0–6%), with coils being more prone to embolize than ADOs [17–26, 28]. In most cases, embolized devices could be readily retrieved without consequences. Apart from operator skill, the occurrence of coil embolization appears to be related to the type of PDA. It was found more likely to occur with PDAs of Krichenko type B (window-like) and C (tubular) [23]. By comparison, coil embolizations in our study were associated with PDAs type C and type A (conical). In addition, it is of immense importance to accurately determine the size of the PDA so that the proper device and its size could be chosen for the procedure. Retrospective analysis of all cases where coil embolization occurred showed that underestimation of the size of the PDA caused the selection of the wrong type or size of the device. As mentioned above, in one patient, complete closure of the PDA was achieved with a larger coil after the smaller one embolized. In four patients, after retrieving the embolized coils, the PDA size appeared larger on aortogram than previously estimated. After reassessing the size of the PDA, we successfully implanted ADO in all four patients.

Apart from the device embolization, another concern is the possibility of device protrusion into surrounding vascular structures, i.e., the descending aorta and the pulmonary arteries. A number of studies have reported the problem of device protrusion and impingement on the lumen of the left pulmonary artery and occasionally the descending aorta, with the incidence ranging 0–14% [17–26]. This was more commonly seen in infants and small children and in patients requiring the placement of additional devices for PDA closure. Device protrusion into the left pulmonary artery was observed in three (2.1%) patients in our study group and was hemodynamically insignificant in all cases, which is comparable to the results from other studies. Two patients (1.4%) had a slight coil protrusion into the descending aorta with repeat aortograms showing a stable position of the device without obstruction to flow. Since both were small children in whom the aortic diameter would increase with growth and since PDAs were completely closed, the coils were left in place. Follow-up echocardiograms revealed no progression of aortic obstruction.

CONCLUSION

Transcatheter closure of PDA using both coils and ADOs is a very safe and effective procedure in pediatric patients beyond the early infancy. ADO proved superior to Flipper coil in terms of complete closure rate within a day after implantation. The good estimate of the ductal size and anatomy is crucial for the optimal choice of the device. This, in turn, prevents the occurrence of complications including device embolization and protrusion into surrounding vasculature, and decreases the incidence of residual shunt.

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Транскатетерско затварање отвореног артеријског канала коришћењем *Flipper coil*-а и дукталног затварача *Amplatzer*: десетогодишње искуство једног центра

Милан Ђукић^{1,2}, Војислав Парезановић^{1,2}, Стефан Ђорђевић^{1,2}, Игор Стефановић^{1,2}, Весна Мирановић³, Слободан Илић^{1,4}, Ида Јовановић^{1,2}

¹Универзитет у Београду, Медицински факултет, Београд, Србија;

²Универзитетска дечја клиника, Одељење кардиологије, Београд, Србија;

³Институт за болести деце, Клинички центар Црне Горе, Подгорица, Црна Гора;

⁴Универзитетска дечја клиника, Одељење кардиохирургије, Београд, Србија

САЖЕТАК

Увод/Циљ Транскатетерско затварање је опробана метода лечења отвореног артеријског канала (ОАК).

Циљ рада је био да упоредимо транскатетерско затварање ОАК коришћењем *Flipper coil*-а и дукталног затварача *Amplatzer* (ДЗА) и да утврдимо учесталост и значај насталих компликација.

Методe У периоду од новембра 2004. до октобра 2014. године код 148 болесника је урађено транскатетерско затварање отвореног артеријског канала. Просечан узраст је био 5,9 (0,9–17,3) година, а телесна маса 21 (8,8–94) kg. Контролни ехокардиографски прегледи су урађени један дан, три месеца, једну и две године после интервенције.

Резултати Просечан најужи пречник ОАК је био 1,5 (0,5–5,6) mm. *Flipper coil* је коришћен код 84 (59,2%), а ДЗА код 58

(40,8%) болесника. Непосредно после интервенције није постојала значајна разлика у учесталости потпуног затварања ОАК између *coil* и ДЗА групе (86,9% тј. 75,9%, $p = 0,089$), али је она била значајно већа у ДЗА групи један дан (83,3% тј. 98,3%, $p = 0,004$), три месеца (85,7% тј. 100%, $p = 0,002$) и једну и две године после интервенције (91,7% тј. 100%, $p = 0,041$).

Укупно се десило 12 компликација у току интервенције, од чега седам при употреби *Flipper coil*-а, а пет при примени ДЗА.

Закључак Транскатетерско затварање је безбедна и ефикасна процедура, било да се користи *coil* или ДЗА. Учесталост потпуног затварања ОАК значајно је већа у ДЗА групи у односу на *coil* групу, већ у року од једног дана од интервенције.

Кључне речи: катетеризација срца; вештачке протезе и имплантати; деца; одрасли