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Percutaneous occlusion of ductus arteriosus with Amplatzer™ Duct Occluder II AS

Oclusão percutânea do canal arterial com Amplatzer™ Duct Occluder II AS

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ABSTRACT – Background: Percutaneous occlusion of ductus arteriosus is well established as the method of choice to treat this structural heart defect. A new generation of Amplatzer™ Duct Occluder II Additional Sizes prostheses, with lower profile and greater flexibility, in addition to smaller retention discs, was developed for percutaneous treatment of patent ductus arteriosus. This study intended to demonstrate the experience of one center with the use of this device, evaluating technical aspects, immediate occlusion rates, and complications. **Methods:** A retrospective study of a cohort of patients with patent ductus arteriosus treated with Amplatzer™ Duct Occluder II Additional Sizes. Between October 2018 and March 2021, 27 patients with patent ductus arteriosus, types A and E according to the Krichenko classification, were treated with Amplatzer™ Duct Occluder II Additional Sizes. The prosthesis was implanted by the usual antegrade approach in 25 patients, and retrograde in two cases. The prosthesis chosen were 2mm larger than the core of the defect, and the length of the prosthesis was 2mm for shorter lesions and smaller infants, and between 4 and 6mm for longer lesions. **Results:** Out of 27 patients, 52% were female, with a mean age and weight of 44.2 months (1 to 135 months) and 15.8kg (2,0 to 29kg), respectively. In the sample, 11 patients presented type A patent ductus arteriosus, and 16 type E, with a mean ratio of 1.9:1 between the prosthesis waist and the central diameter. In all patients, the device was successfully implanted, and only one patient remained with residual shunt, presenting embolization of the prosthesis. This patient had the ductus arteriosus closed by another prosthesis. **Conclusion:** Amplatzer™ Duct Occluder II Additional Sizes demonstrated safety, versatility, and efficiency in cases of appropriate anatomy. The experience demonstrated here is from a single center, with the Amplatzer™ Duct Occluder II Additional Sizes. Its increased flexibility and softness demand greater operator expertise.

Keywords: Ductus arteriosus; Heart defects, congenital; Congenital abnormalities; Prosthesis design

RESUMO – Introdução: A oclusão percutânea do canal arterial está bem estabelecida como método preferencial para o tratamento desse defeito cardíaco estrutural. Uma nova geração de próteses Amplatzer™ Duct Occluder II Additional Sizes, com menor perfil e maior flexibilidade, além de discos de retenção menores, foi desenvolvida para o tratamento percutâneo da persistência do canal arterial. Este estudo objetivou demonstrar a experiência de um centro com o uso desse dispositivo, avaliando aspectos técnicos taxa de oclusão imediata e complicações. **Métodos:** Estudo retrospectivo de uma coorte de pacientes portadores de persistência do canal arterial tratados com Amplatzer™ Duct Occluder II Additional Sizes. Entre outubro de 2018 e março de 2021, 27 pacientes portadores de persistência do canal arterial tipos A e E da classificação de Krichenko foram tratados com Amplatzer™ Duct Occluder II Additional Sizes. A prótese foi implantada por via anterógrada habitual em 25 pacientes e retrógrada em dois casos. A prótese escolhida era 2mm maior que o corpo central do defeito, e o comprimento da prótese foi de 2mm, para lesões mais curtas e lactentes menores, e entre 4 e 6mm, para lesões mais longas. **Resultados:** Dentre os 27 pacientes, 52% eram do sexo feminino, com média de idade e de peso de 44,2 meses (1 a 135 meses) e 15,8kg (2,0 a 29kg), respectivamente. Na amostra, 11 apresentavam persistência do canal arterial tipo A e 16 do tipo E, com média da relação entre cintura da prótese e diâmetro central de 1,9:1. Em todos os pacientes, a prótese foi implantada com êxito, e apenas um paciente permaneceu com *shunt* residual, apresentando embolização da prótese. Esse paciente teve o ducto arterioso fechado por outra prótese. **Conclusão:** A prótese Amplatzer™ Duct Occluder II Additional Sizes demonstrou segurança, versatilidade e eficiência nos casos de anatomia apropriada. A experiência foi demonstrada aqui em um único centro com a prótese Amplatzer™ Duct Occluder II Additional Sizes. Sua maior flexibilidade e suavidade demandam maior experiência do operador.

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Descritores: Canal arterial; Cardiopatias congênitas; Anormalidades congênitas; Desenho de prótese

INTRODUCTION

Patent ductus arteriosus (PDA) occurs in isolation in one in every 2,000 full-term neonates, being more frequent in preterm infants. It accounts for 5% to 10% of all congenital heart diseases, having great relevance. This high prevalence justifies the search for more efficient methods and prostheses. Optimal results were not initially described in the first reports of percutaneous occlusion,¹ and the expectations were not met. Rudimentary prostheses, cumbersome delivery systems and techniques, high rate of complications, and low rates of occlusion did not bring popularity to the new method. Novel and more accessible techniques, development of modern prostheses, high occlusion rates, low complications rates, and the user-friendly delivery systems with lower profile have defined percutaneous occlusion of ductus arteriosus as the treatment of choice in the pediatric population,² sharing this indication only with surgical treatment in low-birth-weight neonates.³

The indications for ductus arteriosus closure are significant left-right shunt, signs of overload in left cavities, which can progress to heart failure, and low weight gain and its many consequences. Multiple ductus arteriosus morphologies, especially Krichenko classification type E,⁴ can be particularly challenging for percutaneous occlusion.

Safety of the percutaneous procedure correlates directly to the operator's experience and knowledge of the material to be used. Several types of prostheses are available for ductus arteriosus occlusion. The most recent prosthesis of the Amplatzer™ Duct Occluder family, ADO II Additional Sizes (St. Jude Medical, St. Paul, Minnesota, USA) (Figure 1) was designed for occlusion of defects smaller than 4mm, in low-birth-weight⁵ preterm babies, and also for defects with shallower ductal ampulla. Smaller and thinner retention discs reduce the possibility of protrusion to the aorta

or pulmonary artery, avoiding obstruction in these territories. Its efficacy is established in the literature,^{6,7} as well as its use for occlusion of shunts other than PDA.⁸

This study intended to demonstrate the experience of one center with the use of the device, evaluating technical aspects, immediate occlusion rates, and complications.

METHODS

Patients

This is a retrospective study conducted with 27 patients diagnosed with PDA, weighting more than 2.0kg, older than 1 month, with no criteria for pulmonary hypertension and diameter of the ductus arteriosus in the pulmonary end smaller than 4mm.

Patients were referred for percutaneous closure of the ductus arteriosus from October 2018 to March 2021. The anatomical profiles Krichenko A and E were preferably selected. Patient and procedural data were collected, and angiographic and hemodynamic findings were obtained. An informed consent was signed before all the procedures.

Prosthesis

Amplatzer™ Duct Occluder II Additional Sizes (ADO II AS) is a self-expanding occluder, formed by a central waist and bilateral retention discs, 1 to 1.5mm wider than the central waist. The devices are classified according to the central portion, into 3, 4 and 5mm. The 3mm prosthesis has, therefore, 4mm retention discs, the 4mm prosthesis has retention discs of 5.25mm, and the 5mm prosthesis, 6.5mm discs (Table 1). The ADO II AS is also classified by the length of the prosthesis as 2, 4 and 6mm. The description of the prosthesis as 2mm in length refers to the distance between the retention discs with no compression (Figure 1).

Table 1. Characteristics of the prostheses and delivery system

Model order n.º	Central* diameter (mm)	Length (mm), retention disc†	Retention disc‡ (mm)	Sheath/size
9-PDA2AS-03-02-L	3	2	4.00	4F/90° curve
9-PDA2AS-03-04-L	3	4	4.00	4F/90° curve
9-PDA2AS-03-06-L	3	6	4.00	4F/90° curve
9-PDA2AS-04-02-L	4	2	5.25	4F/90° curve
9-PDA2AS-04-04-L	4	4	5.25	4F/90° curve
9-PDA2AS-04-06-L	4	6	5.25	4F/90° curve
9-PDA2AS-05-02-L	5	2	6.50	4F/90° curve
9-PDA2AS-05-04-L	5	4	6.50	4F/90° curve
9-PDA2AS-05-06-L	5	6	6.50	4F/90° curve

* Central diameter; † prosthesis length; ‡ retention disc diameters.

Source: AMPLATZER™. Product Portfolio. Abbott; p. 16.

Figure 1. Amplatzer Duct Occluder II AS design. (A) Diameter of central waist. (B) Total length of the prosthesis. (C) Diameter of the retention discs.

The shape of the retention discs was flattened and reduced to minimize the risk of protrusion into the aorta and pulmonary artery, PDA occlusion in low-birth-weight

preterm infants being the main objective of this prosthesis. Its design has denser nitinol mesh distributed in one single layer, reducing the profile of the prosthesis and of the delivery catheter (sheath). The more flexible delivery cable and the smaller pin of the delivery system render the set softer.

Procedures

All procedures were performed under general anesthesia and prophylactic antibiotic therapy, initiated before the procedure and maintained for 24 hours. The ultrasound-guided Seldinger technique was used for femoral puncture with introducers positioned in the arterial and venous accesses. After arterial puncture, 100U/kg heparin was given, and repeated every hour. Aortograms were carried out in the right anterior oblique and left lateral views, using a pigtail catheter, positioned in the descending thoracic aorta. In some patients, the lateral view was extended to 100° or more, for better evaluation and measurement of the ductus arteriosus. The pulmonary end, the aortic end, the body measurement and its length were attained. The prosthesis was preferably released from the pulmonary side. A lateral view of the aortogram and pulmonary arteriogram in left anterior oblique/cranial were subsequently obtained to evaluate residual shunt, and to rule out obstructions in the aorta and left pulmonary artery. Hospital discharge occurred within 24 hours, after physical assessment and echocardiogram.

The follow-up was planned, with the first visit and echocardiogram after discharge scheduled for 7 days later. New visits and echocardiograms were carried out at 30 days, 3 and 6 months, and subsequently, at annual visits.

This study was approved by the Research Ethics Committee (opinion number 4.554.673, CAAE 42757020.8.0000.5265).

RESULTS

From October 2018 to March 2021, 27 patients underwent percutaneous occlusion of the ductus arteriosus using the ADO II AS device. Of these, 13 were male (48%). The mean age and weight were 44.2 months (1 to 135 months) and 15.8kg (2.0 to 29kg), respectively. Eleven patients (41%) presented ductus arteriosus morphology type A, according to the Krichenko classification, and 16, type E. Mean measurements of the ductus arteriosus were 1.6mm in the pulmonary end, 4.6mm in the aortic ampulla, 6.8mm in length, and 2.3mm in central diameter.

The most used device was 4mm wide, for 11 patients (38%), the 4mm long was used in nine patients, one patient used the 2mm, and one case required the 6mm long (Figure 2). Clinical, angiographic, and procedural data are displayed in table 2. The preferred approach was antero-grade, the aortic (retrograde) approach being used in two procedures.

Figure 2. Lateral view of aortogram before and after deployment of the prostheses. (A) Injection of the 4F delivery sheath, arterial occlusion. (B) Prosthesis ADO II AS, ductus type E, prosthesis 4/6. (C) Prosthesis ADO II AS 4/4.

Table 2. Clinical data, ductus arteriosus and prosthesis rates

Patient	Sex	Age (months)	Weight (kg)	Type*	Pulmonary end	Aortic end	Central diameter	Length	Prosthesis	Prosthesis diameter
1	Male	10	6.1	A	1.4	6.7	2.5	3.7	5 2	2
2	Male	44	14.7	E	1.8	5	3	5	5 4	1.7
3	Male	131	28.3	E	1.5	5.2	2.5	7	4 4	1.6
4	Female	58	18.2	E	1.8	5	2.6	7	4 6	1.5
5	Female	79	20.5	E	1.3	4.8	1.5	6	4 4	2.6
6	Male	16	13.7	E	1.4	3.5	1.5	7	3 4	2
7	Female	31	11.2	A	1.5	6	2	4	4 4	2
8	Female	7	6.4	A	1.8	5	2.1	6	5 4	2.4
9	Male	61	18.6	A	1.6	6	2.7	5	4 4	1.5
10	Female	51	19	E	1.3	5	2	8	5 6	2.5
11	Male	60	22	E	1.4	5.6	2	7	5 6	2.5
12	Female	48	15	A	1.8	5.2	2.1	5.4	4 4	1.9
13	Female	47	16	A	1.5	5.6	1.9	5	4 4	2.1
14	Male	32	13	A	2	5.5	2.2	5	4 4	1.9
15	Male	26	14	E	1.2	3.6	2	7	5 4	2.5
16	Female	135	36	E	1.2	1.4	1.8	4	4 2	2.2
17	Male	26	15	E	2	2.1	2.5	5	5 4	2
18	Male	12	11	E	1.2	5	3.5	12	5 6	1.4
19	Female	38	15	E	1	1.5	1.5	10	3 4	2
20	Female	62	21	A	1.5	5	2.5	8	5 4	2
21	Female	11	9	A	2	6.5	2.5	4.5	5 2	2
22	Male	98	29	E	1.1	1.5	2	9	4 4	2
23	Male	51	16	A	1.2	4	2	7	4 4	2
24	Female	13	8.8	E	2	2.8	2.5	10	5 4	2
25	Female	0	4.5	E	4	5	3.5	10	5 6	1.4
26	Female	13	2	A	1.6	9	3	6	5 4	1.6
27	Male	26	13	E	1.5	5	3.5	10	5 6	1.4

* Types E and A of the Krichenko classification.

DISCUSSION

The ADO II AS device has high occlusion rates and safety for percutaneous occlusion of PDA.^{6,8} The immediate follow-up aortogram demonstrated residual flow inside the prosthesis; however, the echocardiogram 24 hours after the procedure did not show any residual flow, except in one single case of prosthesis embolization, in which there was residual shunt. This is due to the denser nitinol mesh distributed in a single layer, and absence of tissue inside the prosthesis. In two patients, the arterial approach was used to release the device, with no technical difficulty or vascular complication. The use of this technique simplifies and speeds up the procedure. ADO II AS has a lower profile delivery system (4F), and the prosthesis is more flexible, enabling the treatment of low-weight patients, which is the primary objective of this device. The choice of prosthesis size considered a prosthesis/body defect ratio of 2:1. The device was preferably used in ductus types A and E, thus

preventing the prosthesis to cause any alteration in the aortic end, staying within the ductus or in the aortic ampulla, usually shallow, in the selected cases. The total length of both the ductus and the device should be considered, to avoid significant protrusion, and the length of the prosthesis is measured between the retention discs (Figure 1 and Table 1), with no compression. Pulmonary protrusion of the prosthesis is unlikely, since only one low-profile disc is positioned on this side of the ductus. No pulmonary or aortic protrusion was seen in our series. In only one patient there was greater than expected residual flow in the follow-up aortogram, the same patient who later presented embolization of the prosthesis. The prosthesis was not recovered, because it was attached to a very small pulmonary branch. The ductus arteriosus was occluded with another prosthesis. We believe this case of failure occurred due to inadequate assessment of the ductus arteriosus in the aortogram, probable spasm or change of ductal anatomy,

and should be attributed to inadequate choice by the operator. Several publications have established the efficacy of Amplatzer™, since ADO I,⁹ ADO II,⁸ and ADO II AS – the latter has been used less often.⁶⁻⁸

We believe this device can be used in ductus arteriosus types A, C and E, especially in small infants and neonates,^{5,9} demanding greater familiarity from the professionals with the use of prosthesis.

Study limitations

More studies, greater number of patients, different anatomies and long-term results must be analyzed for better assessment of the role of this prosthesis for percutaneous occlusion of PDA. Initially conceived to be used in low-weight premature infants, excellent results were attained in older children, having as limitations the size of the ductus and not being adequate for larger ductus arteriosus.

CONCLUSION

The ADO II AS device is safe and effective for the occlusion of selected ductus. The prosthesis can be used for occlusion of ductus arteriosus types A and E, in a safe manner and lower risk of obstruction in the aorta or left pulmonary artery, in children, small infants and newborns. The operator experience and knowledge of the characteristics of the device are important for its use. ADO II AS should be considered as another tool for percutaneous treatment of ductus arteriosus in selected patients.

More studies, greater number of patients, different anatomies and long-term results must be analyzed for better assessment of the role of this prosthesis for percutaneous occlusion of patent ductus arteriosus.

SOURCE OF FINANCING

None.

DECLARATION OF CONFLICTS OF INTEREST

The authors declare having no conflicts of interest.

CONTRIBUTION OF AUTHORS

Conception and design of the study: FB and LAC; data collection: FB and RFA; data interpretation: FB; text writing: FB; approval of the final version to be published: FB.

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