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CLINICAL APPLICATION OF THE SECOND GENERATION OF AMPLATZER PATENT DUCTUS ARTERIOSUS OCCLUDER IN THE INTERVENTIONAL CLOSURE OF CONGENITAL HEART DISEASE AND CASE SERIES

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ADO-II Occluder; Congenital Heart Disease; Interventional Therapy.

ABSTRACT

Background: Some patients with structural heart disease are typically treated or improved by minimally invasive surgeries.
Aim: To summarize the efficacy and experience in the treatment of congenital heart disease (CHD) using the second generation of Amplatzer patent ductus arteriosus (ADO- II) occluder.
Methods: A total of 37 patients who were admitted to the cardiac surgery department of our hospital from June 2014 to April 2019 were included. After preoperative echocardiography and clinical screening, intraoperative transthoracic echocardiography, and cardiovascular angiography, postoperative echocardiography was carried out to evaluate the incidence of residual shunt and the location and morphology of the ADO-II occluder, as well as postoperative complications.
Results: All patients were successfully treated using the ADO-II occluder. There were 27 (73%) cases with patent ductus arteriosus (PDA), as well as 5 (13.5%) cases with ventricular septal defect (VSD), 1 case (2.7%) with VSD combined with PDA, 1 case (2.7%) with aortopulmonary collateral arteries combined with PDA, 1 case (2.7%) with right coronary artery-right atrial fistula, and 2 (5.4%) cases were recanalized after ligation of the main pulmonary artery. All patients had no obvious abnormality in ECG reexamination one month after surgery; The x-ray showed no displacement and shedding, and no long-term significant residual shunt was found in transthoracic echocardiography. No death was reported.
Conclusions: The ADO-II occluder is relatively simple to operate, with a high success rate and few complications, and it can be applied to not only PDA occlusion but also to other CHDs, making it worthy of further clinical promotion under the premise of grasping the indicators of interventional therapy.

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Introduction.

Medical technologies have improved in recent years, of which a noticeable progress was made in the interventional treatment of congenital heart disease (CHD). Some patients with structural heart diseases (SHDs), such as patent ductus arteriosus (PDA), ventricular septal defect (VSD), and aortopulmonary collateral arteries, have been treated or improved by minimally invasive interventional occlusion therapy.

At present, there are few special types of SHDs, such as fine and small PDA, muscular VSD, coronary artery fistula (CAF), large and circuitous pulmonary collateral vessels, pulmonary artery recanalization after pulmonary artery ligation, and the absence of a special occluder or an appropriate delivery sheath. Several cardiac centers use the second generation of Amplatzer ductus arteriosus patent (ADO-II) occluder to successfully treat coronary artery occlusion SHD with satisfactory results, while only some cases have been reported.

AGA Medical Corporation (Golden Valley, MN, USA) fabricated the first generation of Amplatzer device in 1998. Compared with other occluders, its advantages include simple to operate, less damage to the femoral vein, and being convenient for infant patients. In 2008, AGA Medical Corporation designed and developed the second generation of Amplatzer ductus arteriosus patent (ADO-II) occluder, with a dumbbell shape. In addition to infant patients with PDA, its soft texture and thinner transmission sheath system are widely used in the interventional treatment of various SHDs. The present study reviewed 37 patients with CHD who were admitted to the Shanghai Yuanda Cardiothoracic Hospital (Shanghai, China) and underwent ADO-II device for other special SHDs, including PDA, and their clinical experience and the surgical efficacy were evaluated.

1. Study Subjects and Methods.

1.1 Study Subjects.

From June 2014 to April 2019, 37 patients, who were admitted to the Cardiac Surgery Department of Shanghai Yuanda Cardiothoracic Hospital consecutively, underwent ADO-II occluder for SHDs. All the patients were screened by transthoracic echocardiography (TTE) before interventional surgery, and they met the criteria presented for transcatheter intervention of CHD [1] and had no obvious surgical contraindication.

The inclusion criteria were as follows: ① Diameters of VSD, PDA, and target vessels would be ≤6 mm; ② Left-to-right shunt; ③ Pulmonary to systemic blood flow (Qp/Qs) ratio >1.5.

The exclusion criteria were as follows:① The level of aortic valve regurgitation would be higher than mild; ②Distance between VSD edge and aortic valve would be <4 mm.

This study was approved by the ethics committee of the corresponding author's institution, and the necessity of informed consent was waived by the ethics committee.

1.2 Research Methods.

All the surgeries were performed by the same physician with at least 15 years of experience in interventional surgery. Patients who aged older than 8 years old received local anesthesia with lidocaine at the right or left femoral artery, while those who aged younger than 8 years old received basic intravenous anesthesia. The Seldinger method was used to puncture the right femoral artery/vein and the 5F short sheath was placed (Terumo Co., Ltd., Tokyo, Japan).

1.2.1 PDA Occlusion.

After completion of the right heart catheterization, the 5F pig tail catheter (Johnson & Johnson, New Brunswick, NJ, USA) was passed through the femoral artery to the descending part of the aortic arch for multi-position angiography, and the length and diameter of PDA were measured to indicate its shape, so as to determine the specification of the occluder. The pig tail catheter was withdrawn, 4F or 5F long-axis sheath (AGA Medical Corporation) was placed at the vicinity of PDA through the femoral artery, the 260-cm super-slippery guide wire (Terumo Co., Ltd.) was placed to explore PDA, then, the pulmonary artery was successfully entered, and the sheath (AGA Medical Corporation) was delivered into the pulmonary artery. The occluder, ADO-II (AGA Medical Corporation) with the corresponding size (2-3-mm larger in diameter than that in the narrowest part of PDA), was selected [2], and the long-axis delivery sheath was placed after tight exhaust. Slowly pushing the occluder head end of the first disc may launch long-axis sheath distal, after being satisfied

disc form, and then fixed delivery sheath and occluder cable device slowly retreat at the same time, to be the first disc close to PDA pulmonary end openings will produce slight deformation, at this time to occluder cable fixed delivery sheath retreat at the same time, slowly release the occluder waist and second disc. The shape of the occluder was then observed. The position of the occluder could be adjusted. After the shape was determined and satisfied, the contrast agent was administrated manually through the long-axis sheath to assess the residual shunt. Then, the steel cable was slowly rotated counterclockwise to release the occluder successfully (Fig. 1).

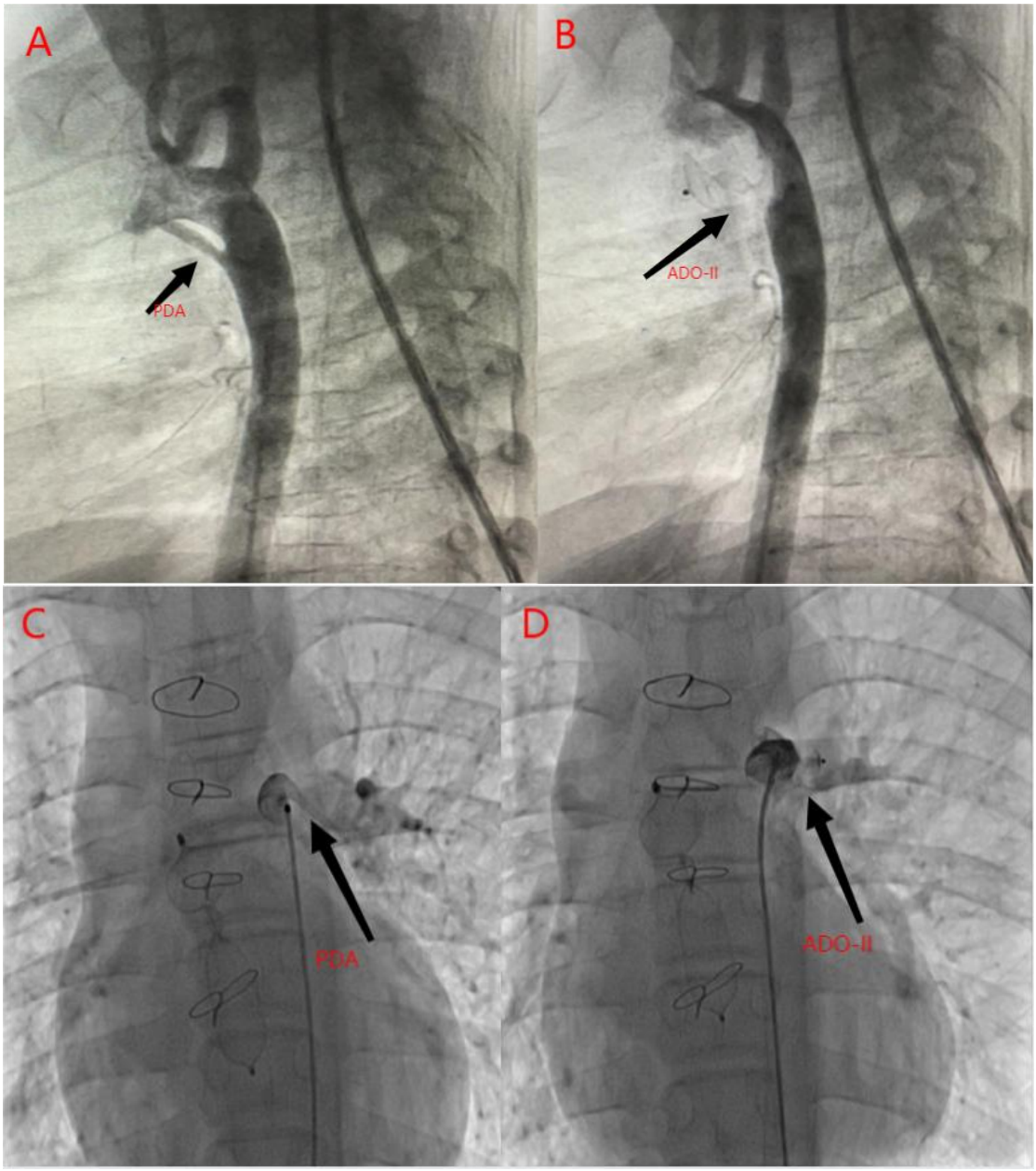

Fig.1 Comparison between before and after PDA occlusion.

A: The size, length, and long strip of the PDA.

B: Angiography was performed immediately after the occluder was released. The results indicated that the shape of occluder remained satisfactory and there was no residual shunt.

C: The angiography suggested an opening of the PDA into the descending thoracic aorta, which was tortuously connected with the left pulmonary artery.

D: A descending thoracic aortogram after the release of the occluder showed no residual shunt, and the occluder was secured with an excellent morphology.

1.2.2 VSD Occlusion.

Right cardiac catheterization was performed first, and then, the 5F pigtail catheter (Johnson & Johnson) was delivered through the femoral artery to the left ventricle for multi-position angiography to determine the diameter, shape, and distance of VSD from the aortic valve, so as to select the occluder model. The pigtail catheter was clipped into an inverted hook shape, and the ultra-smooth (260-cm) guide wire (Terumo Co., Ltd.) was used to guide the left ventricular surface to explore the VSD. After the guide wire could enter the right ventricle to the pulmonary artery via VSD, 5F MPA catheter (Johnson & Johnson) was inserted into the pulmonary artery from the right femoral vein, and the capture device (Shanghai Shape Memory Alloy Material Co., Ltd., Shanghai, China) was utilized to pull out the guide wire from the vein, and artery-venous orbit was then established. The conveying sheath (AGA Medical Corporation) was placed along the orbit, the ADO-II occluder (AGA Medical Corporation) was pushed out, the conveying sheath was slowly pulled back, and the steel cable was pushed until the headend disc was slightly deformed. At this point, the headend disc covered the exit of the VSD right ventricular surface. After fixing the steel cable, the sheath tube was slowly withdrawn until the occluder device was completely opened. Under the left ventriculography and echocardiographic guidance, it was confirmed that the occluder waist was located within the defect and the proximal disc covered the entrance of the VSD left ventricular surface. TTE was used to confirm that the occluder had no effect on the aortic and tricuspid valves. The electrocardiogram (ECG) showed no significant arrhythmia. Subsequently, rotate the handle of the push steel cable counterclockwise, slowly release the occluder, remove the conveying sheath pipe, and timely push the steel cable. Through the femoral artery, the pigtail catheter was returned to the left ventricle and the ascending aorta. The left cardiac catheterization and angiography of the left ventricle and the ascending aorta were performed to assess the surgical efficacy (Fig. 2).

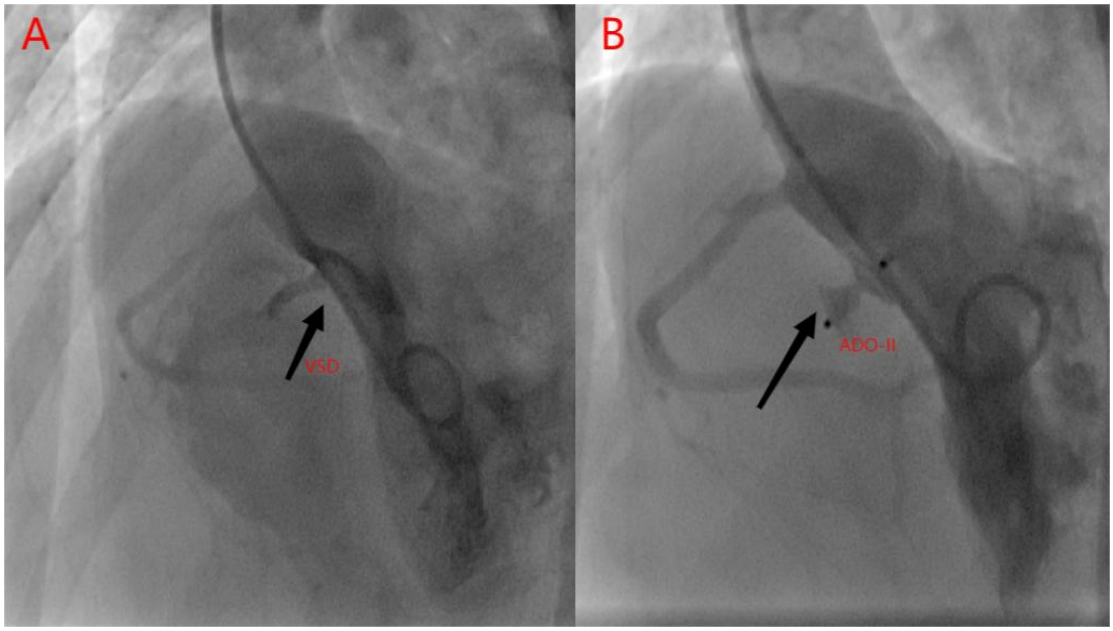

Fig.2 Preoperative angiography and postoperative angiography of the case who underwent VSD occlusion.

A: The left ventricular angiography indicated size and shape of VSD, which would be located in the muscle.

B: The left ventricular angiography immediately indicated that the occluder was kept in a satisfactory shape, the waist was located in the defect, and the discs on both sides were close to the ventricular wall, without a residual shunt.

1.2.3 Occlusion of Aortopulmonary Collateral Arteries.

Occlusion of aortopulmonary collateral arteries was performed the same as PDA occlusion (Fig. 3).

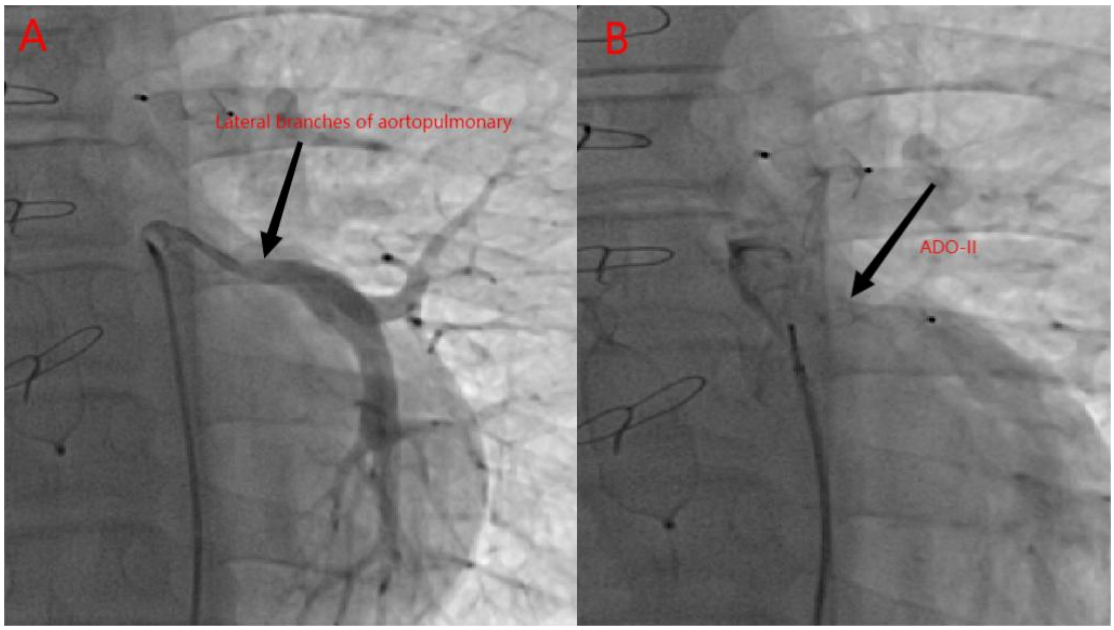

Fig.3 Preoperative angiography and postoperative angiography of a case who underwent occlusion of aortopulmonary collateral arteries.

A: Aortic-selective angiography suggested a large aortopulmonary collateral artery exclusively supplying the lower lobe of the left lung.

B: The aortic selective angiography performed immediately after occlusion of aortopulmonary collateral arteries suggested that the occluder was located in the trunk, with a satisfactory shape, and the collateral vessel was completely blocked and no residual shunt was detected.

1.2.4 Recanalization After Ligation of the Main Pulmonary Artery.

This case is a patient with heart failure who was hospitalized due to recanalization of pulmonary artery ligation after total cavopulmonary connection. The preoperative examination and preoperative preparation were improved, and the interventional plugging surgery was planned to be performed. The 5F pig tail catheter (Johnson & Johnson) was delivered through the femoral vein to the right ventricle for multi-position angiography to measure the diameter of recanalized pulmonary artery and to determine the type of occluder. The super-slippery 260-cm guide wire (Terumo Co., Ltd.) was placed. After repeated testing, the guide wire was re-channeled through the pulmonary artery. Slowly push forward along the guide wire into the delivery sheath (AGA Medical Corporation), and the corresponding size of the ADO-II (AGA Medical Corporation) was sealed. After the first disc of the occluder was sent away from the delivery sheath, slowly pull the sheath and the delivery device backward until the first disc was close to the distal end of the pulmonary artery stenosis. At this time, fix the conveying steel cable, slowly withdraw the conveying sheath pipe, and slowly release the occluder waist and the second disc, until the occluder is fully open. Pulmonary arteriography and echocardiography were performed to reconfirm that the occluder was in the correct position, with normal morphology, without significant shunt at the fistula, and no ST-T changes were detected in the ECG findings. The delivery cable was twisted counterclockwise, and the pulmonary angiography was repeated after releasing the occluder to assess the surgical efficacy (Fig. 4).

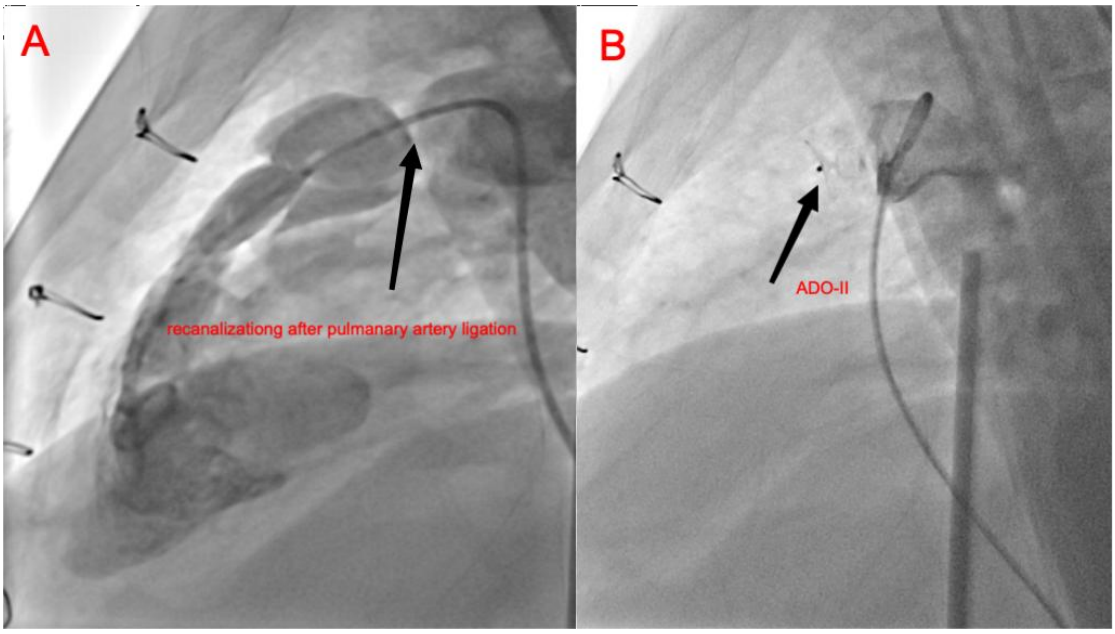

Fig.4 Right ventriculography before occlusion and pulmonary arteriography after occlusion.

A: Right ventriculography in patients with recanalization after pulmonary artery ligation after total cavopulmonary connection showed recanalization at the ligation of the middle segment of the main pulmonary artery.

B: Pulmonary arteriography was performed immediately after the recanalized pulmonary artery was blocked with ADO-II occluder (corresponding size). The results showed that the occluder was well fixed without residual shunt.

1.2.5 CAF Occlusion

This case was a patient with a right coronary artery-right atrial fistula. The operative diagnosis was confirmed by echocardiography and cardiac computed tomography angiography (CTA). The relevant preoperative preparation was improved. Percutaneous femoral arteries and femoral veins were punctured, and cardiac catheterization was performed first. After the replacement of the 5F pig tail catheter (Johnson & Johnson), the origin, direction, and expansion degree of the coronary artery, as well as the location of the fistula and the relationship between the fistula and the heart cavity were explored. The Judking right coronary catheter (Johnson & Johnson) was replaced with selective right coronary angiography through the right femoral artery, in which the fistula diameter was measured, and the specifications of the occluder were determined. The 260-cm superslip guidewire (Terumo Co., Ltd.) was exchanged through the fistula entered the right atrial-superior vena cava, and the guidewire was pulled from the vein using a capture device (Shanghai Shape Memory Alloy Material Co., Ltd. ） through the right femoral vein to establish the arteriovenous track. Then, the delivery sheath (AGA Medical Corporation) and the corresponding size ADO-II occluder (AGA Medical Corporation) were sent along the track through the femoral vein. The occluder was slowly transported under digital subtraction angiography (DSA). After the first disc of the occluder was opened and closed to the aortic side of the coronary fistula, the sheath was pulled back, so that the waist and the second disc of the occluder were located on the right-sided atrium. The satisfactory shape of the occluder and its normal position were confirmed[2]. Selective right coronary angiography, ascending aorta angiography, and echocardiography were performed to reconfirm that the device was correctly positioned, with a normal morphology, without significant shunt at the fistula, and no ST-T changes were recorded. The curative efficacy was assessed by the repeated coronary angiography (Fig. 5).

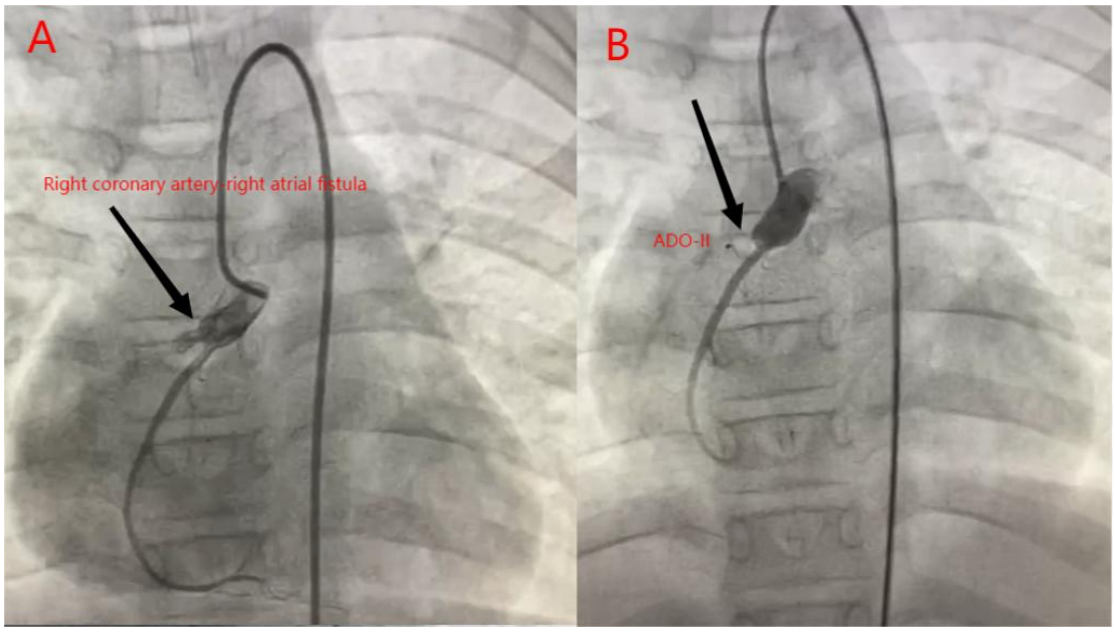

Fig.5 Preoperative angiography and post-occlusion angiography of coronary fistula.

A: Selective right coronary angiography suggested aneurysm-like dilatation of the proximal right coronary artery, with a fistula communicating with the right atrium at the tip of the aneurysm, and there was no significant abnormality in the main trunk of the right coronary artery.

B: Selective right coronary angiography was performed immediately after the coronary fistula occlusion. It suggested that the shape and position of the occluder were normal, with no residual fistula, and it had no effect on the right coronary artery.

1.3 Follow-Up.

Echocardiography, plain chest films, and electrocardiogram findings were reviewed within 24 hours, 1 month, 3 months, 6 months, and 1 year after discharge. The main observation is whether there is residual shunt or displacement of occluders, or arrhythmia Heart auscultation for murmurs was also performed.

2. Results.

The general clinical data of 37 patients are shown in Table 1. There were 21 patients who were younger than 6 years old and 16 patients who were older than 6 years old; in terms of gender, 13 males and 24 females were involved. The disease distribution among 37 patients was as follows: simple PDA in 25 (67.6%) cases; PDA-associated postoperative residual leakage in 2 (5.4%) cases; PDA occlusion + occlusion of aortopulmonary collateral arteries in 1 (2.7%) case; pure VSD in 4 (10.8%) cases; residual leakage after VSD in 1 (2.7%) case; VSD+PDA in 1 (2.7%) case; congenital CAF in 1 (2.7%) case; and recanalization after ligation of the main pulmonary artery in 2 (5.4%) cases. Besides, 2 patients had multi-site occlusion (Table 1).

Table 1. General clinical data and intraoperative and postoperative follow-up data of 37 patients

NO.	GENDER	AGE (YEARS OLD）	DIAGNOSIS	Type of occluding device (waist x length, mm)	Residual shunt	Postoperative complications
01	male	5	VSD 2.5 mm + PDA 3 mm	3×6+6×4	no	No
02	female	8	PDA residual leakage 2.0mm	3×4	no	No
03	female	40	PDA residual leakage 3.7mm	6×4	no	No

04	female	0.4	PDA 3.6mm	6×4	no	No
05	female	2	PDA 2.5mm	4×4	no	No
06	female	10	PDA 2.1mm	3×4	no	No
07	female	21	PDA 3mm	4×4	no	No
08	male	13	PDA 3mm	5×4	no	No
09	female	1	PDA 2.5mm	4×4	no	No
10	female	1	PDA 2mm	4×4	no	No
11	female	6	PDA 2.5mm	3×6	no	No
12	female	0.5	PDA 4mm	6×4	**mild**	No
13	male	5	PDA 2mm	4×4	no	No
14	female	0.5	PDA 4mm	6×4	no	No
15	male	5	PDA 2mm	3×6	no	No
16	female	26	PDA 4mm	6×4	no	**FAF**
17	female	0.8	PDA 2mm	3×4	no	No
18	female	1.6	PDA 2mm	3×4	no	No
19	male	10	PDA 3mm	4×4	no	No
20	male	3	PDA 4mm	4×6	**mild**	No
21	female	4	PDA 2mm	3×4	no	No
22	female	2	PDA 2mm	3×4	no	No
23	female	2	PDA 3mm	6×4	no	No
24	female	6.5	PDA 2mm	3×4	no	No
25	female	37	PDA 2.3mm	4×4	no	No
26	female	3	PDA 2mm	4×4	no	No
27	male	2	PDA 2mm	3×4	no	No
28	female	1.5	PDA 2mm	3×4	no	No
29	male	5	Right coronary artery-right atrial fistula 2.6mm	4×4	no	No
30	male	16	VSD residual leakage 2mm	3×4	no	No
31	male	6	VSD（muscular）4mm	5×6	no	No
32	female	11	Recanalization after ligation of main pulmonary artery 3mm	6×6	no	No
33	female	20	Recanalization after ligation of main pulmonary artery 5mm	6×4	no	No
34	male	9	VSD 3mm	4×6	no	No
35	male	5	VSD 2mm	3×4	no	No
36	female	10	VSD 2.5mm	3×4	no	No
37	male	13	PDA 3mm +aortopulmonary collateral vascular 4mm	3×6 4×6	no	No

Note: VSD: ventricular septal defect; **PDA**: patent ductus arteriosus; **mild**: a little line-like shunt; **FAF**: femoral arteriovenous fistula (A faulty femoral artery puncture caused the formation of a fistula between the femoral artery and the femoral vein).

2.1 Surgical Data.

All the 37 patients underwent interventional occlusion via the ADO-II occluder. The occlusion was performed smoothly, without displacement of the occluder, and no shedding or life-threatening

complications could be detected (Table 1). Moreover, 2 PDA patients experienced a slightly linear shunt, and femoral arteriovenous fistula was found in 1 PDA patient. One patient with PDA and VSD underwent PDA and VSD occlusion at the same period. One patient with PDA and aortopulmonary collateral arteries concurrently underwent PDA occlusion and occlusion of aortopulmonary collateral arteries.

2.1.1 PDA.

The average PDA diameter in 27 patients with PDA and 2 patients with residual leakage after PDA ligation was 2.73 ± 0.79 mm. One patient had comorbid aortopulmonary collateral vessel formation (refer to case #37 in Table 1) and simultaneously underwent PDA closure + aortopulmonary collateral closure, and no complication was detected. Furthermore, 2 patients underwent aortography immediately after PDA occlusion, suggesting a slightly linear shunt (refer to cases #12 and #20 in Table 1). In one patient, a continuous murmur could be detected and hematoma formed after the postoperative puncture. Lower limb vascular ultrasound examination was performed at 48 h after compression, which indicated right femoral arteriovenous fistula (refer to case #16 in Table 1). The right femoral arteriovenous fistula repair was performed under general anesthesia, in which postoperative limb vascular ultrasound showed no abnormality, and the patient had normal sensory and motor function of the lower limbs. Furthermore, 29 patients had no residual shunt, no displacement and shedding of the occluder, or no pulmonary artery and descending aortic obstruction. The surgical efficacy was satisfactory. The review of ECG findings showed no significant arrhythmia.

2.1.2 VSD

The average diameter of the 6 VSDs was 3.00±1.05 mm, one of which was a muscular VSD (refer to case #31 in Table 1), which was located in the muscular ventricular septum and was an elongated tunnel. Due to the difficulty of applying conventional VSD packers, the ADO-II occluder was used for plugging. The occluder was released on the aortic side (Figure 2B), in which postoperative TTE indicated a satisfactory tricuspid valve closure, and no residual shunt or significant abnormality was detected in the ECG findings. The other case was a patient with residual fistula after VSD repair (refer to case #30 in Table 1). Due to abnormal VSD walking and small shunt mouth, an ordinary 7F long-axis sheath could not pass through the shunt mouth. Finally, the 4F long-axis sheath (AGA Medical Corporation) was selected. The "3×4" ADO-II model was blocked successfully, and findings of postoperative echocardiography and ECG were normal. The remaining four patients had VSDs and membrane formation (refer to cases #1, #34, #35, and #36 in Table 1). The surgical procedure was performed the same as above, and findings of postoperative ECG and echocardiography were normal.

2.1.3 CAF.

The only male patient with right coronary artery-right atrial fistula (refer to case #29 in Table 1) aged 5 years old, and he always had post-active shortness of breath and recurrent respiratory tract infection. Physical examination indicated a continuous heart murmur. The ECG revealed a sinus tachycardia with no ST-T changes.

Echocardiography confirmed the diagnosis of a right coronary artery-right atrial fistula. Selective coronary angiography suggested an aneurysm-like dilation of the proximal right coronary artery, with a fistula at the aneurysm tip and the right atrium, and a fistula size of 2.6 mm. A 44-mm ADO-II device was utilized, in which no ECG ST-T changes were observed during and after surgery, and coronary angiography and echocardiography suggested that the device was in an appropriate position and no residual shunt was detected. The ECG was reviewed at 24 hours, 1 month, 3 months, 6 months, and 12 months after surgery, with no abnormal echocardiography finding.

2.1.4 Recanalization After Ligation of the Main Pulmonary Artery.

Among 2 female patients, the first patient (refer to case #33 in Table 1) aged 20 years old and underwent total cavopulmonary connection as a result of "single ventricle, pulmonary artery stenosis, and patent foramen ovale" at 7 years before her admission. Reviewing the echocardiography findings at 2 years after surgery revealed that the pulmonary artery at the original ligation was recanalized, and family members did not pay attention to it. In recent years, the clinical manifestations of right

ventricular dysfunction, such as bilateral lower extremity edema, hepatosplenomegaly, abdominal swelling, and ascites formation were gradually developed. After evaluation, considering the high risk of rethoracotomy and the intolerance of large surgery in the patient's physical conditions, the intervention was optimal. The diameter of the pulmonary artery recanalization was 5 mm, the 6×4 mm ADO-II occluder was selected for plugging, and the procedure was smoothly conducted. After releasing the occluder, the pulmonary angiography showed no residual shunt, and the occluder was fixed and had a satisfactory shape. Echocardiography revealed no obstruction of the left and right pulmonary arteries. Postoperative ECG indicated no significant abnormality. One month after surgery, the symptoms of right cardiac dysfunction were resolved. Three months after surgery, the patient could move normally. Another female patient (refer to case #32 in Table 1) aged 11 years old, and 1 year before her admission, she underwent total cavopulmonary connection due to "single ventricle, right ventricular double outlet, and pulmonary artery stenosis". A recent review indicated that the patient who underwent pulmonary artery recanalization had no obvious symptoms of right ventricular dysfunction. After evaluation, it was attempted to perform interventional occlusion, and the patient's family members accepted it. The diameter of the pulmonary artery recanalization was 3 mm, thus, the 6×6 mm ADO-II packer device was utilized, and the procedure was conducted smoothly. Immediate echocardiography and pulmonary angiography indicated no residual shunt, as well as satisfactory shape and position of the blocking device. The ECG showed unremarkable findings.

2.1.5 Aortopulmonary Collateral Vascular Formation.

This patient (refer to case #37 in Table 1) was male and aged 13 years old. At birth, due to the detected cyanosis of the mouth, the examination indicated "CHD, and pulmonary artery atresia", and he underwent "bidirectional cavopulmonary shunt", which is a palliative surgical modality that improves cyanosis symptoms and activity tolerance, in 2012, and the postoperative exercise tolerance was significantly improved. In 2014, the review of echocardiography findings suggested that the ligated azygos vein was recanalized and blocked in DSA in our hospital, in which the surgical procedure was smoothly carried out and the postoperative recovery was satisfactory. In order to perform stage II surgery, the patient was diagnosed with "CHD, pulmonary artery atresia, VSD, patent foramen ovale, PDA, aortopulmonary collateral vascular formation, and postoperative state of bidirectional cavopulmonary shunt" and was admitted to the hospital. After preoperative discussion, it was attempted to simultaneously perform PDA occlusion + aortopulmonary collateral occlusion under DSA (Figs. 1C, D and Figs. 3A, B), followed by "total cavopulmonary connection". During the interventional occlusion, the angiography of PDA first suggested that the PDA was open in the descending thoracic aorta, with the diameter of about 10 mm, and then circled and connected with the left pulmonary artery. The diameter at the narrowest point was about 3 mm. The 3×6 mm ADO-II occluder was selected for plugging, and the surgical procedure was smoothly carried out. After releasing the occluder, the descending aortic angiography showed the PDA without residual shunt, and the occluder was fixed in place with a good shape.

Replacement of the Cabro2 catheter (Johnson & Johnson) for selective aortopulmonary collateral angiography revealed a large aortopulmonary collateral vessel, supplying the lower lobe of left lung (Fig. 3A) with diameter of about 4 mm at the maximum stenosis.

The 4×6 mm ADO-II occluder was therefore utilized for plugging. After releasing the occluder, descending aortic angiography revealed that the collateral vessel was completely blocked without residual diversion, and the occluder was fixed in place with an acceptable shape. The decrease in oxygen saturation was not significant. Immediately after completion of the interventional occlusion, the median sternotomy was performed, followed by the "total cavopulmonary connection". The surgery was successful, and he was discharged at 2 weeks after surgery. The review of echocardiography findings and chest X-ray films at the first month, third month, and sixth month after surgery indicated that the blocking device was fixed in place, without displacement and shedding. The patient could go to school normally and resume his physical activities at 1 year after surgery.

2.2 Follow-Up Data.

The follow-up rates were 97.3% at 1 month, 89.2% at 3 months, 75.7% at 6 months, and 64.9% at 12 months after surgery. None of the 37 patients had obvious abnormality in

electrocardiogram reexamination at 1 month after surgery; X-ray showed that the cardiothoracic ratio was lower than that before surgery, and color Doppler echocardiography revealed no residual shunt.

3. Discussion.

Interventional therapy has become the preferred method for SHDs due to its advantages of less trauma, less pain, fewer complications, low mortality rate, safety, high efficacy, and no scar [4]. In order to achieve a satisfactory efficacy, it is necessary to strictly grasp the indicators of interventional therapy. At present, there are various types of seals on the market, while they all correspond to the corresponding diseases. In the present study, we showed that the second generation of Amplatzer PDA occluder could not only be used for pure PDA, but also for other SHDs. For those SHDs with complicated structure and difficult surgical procedure, the surgical procedure can not only be simplified, but also the sealing effect is satisfactory.

AGA Medical Corporation designed and developed the second generation of occluder (ADO-II) in 2008. The occluder consists of three special mesh blades to form double plates on both sides and middle waist, which is similar to a dumbbell after expansion. The occluder includes the following two characteristics: 1) Good flexibility, in which the occluder can be released by the forward or reverse direction. For PDA with different lengths, the occluder can be stretched lengthways, and the occluder disc can be changed angular, which can be applied to different angles between the ductus arteriosus and the main pulmonary artery and descending aorta. 2) Easy transportation: The occluder is dense and soft, woven from nickel-titanium alloy, filled without polyester fiber, and small and easy to deliver (4F or 5F long-axis sheath), making it appropriate for the interventional treatment of young or low weight infants.

For small PDA, because of the small opening of pulmonary artery end, it is very difficult to send guide wire from pulmonary artery end to the aorta through PDA. However, using the unique dumbbell-like structure of ADO-II, it is easier to establish tracks from the delivery guide wire on the aortic side. A satisfactory blocking effect can be achieved by reverse release (the head disc on the pulmonary side, the second disc and connector on the aortic side, and releasing the occluder on the aortic side) or forward release (the head disc on the aortic side, the second disc and connector on the pulmonary side, and releasing the occluder on the pulmonary artery side). According to the above-mentioned characteristics of ADO-II, in addition to its clinical application for infants with PDA, studies have shown that it can be utilized for some special types of VSD, pulmonary arteriovenous fistula, CAF, and aortopulmonary collateral arteries[2]. According to the analysis of the above-mentioned cases, the ADO-II occluders were all appropriate for CAF (1 case), VSD (6 cases), aortopulmonary collateral arteries (1 case), and pulmonary artery recanalization (2 cases). Besides, the ADO-II occluders can be delivered via a minimum 4F long-axis sheath, reducing vascular damage.

For the CAF, due to their complex structure, the diversified connection of the fistula and the adjacent compartment, and no dedicated occluder, the ADO-II can perfectly solve this problem. CAF is a congenital or acquired abnormal vascular communication of coronary arteries. Abnormal channels between the coronary artery and other blood vessels or chambers account for 0.4% of all CHDs, in which right CAF is the most common one. In 1983, Reidy et al., for the first time, reported that spring coil, PDA occluder, and muscle VSD occluder could be used to block such vascular malformations [5,6]. Some scholars demonstrated that the application of ADO-II in sealing CAF proved to be safe and effective in clinical practice [7]. ADO-II can pass through the 4F delivery sheath very smoothly, and can also pass through the curved and variable vessels, which can significantly shorten the operation time, reduce trauma, and decrease the risk of surgery.

For patients with pulmonary arteriovenous fistula, due to their large blood vessels, circuitous walking can be conveniently applied, which is in line with the characteristics of ADO-II occluder. For complicated CHD with aortopulmonary collateral arteries, collateral blood supply not only affects the surgical field, but also influences the postoperative efficacy, making it very important for the preoperative diagnosis and early intervention of aortopulmonary collateral arteries. However, due to the changeable anatomical position of the aortopulmonary collateral arteries, intraoperative exploration and surgical ligation are difficult, which may not only cause great trauma, but also may require a complicated surgery. In recent years, in order to shorten the operation time, reduce the surgical trauma, and improve the surgical efficacy, several cardiac centers adopted interventional sealing and surgical treatment (hybrid surgery or mosaic treatment) to achieve a satisfactory clinical efficacy.

Regarding pulmonary artery recanalization after palliative surgery for complex CHDs, and due to the lack of a special occlusion device and the difficulty of using a conventional catheter to establish a delivery track, we perfectly overcome the above-mentioned difficulties using the softness and easy delivery features of the ADO-II occluder.

With fabrication of the Amplatzer VSD occluder, it has been reported that occluders are prone to atrioventricular obstruction and valve regurgitation due to compression of surrounding conduction tissues. The ADO-II occluder was originally designed to eliminate the problem of closure of PDA in infants. As a supplement to the classic catheter closure device, because of its density and softness, it eliminates the central polyester layer and slightly exerts pressure on the cardiac conduction tissue. Satisfactory results could be obtained with the closure of VSD. The present study showed that the success rate of VSD occlusion was 100%. Compared with other studies, the success rate of instant occlusion of VSD in children was 78%[8], indicating noticeable effects. In addition, in our study, none of the 5 patients who underwent VSD occlusion developed atrioventricular block, indicating that the incidence of ADO-II-induced atrioventricular block was very low. Moreover, for muscular-VSDs, their location is relatively deep, the trabeculae are abundant, and no specific VSD can be exposed, thus, performing surgery is quite difficult. Compared with conventional occluders for muscular-VSDs, the ADO-II occluder can establish aorta-left ventricle-VSD-right ventricle-right atrium-femoral vein tracks through small delivery pipelines. Due to its soft and flexible characteristics, as well as the reversible and forward release, the surgery can be conducted easier.

We also identified 5 adult patients who aged older than 18 years, of whom 4 cases had PDA (cases #3, #7, #16, and #25) and one case had pulmonary artery recanalization (case #33). The PDA in 4 patients was elongated, with a diameter of less than 4 mm, and ADO-II occluder was applicable. Although patients with pulmonary artery recanalization were adult, the traffic mouth was less than 5 mm, and because the conventional delivery sheath was thick, which was not easy to bend remarkably, the ADO-II occluder and supporting delivery pipeline (4F or 5F) could be perfectly applied.

4. Conclusions.

The ADO-II occluder is relatively simple to operate, with a high success rate and few complications, and it can not only be applied to PDA occlusion, but also to other CHDs. It can also be applied in young and low weight children, as well as for the blockage of SHDs in adults. However, the indicators for clinical application of the ADO-II occluder still need to be strictly limited. With a slender PDA of less than 6 mm, other long tunnel defects, circuitous and thick blood vessels, and various morphological and complex fistulas, the ADO-II can be applied in the absence of a special occluder. Regarding the limitations of this study, as it was a single-center, non-randomized study, a long-term follow-up is still needed to evaluate the safety and efficacy of the ADO-II occluder. Moreover, few cases were enrolled, and except for the large number of PDA patients, additional cases with the other relevant diseases should be identified. Thus, further study is required to eliminate these limitations and to improve the surgical methods.

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Data Availability Statement

The authors confirm that the data supporting the findings of this study are available within the article [and/or] its supplementary materials.

Statements and Declarations

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Authors' Contributions

All the authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by [Zhangxiaofei] and [NiBin]. The first draft of the manuscript was written by [Zhangxiaofei], and all the authors commented on previous versions of the manuscript. All the authors read and approved the final manuscript.

Ethical Standards

We declare that all human and animal studies have been approved by the ethics committee and have been performed in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments. All patients provided informed consent prior to their inclusion in the study.

Consent to participate

Informed consent was obtained from all participants who were included in the study.

Consent to publish

The authors affirm that human research participants provided informed consent for publication of the findings.