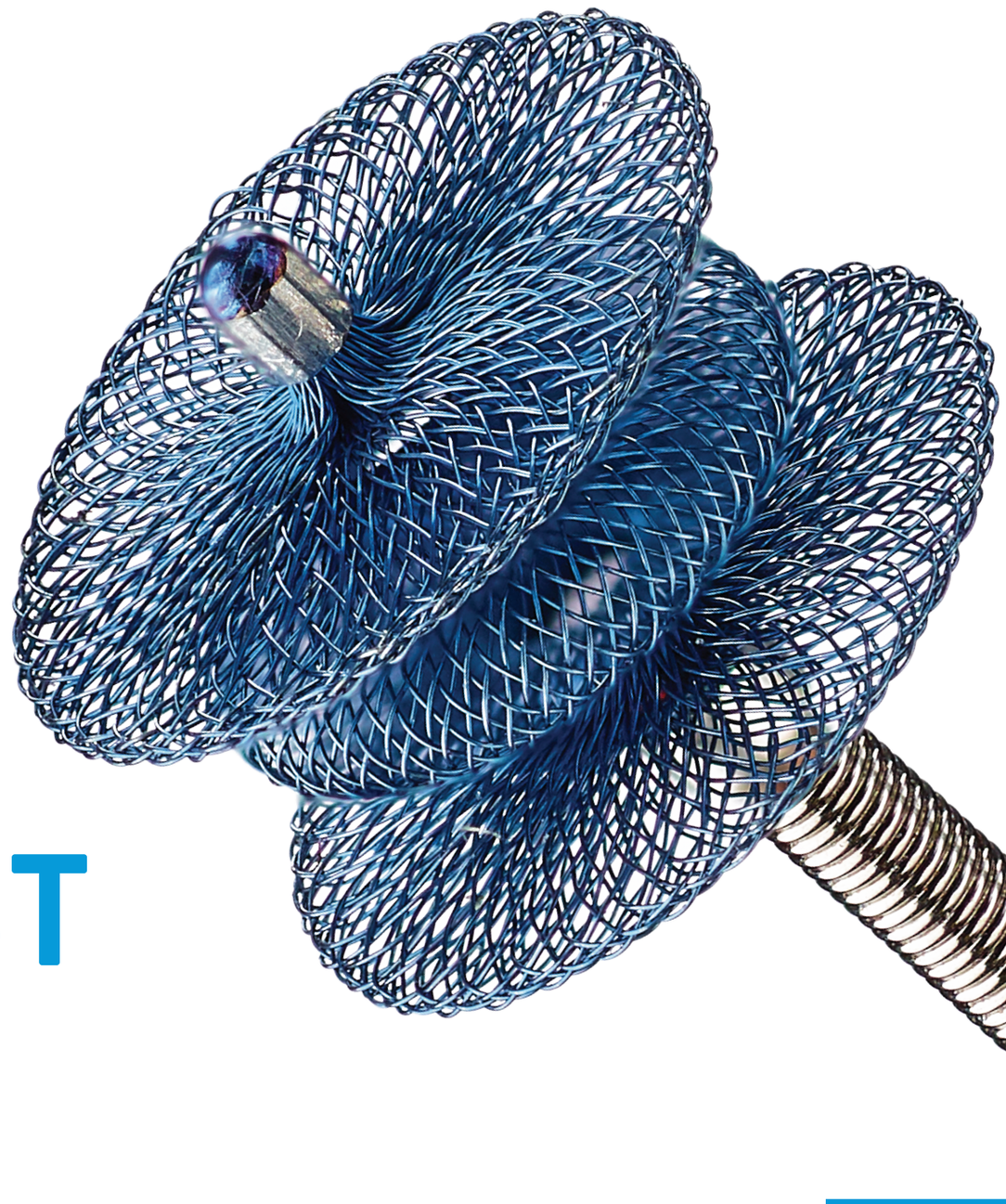
# RELIABLE PRECISION WHEN IT MATTERS MOST

## EXPERIENCE WITH THE AMPLATZER PICCOLO™ OCCLUDER



## CLINICAL CASE REPORTS

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CASE #1

# PERCUTANEOUS CLOSURE OF DUCTUS ARTERIOSUS WITH AN **AMPLATZER PICCOLO™ OCCLUDER** IN A PREMATURE BABY WITH PULMONARY HYPERTENSION

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## ABSTRACT

Percutaneous closure of the ductus arteriosus in premature babies has become an effective therapeutic strategy with low associated morbidity and mortality, allowing the measurement of pulmonary arterial pressures and their changes with duct occlusion. We present the case of a premature baby with a patent ductus arteriosus and pulmonary hypertension, who underwent percutaneous duct closure with the Amplatzer Piccolo™ Occluder.

## INTRODUCTION

Percutaneous closure of the ductus arteriosus is the treatment of choice in children weighing over 6 kilograms. However, the development of new devices has made it possible to apply such percutaneous treatment also to smaller patients.

The indications for interventions aiming to close the ductus arteriosus in premature babies are still debated. However, there is abundant evidence in the literature highlighting the benefits of duct closure in this type of patient, since it reduces the risk of hemodynamic instability, pulmonary hemorrhage and progression of bronchopulmonary dysplasia. Initially, surgical closure was the usual strategy in these patients. However, the development of new percutaneous devices such as Amplatzer™ Duct Occluder-II, and especially the Amplatzer Piccolo™ Occluder, allow successful duct occlusion by catheterization, but with lower morbidity and mortality as compared to surgery.

In addition, preterm babies with patent ductus arteriosus have a high incidence of pulmonary pathology, mainly bronchodysplasia, which is often associated with elevated pulmonary arterial pressures. Percutaneous closure has the advantage of allowing detailed measurements of these pressures, as well as duct occlusion tests, with consequent benefits in terms of clinical management.

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## CLINICAL CASE

We present the case of a premature baby born at the gestational age of 23 weeks weighing 635 grams at birth, who was referred to us with the diagnosis of patent ductus arteriosus diagnosed by 2DDC echocardiography. The baby had been having feeding difficulties (need for feeding tube), suffered a subependymal hemorrhage and had developed bronchopulmonary dysplasia (support with noninvasive ventilation). The duct measured 3.2mm in diameter and 4.5mm in length on echocardiography, with left-to-right shunt (Figure 1A, 1B) and indirect evidence of pulmonary arterial hypertension (flattening of the interventricular septum (Figure 2A), and tricuspid insufficiency with a gradient of 36 mmHg). After discussing the case in our clinical meeting, it was decided to perform cardiac catheterization to evaluate the duct and pulmonary arterial pressures. The procedure was performed on the 45th day of life when the baby weighed 1400 grams. Radioscopy revealed the glassy pattern of the lung fields typical of pulmonary bronchodysplasia (FIGURE 3). Only the right femoral vein was cannulated with a 4F introducer, accessing the pulmonary trunk and duct to reach the descending aorta. Pulmonary pressures were at 2/3 systemic pressures. The duct was type F of

Krichenko classification, measuring 3.2 mm in diameter and 5.4 mm in length. Using the usual technique, the duct was probed from the pulmonary artery using an Amplatzer™ TorqVue™ LP 4F sheath with a Progreat‡ microcatheter inside it to facilitate navigability. An Amplatzer Piccolo™ Occluder 5/4 device was successfully deployed (FIGURE 4), and significantly decreasing pulmonary arterial pressures.
The postoperative course was very favorable; all the ventilatory assistance and feeding tube were withdrawn within 48 hours. Echocardiography confirmed correct placement of the device with no residual shunt, no narrowing of the descending aorta or left pulmonary artery (**Figure 5A,5B**), and normalization of pulmonary arterial pressures (**Figure 2B**). The patient was discharged from hospital 7 days after the procedure weighing 2030 grams.

## DISCUSSION

The need for closure of a patent ductus arteriosus in preterm babies remains a controversial issue. The evolution of percutaneous closure techniques minimizes the morbidity and mortality as compared to surgery. Consequently, this therapeutic approach is increasingly advocated. Furthermore, the possibility of performing this procedure in the intensive care unit under only echocardiographic control is yet another advantage of this approach, since this obviates patient transfer, which often destabilizes critically ill patients. Likewise, the possibility of measuring pulmonary pressures and the changes produced by duct occlusion significantly helps in the management of these patients, many of whom suffer from pulmonary pathologies such as bronchodysplasia, which elevates pulmonary arterial pressures. Percutaneous duct closure in our patient was performed without complications despite extreme prematurity and low weight. It is evident that percutaneous closure of the duct provided a clear short-term benefit with positive results within a few hours, with withdrawal of respiratory and feeding support. In addition, in the long term, it decreases the risk of development of established pulmonary hypertension.

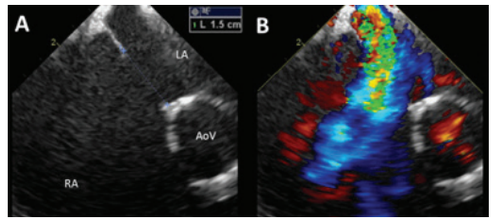


**Figure 1:**
ECHOCARDIOGRAM. Persistent arterial duct. A: measure of duct. B: Left-to-right shunt.

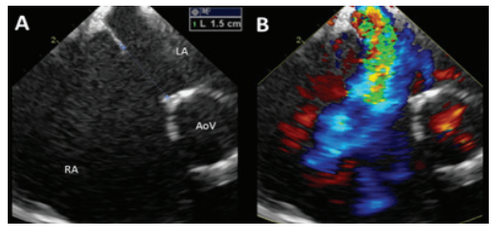


**Figure 2:**
ECHOCARDIOGRAM. A: flattening of the interventricular septum. B: normalization of the interventricular septum.

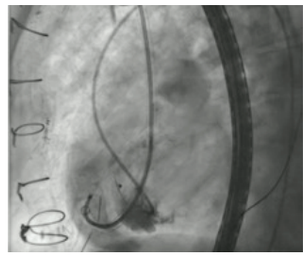

**Figure 3:**
X-RAX. Glassy pattern of the lung fields. Device in correct position after closure.

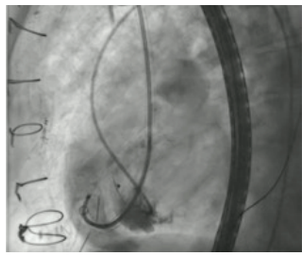

**Figure 4:**
CATHETERIZATION. Closure of the duct with Piccolo Device.

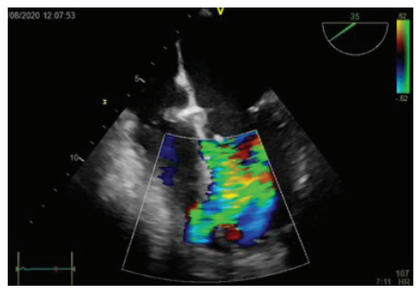

**Figure 5:**
ECHOCARDIOGRAM. A: Arrow shows the correct position of the device. B: Normal flow of left pulmonary artery and aorta after closure.

## CONCLUSION

Percutaneous closure of the ductus arteriosus in the premature baby is offered as an effective diagnostic and therapeutic tool; it is less invasive and is associated with a shorter post-procedural recovery time than surgical closure. Additionally, knowledge of pulmonary arterial pressures and resistances provides added value to this strategy, thus refining clinical management. All this, together with the evolution of closure devices and interventional techniques, could increase the number of patients who can benefit from this procedure.

CASE #2

# PDA CLOSURE IN A PRETERM NEONATE WITH THE AMPLATZER PICCOLO™ OCCLUDER

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## ABSTRACT

The treatment of patent arterial duct (PAD) in symptomatic preterm neonates is surgical closure if the previous treatment with non-steroidal anti-inflammatory drug

(NSAID) has failed. Since surgery is not free of complications a percutaneous new option is currently available. We describe a critically ill, preterm neonate successfully treated percutaneously.

## INTRODUCTION

The presence of a PDA is a frequent and serious complication in prematurely born infants. It predisposes to serious complications such as cerebral hemorrhage, necrotizing enterocolitis, renal dysfunction, pulmonary bronchodysplasia and heart failure[1]. In premature infants with systemic complications, the risk of the surgical closure of a PDA is increased but it has been the most used treatment modality when intravenous treatment with cyclo-oxygenase inhibitors has failed[2].

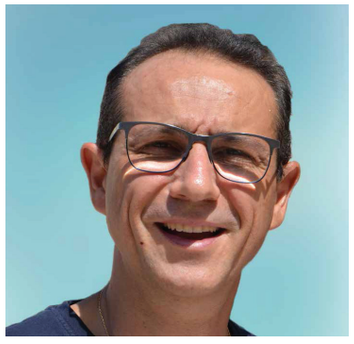
## CASE PRESENTATION

A 27 weeks old premature neonate received percutaneous treatment to close a PDA. He had maternal history of severe eclampsia, after birth a membrane hyaline disease was treated and since then, he was on mechanical ventilation and inotropic support. He also presented necrotizing enterocolitis with jejunal perforation, cerebral hemorrhage, hydrocephalus and renal failure. In the 2nd week of life, he received Paracetamol due to a 2,4 mm PDA with hemodynamic repercussion. At 27 days of life, with a weight of 800 grams, the PDA was percutaneously closed as was described by Zahn[3]. Femoral vein was punctured and a 4F introducer was placed; 80 IU of Heparin was administered.

The 4F delivery catheter (TorqVue™) was used as a multipurpose catheter and a 0.014" guidewire with a floppy end was used to reach the descending aorta. An aortography was performed. The Amplatzer Piccolo™ 4x2mm ductal occluder device was released with the aid of echocardiography and fluoroscopy. A nasogastric tube also served as a reference. Prior to device release, occlusion of the left pulmonary artery and descending aorta were excluded.

After ductal closure it was possible to withdraw inotropic support and days later mechanical ventilation could be withdrawn.

Dr. Fredy Prada



Dr. Juan Carretero

## DISCUSSION

This premature newborn presents practically all the complications of prematurity, including ductal persistence, which conditions the other complications. The impossibility of using Ibuprofen due to renal dysfunction and the failed response to Paracetamol favored percutaneous treatment. Once the ductus arteriosus was closed, the prolonged inotropic support he had been receiving since birth could be withdrawn, as well as the need for prolonged mechanical ventilation.

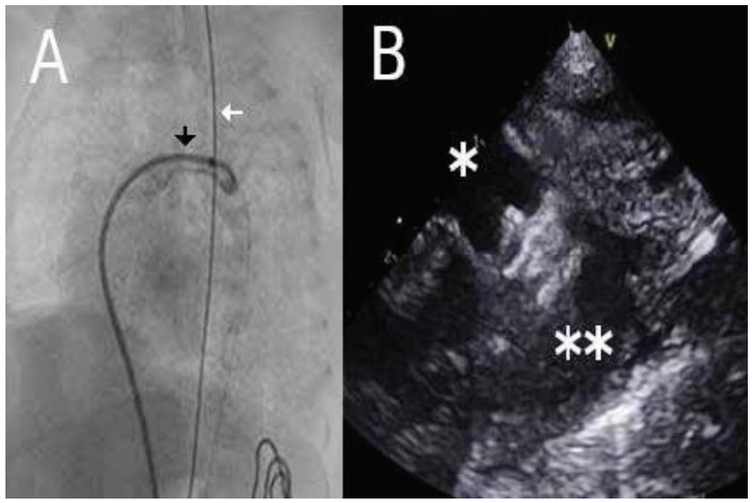



**Figure 1:** (A) Aortography in LAO projection. PDA is delineated (black arrow) with a hand injection of 1 ml of contrast. Nasogastric tube (white arrow) was also helpful during deployment of the device. (B)Echocardiography shows the Piccolo device interposed between the Pulmonary trunk (*) and the descending Aorta(**)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2. Su BH, Lin HY, Chiu HY, Tsai ML, Chen YT, Lu IC. Therapeutic strategy of patent ductus arteriosus in extremely preterm infants. Pediatr Neonatol. 2020 Apr;61(2):133-141. doi: 10.1016/j.pedneo.2019.10.002. Epub 2019 Oct 29. PMID: 31740267.

3. Zahn, E.M., Nevin, P., Simmons, C. and Garg, R. (2015), A novel technique for transcatheter patent ductus arteriosus closure in extremely preterm infants using commercially available technology. Cathet. Cardiovasc. Intervent., 85: 240-248. https://doi.org/10.1002/ccd.25534


## CONCLUSION

Percutaneous closure is an effective technique that allows hemodynamic and respiratory stabilization in premature infants with PDA.

CASE #3

# IATROGENIC AORTA COARTATION: TWO WEEKS AFTER PATENT DUCTUS ARTERIOSUS PERCUTANEOUS CLOSURE **WITH AN AMPLATZER PICCOLO™ OCCLUDER.**

## MOVING FROM A GOOD SITE TO A BAD

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## ABSTRACT

Although the treatment of hemodynamically significant patent ductus arteriosus (hsPDA) in the preterm new-born has been pharmacological or surgical, in recent years, percutaneous treatment is playing an increasingly relevant role in new-borns <2 kg. The incorporation of the Amplatzer Piccolo™ Occluder has been definitive to establish interventionism as a real therapeutic option.

However, as it is a self-expanding device with occluding discs, the possibility of occlusions of the pulmonary arteries and the aorta must be considered, especially in patients as small as premature infants. We present, to our knowledge, the only case of Iatrogenic Coarctation of the Aorta caused by Piccolo Occluder, due to a partial mobilization of the device towards the aortic lumen two weeks after its implantation, possibly due to a transient increase in pulmonary pressure.

## INTRODUCTION

Presence of a PDA beyond the first week of life occurs in as many as 50% of premature babies and in more than 80% of severely premature extremely low birth weight (ELBW) infants (<1,000 g at birth). Persistence of a hsPDA in these children has been associated with an increased risk of developing necrotizing enterocolitis, chronic respiratory disease, pulmonary haemorrhage, intraventricular haemorrhage, and death.

Current treatment options for hsPDA closure in a premature infant include medical management or surgical ligation. Medical management closing consists of intravenous administration of cyclooxygenase inhibitors (Ibuprofen) or acetaminophen. Unfortunately, this treatment is effective in only approximately 50% of ELBW infants and is associated with significant side effects, including permanent or transient alterations in renal function, necrotizing enterocolitis, gastrointestinal perforation, and impairment of cerebral blood flow. Surgical ligation, while effective, has been associated with significant procedural and post-procedural complications and poor long-term outcomes, including worsening lung disease and poor neurodevelopmental outcomes.

Recently, with the incorporation of Amplatzer Piccolo™ Occluder (Abbott Structural Heart, Plymouth, MN) a growing body of clinical evidence has emerged suggesting that transcatheter closure of PDA can be performed safely and effectively in premature infants as small as 700 g or smaller. The Amplatzer Piccolo™ Occluder has obtained FDA approval and CE-Mark in the last two years.

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 occluder comes pre-loaded on a delivery wire, which has a soft floppy distal end with a micro screw attachment at the tip. It can be delivered through a 4 F Amplatzer™ TorqVue™ LP catheter (Abbott Structural Heart, Plymouth, MN).

Despite the low profile and small dimensions of the Amplatzer Piccolo™ Occluder, obstructions of adjacent vascular structures have been described, due to the small size of the preterm vessels. Most are related to the

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obstruction of the origin of the left pulmonary artery, and only in isolated cases, obstruction of the aortic arch produced by the left retention disc has been observed. We describe here a case of Iatrogenic Coarctation of the Aorta, due to the displacement of the device 2 weeks after its implantation.

## CASE PRESENTATION

New-born of 26 weeks of gestational age, weight 800 gr, Apgar 4-6. Intubation and mechanical ventilation from the delivery room. During his stay in the NICU, he presented hemodynamic instability due to moderate ductus arteriosus, and intermittent episodes of abdominal septicaemia. The PDA was treated with 3 cycles of iv paracetamol without result. Ibuprofen was not administered due to suspected intestinal ischemia.
At 27 days of life, with a weight of 970 grams, percutaneous closure of the PDA (Amplatzer Piccolo™ Occluder 4/4) was performed with good results, without stenosis of the origin of the left pulmonary artery, or protrusion of the device in the aortic lumen. Since the procedure, the patient presents hemodynamic improvement with a decrease in the need for inotropes and diuretics. However, 12 days after implantation, he presented an abdominal worsening on clinical examination, for which he underwent laparotomy, a 10-cm resection of the distal ileum and discharge ileostomy.

Before the surgery, an echocardiography was performed that showed a good location of the device, without aortic arch obstruction. Upon arrival in the NICU from the operating room, the neonate had extreme hypotension and metabolic acidosis, with a dramatic decrease in somatic O2 Saturation. Urgent echocardio-graphy was repeated, diagnosing an obstruction of the aortic arch due to displacement of the left Amplatzer Piccolo™ Occluder disc, with a gradient of 35 mmHg and significant diastolic extension on the Doppler.
The patient is urgently transferred to Cath-lab, through a 5F introducer, a 5 x 12 mm Formula Stent (Cook, USA) is implanted via the carotid route, Fig 1. The patient develops well until being extubated and discharged from NICU at three months of age.

Two years later, a new catheterization was performed since gradient by doppler through the stent was 35 mm with moderate diastolic extension. Through the femoral route, the stent was dilated with a Sterling 8 x 20 mm balloon (Boston, USA), up to an inflation pressure of 12 atmospheres, good results without a gradient in the final pressure measurement, and adequate expansion of the endoprosthesis, fig 2. After 2 years of follow, our patient is asymptomatic, without signs of ventricular dysfunction, and without a Doppler gradient in the aortic arch.

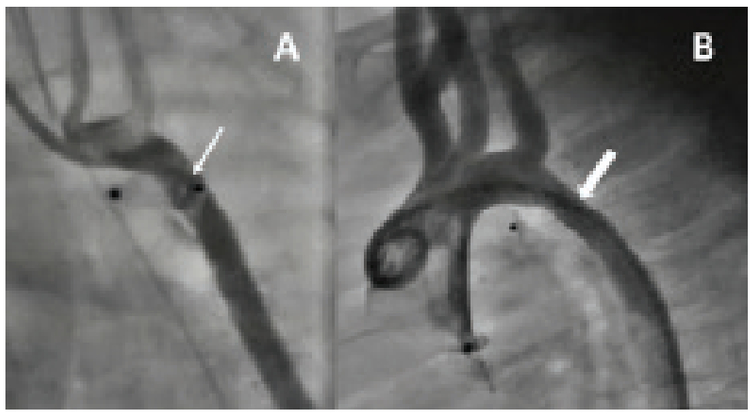


**Figure 1:** A; Protrusion of the left occlusive disc in the aortic lumen, producing severe stenosis (thin arrow). B; Stent Formula Implanted by carotid route, Occluder exclusion from the aortic lumen, good result, no gradient

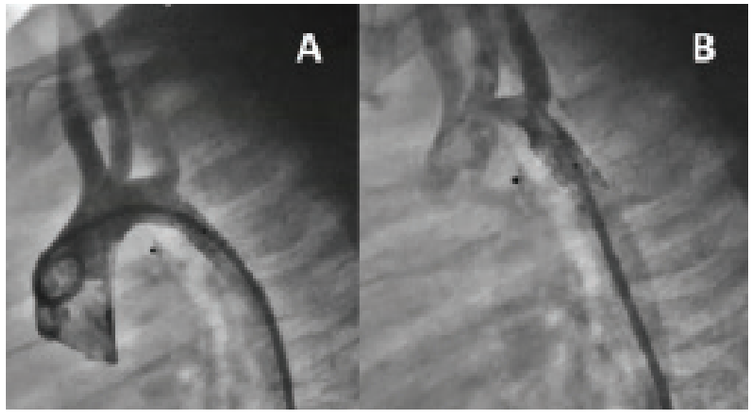


**Figure 2:** A; Stent Formula implanted in the Neonatal period, restrictive angiographic appearance, peak-peak gradient 25 mmHg. B; Appearance of the stent after overdilation with a Sterling balloon (8 x 20 mm) at 8 atmospheres. Good expansion of the endoprosthesis and complete disappearance of the gradient.

## DISCUSSION

The treatment of PDA with the Amplatzer Piccolo™ Occluder is already a clinical reality for premature babies with a weight range of 700-2000 grams. However, it is technically demanding, and the possibility of interfering with the flow of the aorta and pulmonary arteries must be considered.
The obstruction of LPA origin is widely described, it is usually moderate, and with exceptions, it disappears with the growth of the arterial vessel in the months following the implantation. However, Iatrogenic Coarctation of the Aorta is much less frequent, although it can be much more serious.

Iatrogenic Aortic Coarctation (IACoA) by the device usually occurs acutely during the procedure due to a poor position during implantation, or displacement of the occluder during release manoeuvres. IACoA can be diagnosed in the days following implantation due to the existence of a mild, undiagnosed native coarctation of the native aorta, and it is possible, that in patients with a suboptimal implantation (with a slight protrusion of the left disc in the aortic lumen). In both circumstances ductal tissue retraction could causes a significant gradient into aortic arch, in following days after implantation.

However, this is the first reported case of displacement of the device towards the aortic lumen days after implantation. We believe that increased venous and pulmonary pressure during abdominal surgery may be the cause for the occluder to shift to the left side, since the ultrasound just before abdominal surgery showed an aortic arch with normal flow. Therefore, ultrasound surveillance of these devices should be prolonged weeks after implantation, and the ultrasound should be repeated after all those procedures that may punctually increase pulmonary pressure (surgeries, endoscopies, intubations...). Carotid access for urgent stenting is the best alternative to improve these patients in a life-threatening situation.

CASE #4

# INDIAN EXPERIENCE OF AMPLATZER PICCOLO™ OCCLUDER

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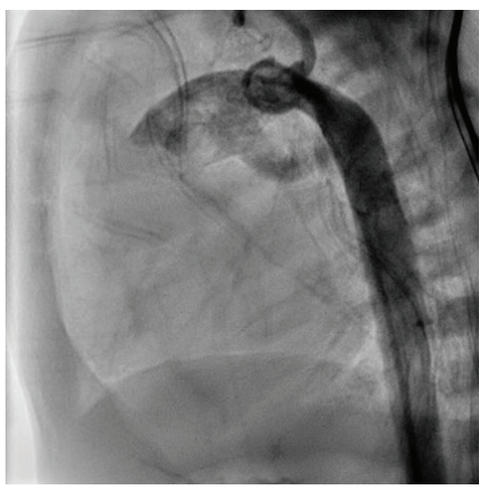
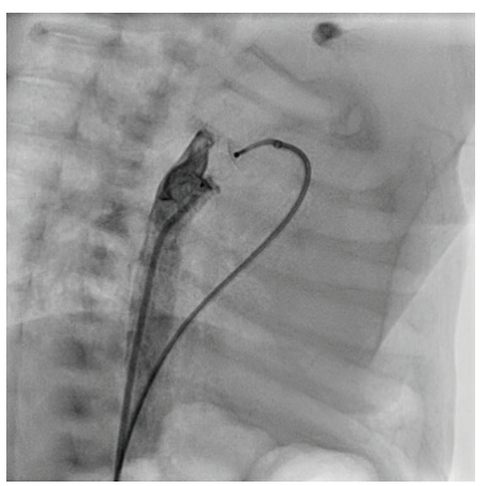
## ABSTRACT

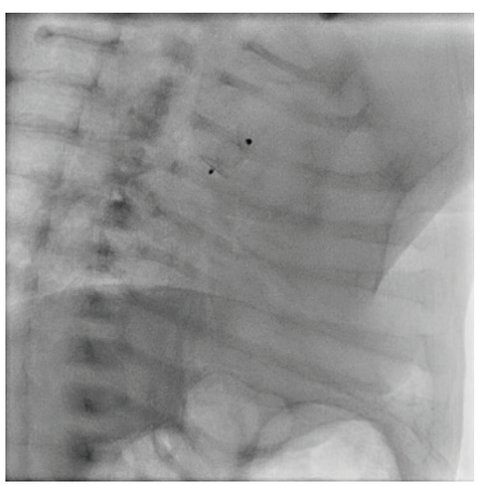
Herein we report our initial experience of patent ductus arteriosus (PDA) closure with Amplatzer Piccolo™ Occluder. We report 7 cases of PDA with age ranges from 21 days to 4 ½ years with median age of 6 months and the size of PDA ranges from 3 mm to 4 mm with median size of 3.5 mm closed with Amplatzer Piccolo™ Occluder. We achieved 100% success rate.

## INTRODUCTION

Device closure of symptomatic PDA in newborn are challenging due to small sized ampulla and small caliber femoral artery and vein. Because of these drawbacks we were relying on surgical intervention to close these types of PDAs in newborns. With introduction of low-profile Amplatzer Piccolo™ Occluder, we were able to close the symptomatic PDAs whose medical management failed to control the heart failure. The Amplatzer Piccolo™ Occluder is low profile device made of Nitinol material and can be delivered through 4F sheath. Many a times we can use only femoral vein without using the femoral artery for the deployment of this device. This advantage of venous alone deployment prevents femoral artery damage.







**Patient 1:** 21 days old child with weight of 3 kg, with PDA size of 3.7 mm and Amplatzer Piccolo™ Occluder size of 5/4 mm implanted

Dr. M. Kalyanasundaram

## MATERIALS AND METHODS

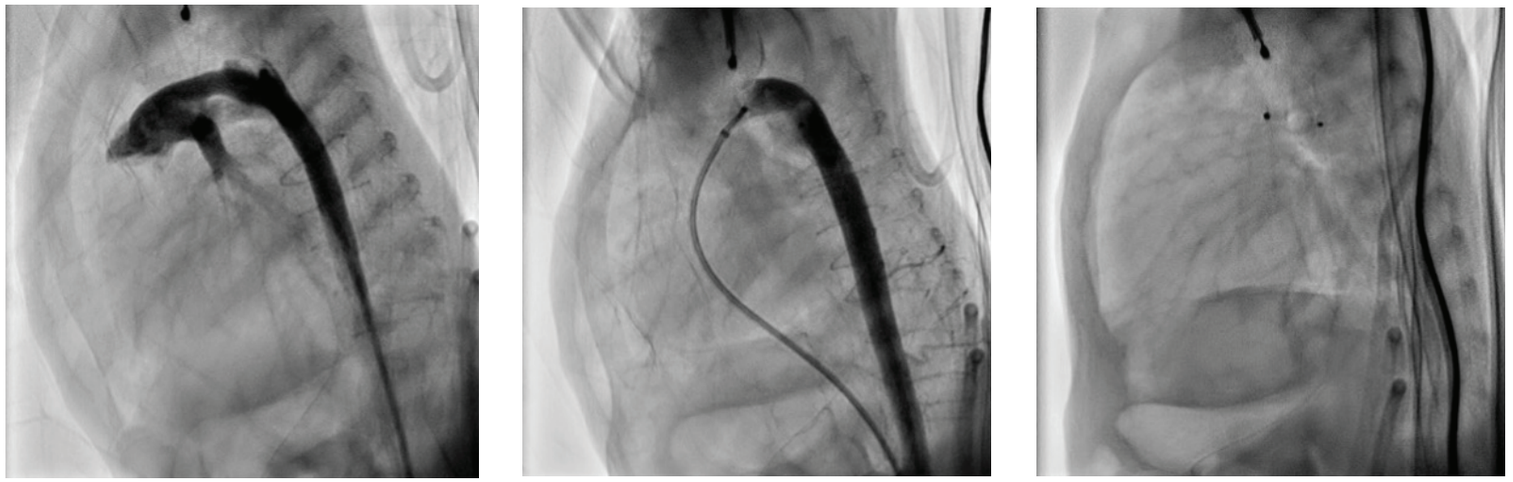
7 cases of children with symptomatic PDA were selected for the Amplatzer Piccolo™ Occluder deployment. Age ranges from 21 days to 4 ½ years with median age of 6 months and 6 children were male. The size of the PDA ranges from 3 mm to 4 mm with median size of 3.5 mm. We used both femoral artery and femoral vein approach, since we did not have much experience with femoral vein alone approach. As per the Amplatzer Piccolo™ Occluder deployment guidelines, we positioned device in the middle of the duct without retention skirt abetting on the aortic or pulmonary artery ends. Post deployment angiogram done after a wait of 15 minutes did not show residual shunt. All patients were extubated on table. Patients below 1 month old would be kept overnight in ICU, while patients above 1 month old would be observed in ICU for 2 hours.

## DISCUSSION

We achieved 100% success rate without any major complications. Since the device can be deployed in 4F sheath we did not have any major vascular complications. Two children had low volume femoral artery pulse on the side of puncture over the next 12 hours. We did not use vein alone deployment technique due to lack of experience.

## CONCLUSION:

Our initial experience with Amplatzer Piccolo™ Occluder showed that device closure of symptomatic PDA in newborn is feasible and safe in hospital with an experienced operator with good intensive care support.



**Patient 2:** 43 days old child weight of 1.3 kg, with PDA size of 3.7 mm and Amplatzer Piccolo™ Occluder size of 5/4 mm implanted

**CASE #4 – INDIA:** CASE REPORT: INDIAN EXPERIENCE OF AMPLATZER PICCOLO™ OCCLUDER

All content provided by Dr. M. Kalyanasundaram unless otherwise noted.



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CASE #5

# RETRIEVAL AND REPOSITIONING OF AMPLATZER PICCOLO™ OCCLUDER IN PRETERM PATENT DUCTUS ARTERIOSUS OCCLUSION

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## INTRODUCTION

Percutaneous transcatheter closure of patent ductus arteriosus (PDA) has been established for over more than 40 years. Institut Jantung Negara (IJN)/National Heart Institute has started the program since 1996. The Amplatzer Piccolo™ Occluder (Piccolo) low-profile device is well established for closure of patent ductus arteriosus in preterm and low birth weight (LBW) infants. Device embolization and malalignment is well known consequences of this procedure even though it is rare. In this report, we highlighted the successful of Piccolo device retrieval and repositioning.

## CASE REPORT 1

A day 30 of life ex-premature baby was taken into invasive catheterisation laboratory (ICL) to perform percutaneous closure of PDA by using Piccolo device. The procedure was performed under general anaesthesia. Right femoral vein was cannulated and 4Fr slender sheath was placed. 4Fr glide catheter was advanced via 0.035mm curved Terumo guidewire. The catheter was placed opposite the tricuspid valve and guidewire was advanced into right ventricle, crossing pulmonary valve, main pulmonary artery, PDA and parked at the descending aorta. Initial hand-shot angiogram using 2 ml diluted warm contrast showed a conical shaped PDA with diameter was about 3.8mm. 4Fr Torque delivery catheter was then advanced across the PDA. Piccolo device size 5/2 was delivered and positioned in the PDA under fluoroscopy and transthoracic echocardiography guidance. Subsequently, the device was released. There was no residual shunt and patient was stable haemodynamically. The patient was then transferred to the ward. The attending clinician noticed a drop in diastolic pressure and continuous murmur was heard. Echocardiography revealed a PDA and chest radiograph revealed a device in right pulmonary artery. The child was brought back to ICL and the right femoral sheath was placed and glide catheter over 0.035 Terumo guidewire was advanced. The guidewire was placed distal to the device into right pulmonary artery and the catheter was advanced crossing the device.

The goose-neck snare was advanced and captured the knob of the device and retrieved into the 4Fr sheath. The initial plan was to place another device to occlude the PDA, however due to limitation of device availability, the patient was subjected for a surgical intervention. The baby was doing very well and discharged 2 days later.

## CASE REPORT 2

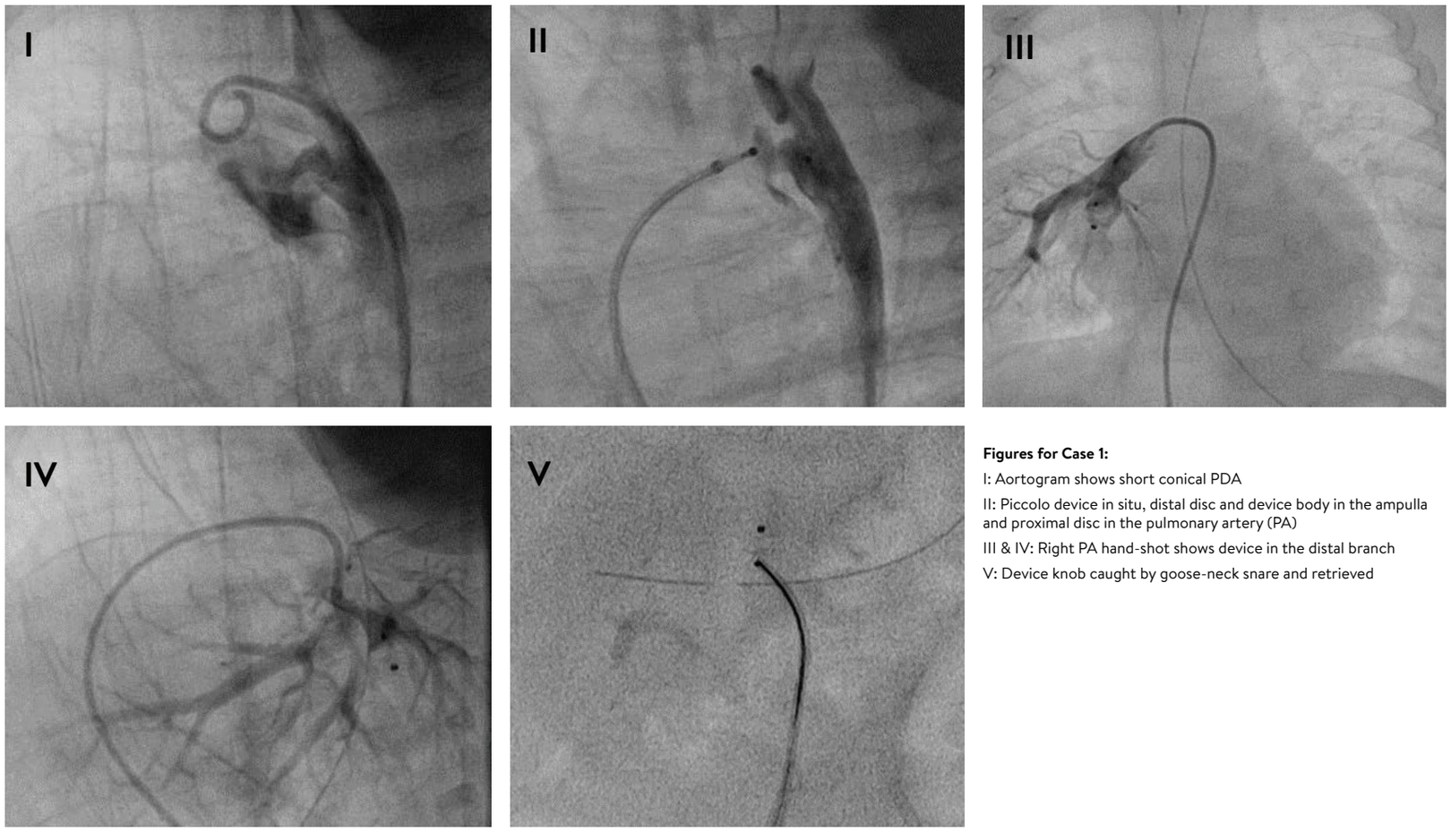
A day 30 of life, preterm infant weighing 1.5kg diagnosed to have haemodynamically significant PDA and subjected for a device closure. He was brought to ICL and the procedure was performed under general anaesthesia. The similar approach of access was done (compared with case 1). Piccolo device size 4/2 was positioned under fluoroscopy and echocardiography guidance. Multiple echocardiography noticed the device was jutting into the aorta.

Marhisham Che Mood M.D.

## DISCUSSION

The device was then retrieved into the delivery catheter and repositioned. The second echocardiography showed the distal disc splaying into the pulmonary artery and the device was retrieved again. The device was then repositioned and echocardiography showed good device position in the PDA lumen and it was released. The device then remained stable and there was small residual shunt through the device. No residual shunt noted on subsequent echocardiography.

Various closure device has been used to occlude the PDA. It has been shown that the use of the Amplatzer Piccolo™ Occluder was safe and relatively high success rate in preterm infants. However, complication such as device embolization or malalignment are known complications to this procedure. Judicious case selection is utmost important. The large conical and tubular type PDA might not be suitable for closure with Piccolo device. These two cases highlighted the simplicity and how feasible to retrieve this low-profile device without upsizing the venous sheath and catheter. The device can also be pushed and pulled into the delivery catheter multiple times without compromising its configuration.




**Figures for Case 1:**

I: Aortogram shows short conical PDA

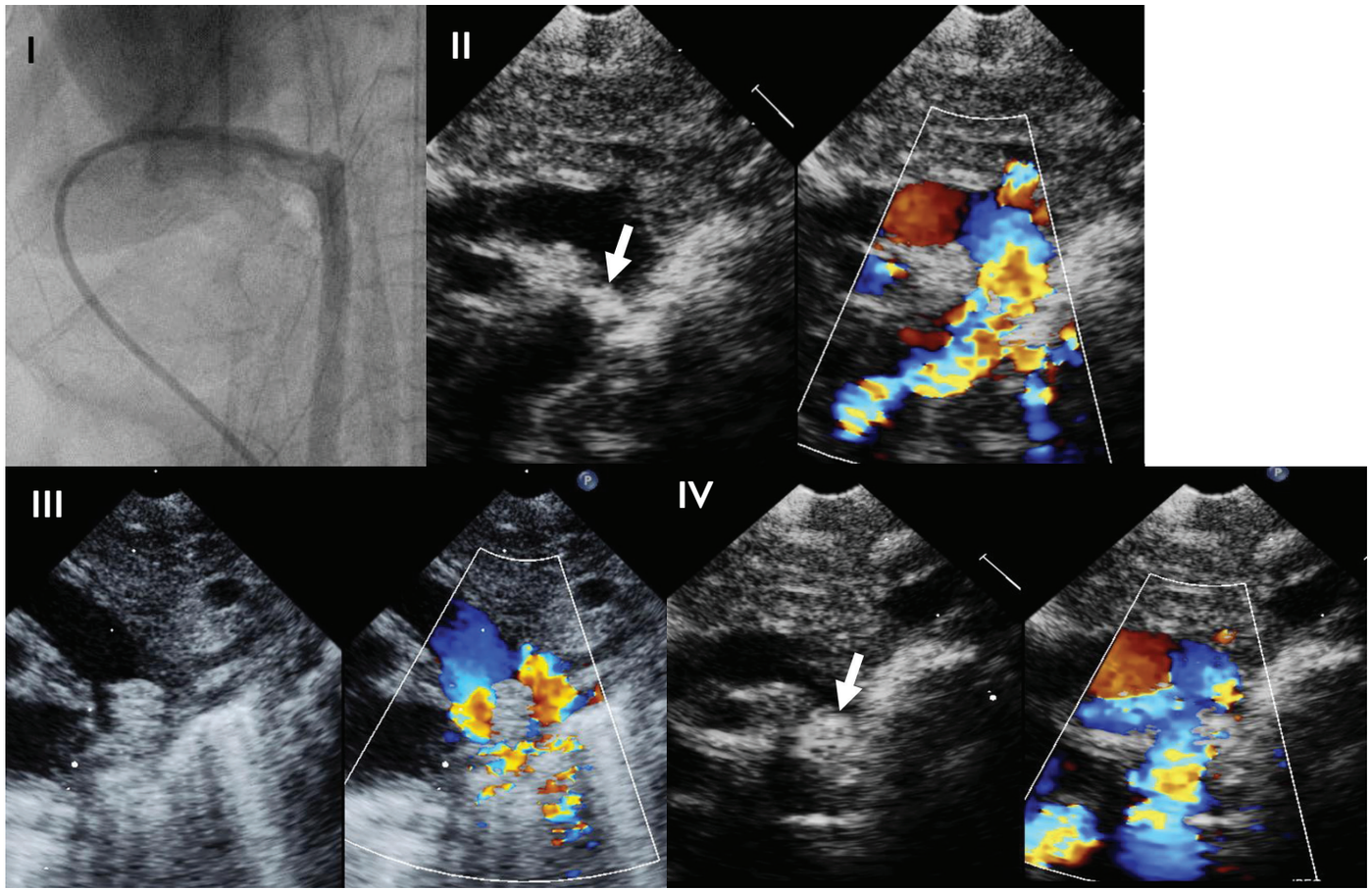
II: Piccolo device in situ, distal disc and device body in the ampulla and proximal disc in the pulmonary artery (PA)

III & IV: Right PA hand-shot shows device in the distal branch

V: Device knob caught by goose-neck snare and retrieved



All content provided by Dr. Marhisham Che Mood unless otherwise noted.




**Figures for Case 2:**

I: Aortogram shows typical fetal type PDA

II: Amplatzer Piccolo™ Occluder in situ (arrow), distal disc protrudes to aorta

III: Obstruction of left pulmonary artery (PA)

IV: Piccolo Occluder (arrow) in good position and no obstruction of left PA

## CONCLUSION

The cases demonstrated the great importance of device selection and placement in preterm PDA.
The Amplatzer Piccolo™ Occluder is feasible for retrieval and repositioning without compromising its configuration and patency. Good echocardiography images are crucial to ensure device position and the relationship with the surrounding structures.

**Reference:**

1. Carl H. Backes, Sharon L. Cheatham, Grace M. Deyo et. al.; Percutaneous Patent Ductus Arteriosus (PDA) Closure in Very Preterm Infants: Feasibility and Complications; (J Am Heart Assoc. 2016;5:e002923 doi: 10.1161/JAHA.115.002923).
2. Ranjit Philip, Rush Waller, Vijaykumar Agrawal et. al.; Morphologic Characterization of the Patent Ductus Arteriosus in the Premature Infant and the Choice of Transcatheter Occlusion Device; Catheterization and Cardiovascular Interventions 87:310–317 (2016).

CASE #6

# BILATERAL PDA OCCLUSION WITH 2 AMPLATZER PICCOLO™ OCCLUDER IN A 3-KG INFANT WITH A RIGHT AORTIC ARCH AND ISOLATED LEFT SUBCLAVIAN ARTERY

**Ghee Tiong KOH**
Serdang Heart Centre, Malaysia

## ABSTRACT

Transcatheter closure of patent ductus arteriosus has been a well-established treatment modality. However, current devices and coils are limited to infants with a weight of more than 6kg. The availability of Amplatzer Piccolo™ Occluder (Abbott Structural Heart, Plymouth, MN) has expanded the transcatheter technique to smaller infants and premature infants.

The case described here was a bilateral PDA occluded with 2 Amplatzer Piccolo Occluders in a 3-kg infant with a right aortic arch and isolated subclavian artery.

## INTRODUCTION

Transcatheter device closure of PDA is the primary treatment modality in larger infants, children, and adults. Currently, transcatheter closure of PDA can be performed with different types of Amplatzer Duct Occluder (Abbott Structural Heart, Plymouth, MN) and its similar variants, Amplatzer Duct Occluder II (Abbott Structural Heart, Plymouth, MN), Cook coil (COOK Medical, Bloomington, IN), Nit-Occlud (pfm, Cologne, Germany) and Amplatzer Vascular Plugs (Abbott Structural Heart, Plymouth, MN). In rare instances, especially in the adults, Amplatzer Muscular VSD Occluder (Abbott Structural Heart, Plymouth, MN) and Amplatzer Septal Occluder (Abbott Structural Heart, Plymouth, MN) have been used to occlude the PDA.

The Amplatzer Piccolo Occluder is a self-expandable Nitinol mesh device with a central cylindrical waist and low-profile retention discs on both sides that are 1.0 to 1.5mm larger than the waist. The device is pre-loaded on a delivery wire with a soft floppy distal end with a micro crew attachment at the tip. It can be delivered through a 4F Amplatzer TorqVue LP catheter (Abbott Structural Heart, Plymouth, MN).

The Amplatzer Piccolo Occluder comprises three waist diameters (3, 4, and 5 mm) and three lengths (2, 4, and 6 mm) that have nine sizes. The advantages of the Piccolo occluder are soft and low-profile device, antegrade and retrograde deployment, a floppy distal end of the delivery wire and variable sizes, particularly a short device length of 2mm, which is particularly suitable to occlude PDA in small and premature infants. Technically, it is also easier to retrieve in the event of device embolization.

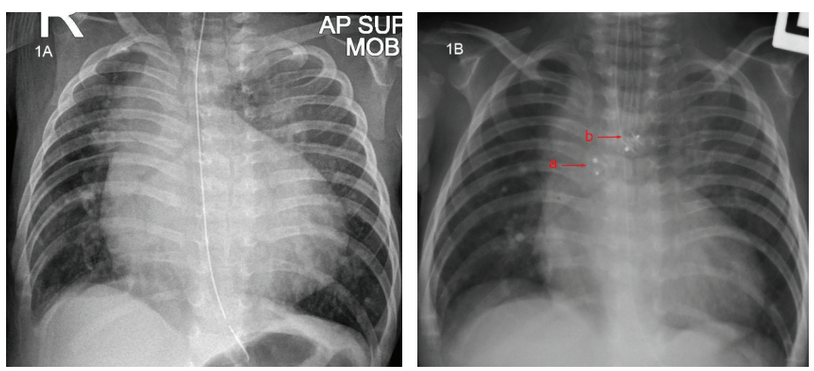



**Figure 1** CXR showed cardiomegaly and pulmonary plethora prior to occlusion (A). Post occlusion CXR showed reduced cardiac enlargement with both devices in situ (B) (a) Amplatzer Piccolo Occluder 05-02 mm (b) Amplatzer Piccolo Occluder 04-02 mm

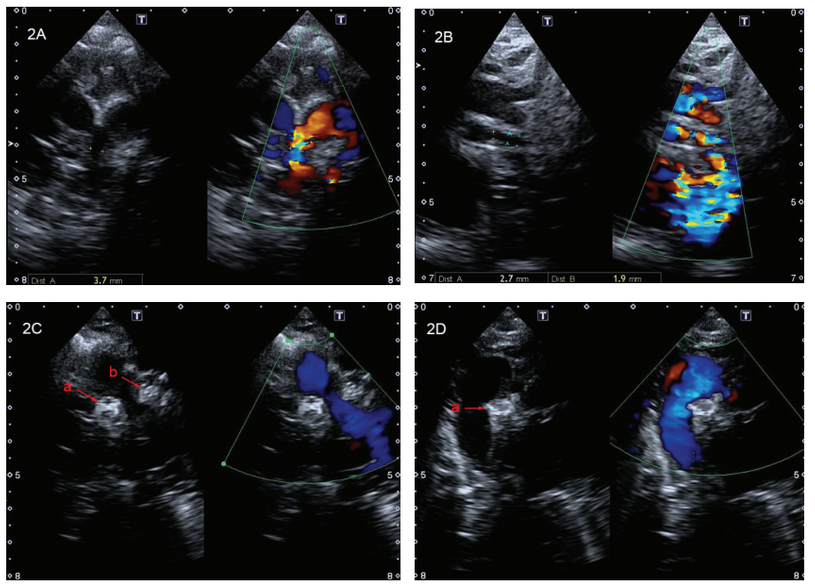



**Figure 2** Echocardiogram showed a large PDA measuring 3.7mm from the descending aorta to the right pulmonary artery (A). A small PDA measured 1.7mm to the left pulmonary artery (B). Post occlusion showed no left pulmonary artery obstruction (C) and no descending aorta obstruction (D).

## CASE PRESENTATION

A 3-month-old baby girl was referred to our institution for PDA ligation. She was born term with a birth weight of 2.9kg. On day 6 of life, she was intubated for nosocomial pneumonia and subsequently weaned to nasal oxygen. She was noted to have a heart murmur, and an initial echocardiogram evaluation showed a PDA of 2mm. Further evaluation on day 47 of life showed a moderate PDA. She was started on diuretics and referred for further intervention. On examination, she was pink with more than 95% oxygen saturation on nasal oxygen 0.5L/min. Her respiratory rate was 50 per minute with subcostal recession. Cardiovascular examination revealed a continuous murmur at upper left sternal edge grade 3/6. Her chest X-ray showed an enlarged heart with pulmonary plethora. Our echocardiogram assessment showed a right aortic arch with a large PDA measuring 3.7mm from the descending aorta to the right pulmonary artery. Another small PDA measured 1.7mm with its' flow to the left pulmonary artery. Her cardiac CT scan, which was done from the referring centre, could not delineate the PDA and other vascular structures.

She was subsequently sent to our cardiac catheterization laboratory for diagnostic catheterization and percutaneous PDA closure if feasible. A descending aortogram showed a right aortic arch with a large PDA measuring 3mm using a Cook 4F pigtail catheter (COOK Medical, Bloomington, IN). The PDA was occluded with an Amplatzer Piccolo™ Occluder 05-04 mm (diameter-length) device retrogradely under fluoroscopic and echocardiographic guidance. Selective injection at the brachiocephalic and left common carotid did not reveal a second PDA or vascular connection to the pulmonary artery. An incidental finding of selective collateral contrast injection revealed a collateral flow to the isolated left subclavian artery with a "steal" flow from the left subclavian artery to the pulmonary artery via PDA. The PDA was crossed using a Cordis 4F JR 3.5 catheter (Cordis, Santa Clara, CA, US) and coronary wire 0.014" from the main pulmonary artery. Selective injection showed a small PDA connection measuring 1.9mm. The PDA was then occluded with a Piccolo 04-02 mm. An echocardiogram showed both devices in situ with no residual flow the next day.

## CASE DISCUSSION

The case reported was the first case of using two Amplatzer Piccolo™ Occluders to occlude a bilateral PDA with an isolated left subclavian artery. This case is an extremely rare entity. This case illustrated the availability of Amplatzer Piccolo Occluder that makes it possible to occlude the bilateral PDA in such a small infant.

The first PDA was easily occluded via retrograde technique because of its low-profile device that can go through a 4F Torque LP delivery catheter via a 4F femoral sheath. The second PDA that connects with the isolated left subclavian artery was feasible to occlude with this device because of a short device length of 2mm without causing protrusion to the pulmonary artery or obstruction to the left subclavian artery. Overall, transcatheter occlusion of these bilateral PDAs is technically feasible and straightforward with the availability of Amplatzer Piccolo Occluders.

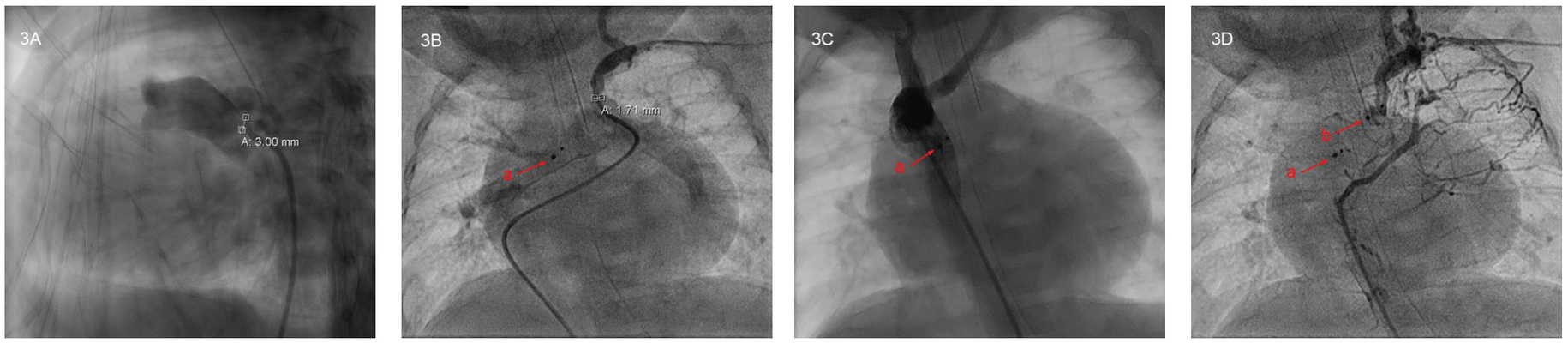



**Figure 3** Selective injection with a JR catheter at the PDA delineated the PDA morphology and size (A). Selective injection at the isolated subclavian artery showed the PDA connection to the pulmonary artery and its narrowest diameter (B).

Post occlusion descending aortogram showed no residual flow across PDA from the descending aorta (C). Selective injection at a collateral showed the occluded PDA connecting the isolated subclavian artery to the pulmonary artery (D).

(a) Amplatzer Piccolo Occluder 05-02 mm

(b) Amplatzer Piccolo Occluder 04-02 mm



All content provided by Dr. Ghee Tiong KOH unless otherwise noted.

CASE #7

# TRANSCATHETER PDA CLOSURE IN A PREMATURE LOW-WEIGHT INFANT WITH THE AMPLATZER PICCOLO™ OCCLUDER **LOW PROFILE DELIVERY SYSTEM, SOFTNESS AND PREDICTABLE POSITIONING INTO THE DUCT**

**Dr. Gianfranco Butera,**
**Dr. Enrico Piccinelli**
IRCCS Ospedale Pediatrico Bambino Gesù, Rome, Italy

## ABSTRACT

A patent ductus arteriosus (PDA) is a common condition in the preterm infant population but the ideal management is still controversial. We report a case of successful PDA transcatheter closure with a 5/2 mm Amplatzer Piccolo™ Occluder in a 1200 g premature female infant that was referred to our centre for a haemodynamically significant PDA. The features of the Piccolo device facilitated its implantation with excellent result and no residual shunt, allowing the improvement in her general and respiratory condition.

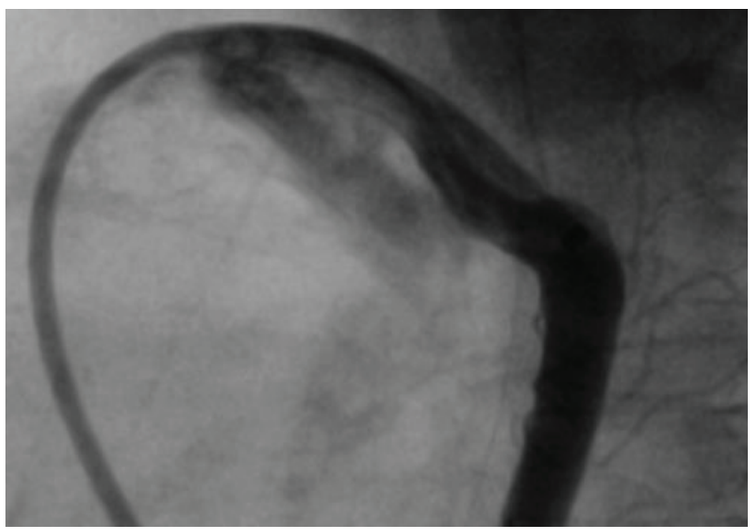


**Figure 1:**
Aortography into the descending aorta showing a fetal type PDA with left to right shunt measuring 4,5 mm at the aortic end and 3,5 mm at the pulmonary end.

## INTRODUCTION

A patent ductus arteriosus (PDA) is a common condition in the preterm infant population. It's estimated that its frequency varies between 40% and 55% in infants <29 weeks gestational age. The persistence of a hemodynamically significant duct with a left to right shunt increases the risk of major clinical complications such as an increased risk of prolonged mechanical ventilation, bronchopulmonary dysplasia, intraventricular haemorrhage, necrotizing enterocolitis. The first line treatment for hemodynamically significant ductus arteriosus is pharmacological, while percutaneous or surgical treatment is reserved for non-responders to drug therapy. The recently introduced Amplatzer Piccolo™ Occluder was developed to offer a solution for PDA closure in premature infants, allowing an effective and safe alternative in a wide range of patients. Here, we report our experience with the Piccolo™ Occluder employed during a successful transcatheter PDA closure in a premature infant.

## CASE PRESENTATION

A 30-weeks old, 1200 g premature female infant was referred to our centre at 40 days of life for a haemodynamically significant PDA. She necessitated non-invasive respiratory support with multiple failed weaning attempts. Moreover, four attempts of pharmacological closure of PDA with paracetamol, Ibuprofen and Indomethacin were unsuccessful and complicated by haematochezia. Considering the clinical picture with respiratory instability, no weight gain and multiple unsuccessful attempts of pharmacological closure of PDA, she was accepted for percutaneous closure of her PDA.

The baby was transferred to our intensive care and cath lab that was carefully prepared for the procedure. A 4F short sheath was positioned under US-guidance in the right femoral vein. Then, a 3F cerebral catheter

Dr. Gianfranco Butera

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(Cordis Corporation, FL, USA) was positioned in the right atrium pointing towards the tricuspid valve without crossing it. A 0.014" coronary wire was then advanced throw the PDA into the descending aorta. Subsequently, a Progreat® microcatheter (Terumo Corp., Tokyo, Japan) mounted coaxially with a 4F Amplatzer™ TorqVue™ was advanced into the descending aorta.

An aortography was performed into the descending aorta showing a fetal type PDA with left to right shunt measuring 4,5 mm at the aortic end and 3,5 mm at the pulmonary end with 8 mm lenght. **Figure 1** Therefore, a 5/2 mm Amplatzer Piccolo™ Occluder was implanted and released under fluoroscopic and echocardiographic guidance with excellent result. **Figure. 2** There were no complications and the final transthoracic echocardiogram confirmed the good position of the device with no residual shunt, no coarctation of the aorta or pulmonary stenosis. **Figure 3** The child progressed well in the following days in our paediatric intensive care unit with a brief need for inotropic support due to transient left ventricular dysfunction due to the haemodynamic changes after PDA closure. The baby was then transferred to the local hospital in good clinical condition, not needing further respiratory support.

## CASE DISCUSSION

The ideal management of preterm infants with haemodynamically significant PDA is controversial despite the mortality and the morbidity associated with PDAs in this population being well known. In most centres, the first-line treatment is pharmacological but promising results are coming from the initial experience of PDA percutaneous closure in low weight infants. Numerous studies have demonstrated the feasibility and safety of transcatheter PDA closure in preterm neonates with the Amplatzer Piccolo™ Occluder, even in comparison with surgical treatment. In our experience, this device showed to be ideal especially for very premature and low-weight babies due to the 4 Fr delivery system that facilitates the implantation and flexibility in small vasculatures. Moreover, the device structure and shape allows predictable positioning into the duct, significantly reducing the risk of protrusion into the aorta and pulmonary arteries. In the presented case the features of Amplatzer Piccolo™ Occluder were fundamental in achieving an excellent result as its softness allowed complete accommodation of the device into the duct without protrusion or distortion of the nearby structures. This is especially true in low-weight infants with a fetal type duct, often found in premature babies. Indeed the small size and weight of these infants and the long, tortuous and wide anatomy of their PDAs make impossible the use of other conventional devices.

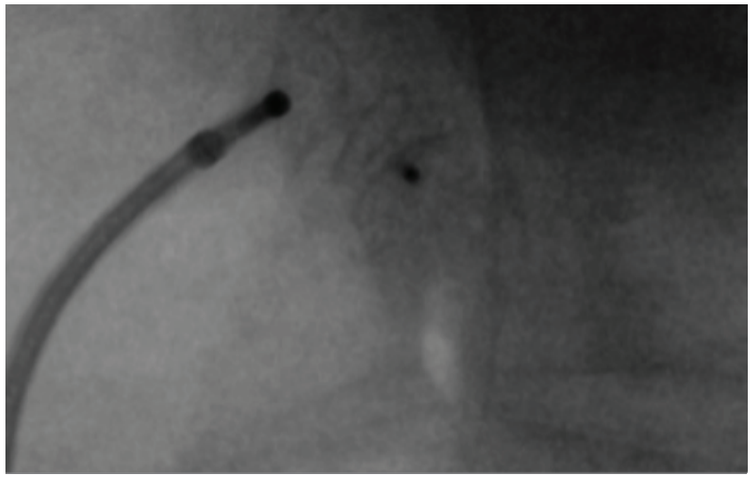

**Figure 2:**
A 5/2 mm Amplatzer Piccolo™ Occluder was implanted and release with excellent result.

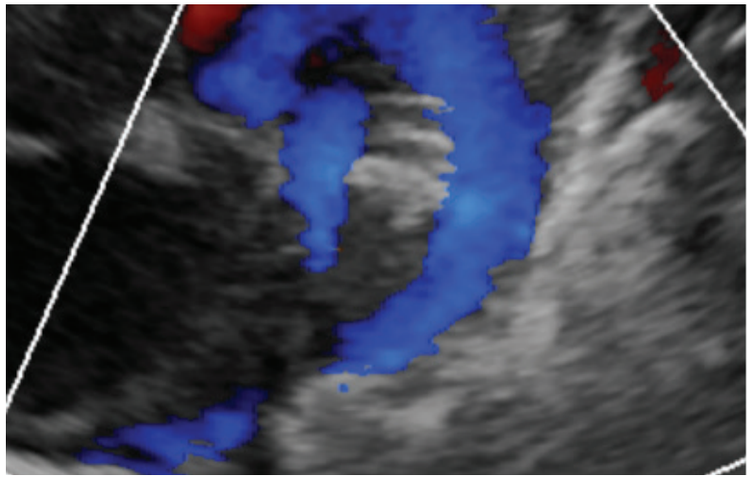

**Figure 3:**
The final transthoracic echocardiogram confirmed the good position of the device with no residual shunt, no coarctation of the aorta or pulmonary stenosis.

## CONCLUSION

The Amplatzer Piccolo™ Occluder is an effective and safe solution for PDA percutaneous closure in premature low-weight infants due to its low profile delivery system, softness and predictable positioning into the duct.

**CASE #7 – ITALY:** TRANSCATHETER PDA CLOSURE IN A PREMATURE LOW-WEIGHT INFANT WITH THE AMPLATZER PICCOLO™ OCCLUDER LOW PROFILE DELIVERY SYSTEM, SOFTNESS AND PREDICTABLE POSITIONING INTO THE DUCT

All content provided by Dr. Gianfranco Butera and Dr. Enrico Piccinelli unless otherwise noted.



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CASE #8

# LARGE PDA IN EXTREMELY LOW BIRTH WEIGHT INFANT SUCCESSFULLY TREATED WITH AMPLATZER PICCOLO™ OCCLUDER

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**Alessio Peretti MD, Pediatric Cardiology**
ASST Grande Ospedale Metropolitano Niguarda, Milan, Italy

## ABSTRACT

We report our experience in transcatheter closure of a patent ductus arteriosus (PDA) in an extremely premature infant using the recently introduced Amplatzer Piccolo™ Occluder device. The patient's weight at the time of procedure was 1100 grams. The percutaneous closure was performed with an echo guided technique, using a single femoral vein access with an anterograde approach. A single 2 mL contrast hand injection was administered. The procedure lasted 130 minutes overall, with an optimal outcome (no residual shunt, no intraprocedural complications, with no need for post-procedural inotropic support). The Amplatzer Piccolo™ Occluder device has made transcatheter PDA closure possible and safe in preterm patients weighing ≥700 grams.

## INTRODUCTION

Transcatheter closure of patent ductus arteriosus (PDA) has been the gold standard for interventional treatment of hemodynamically significant PDA, in children who weigh more than 5 Kg, for several years now.
There was no dedicated device to treat premature infants until the end of 2019, when the Amplatzer Piccolo™ Occluder was officially introduced. The presence of a hemodynamically significant PDA is linked with increased morbidity and mortality in children born premature.

With this miniaturized device and its dedicated delivery sheath, it is possible to effectively and safely perform percutaneous PDA closure in patients weighing ≥700 grams and up to 2 kg. This self-expanding device is composed of a central waist with two retention disks: the waist's diameter range from 3 mm to 5 mm; the disks' diameters range from 4 mm to 6.50 mm. Total length of the device range from 2 to 6 mm. The closure can be performed with a single vascular access, either with a venous anterograde or an arterial retrograde approach. When treating infants weighing < 2 kg, the Amplatzer Piccolo™ should be completely deployed within the duct; therefore, a device as short as possible should be preferred, depending on the duct's anatomy.

The ideal PDA characteristics are represented by a length > 3 mm with a diameter ≤ 4 mm, calculated at the site of maximum constriction, which is usually located at the pulmonary end. We report our experience with the Amplatzer Piccolo™ for percutaneous closure of a PDA in a child with a weight at the time of procedure of 1100 grams.

Dr. Giuseppe Annoni

## CASE PRESENTATION

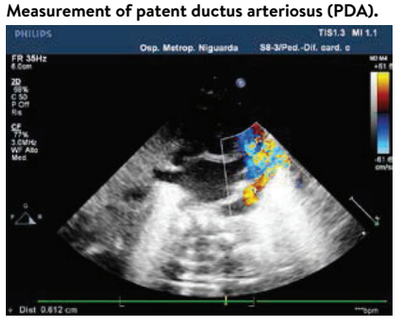
At the end of February 2021 a preterm infant 27+4 weeks was born due to placental abruption. Birth weight was 980g. The infant required assisted ventilation since birth. Hemodynamically significant ductus arteriosus was observed from the second day of life with progressive worsening. The infant was initially treated with Paracetamol for 4 days, then with 3 intravenous ibuprofen and 2 indomethacin administrations.
All pharmacological treatments failed to close the PDA. Due to heart failure, still on mechanical ventilation without significant improvement, percutaneous closure of the PDA was considered as a good option. At 21days of life the neonate was sent to our institution directly to cath lab, for transcatheter closure of the PDA; the body weight at that time was 1100g. Through femoral vein access (3.3F introducer) a JR 3F was advanced in right atrium, and a coronary guidewire 0.014 was then passed in right ventricle, pulmonary trunk and finally in descending aorta through the PDA. The JR was advanced in descending aorta and the guidewire was exchanged with a 0.025 J guidewire, and then the delivery catheter 4F was placed in aorta. At angiographic evaluation PDA has a fetal morphology; on aortic side diameter was 3.2mm and 2.2mm on pulmonary side, PDA length was 6mm.

The procedure was successfully performed, and a Amplatzer Piccolo 4-2 was correctly placed in the PDA with echocardiographic and fluoroscopy images. Piccolo occluder was placed completely inside the PDA without any protrusion in aorta or even in the pulmonary artery. Post procedural angiography was not required. No device or procedure complication occurred. Fluoroscopy time was 4.55 minutes. Procedure time was 110 minutes.
Mild residual shunt was observed until two weeks after percutaneous closure. Successful extubation occurred two days after procedure. Weaning from high flow nasal cannula (HFNC) required some more weeks, and then the baby was discharged home. Long term follow-up was completed, and no post procedural late complication were observed.

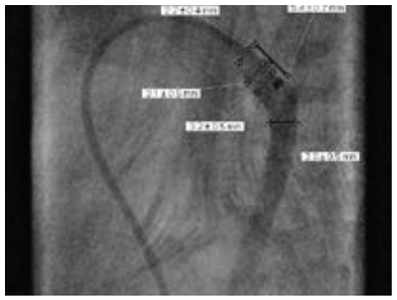
## CASE DISCUSSION

We present our experience with Amplatzer Piccolo™ Occluder device in preterm infant. The device can be easily placed in the PDA. The final position require attempt Echo evaluation to avoid aortic and pulmonary protrusion of the discs. The procedure is fast, safe and require a team work to better manage this particularly patient in cath lab.

**Measurement of patent ductus arteriosus (PDA).**

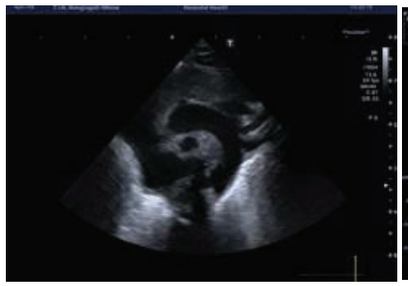



Echocardiographic PDA lenght evaluation.

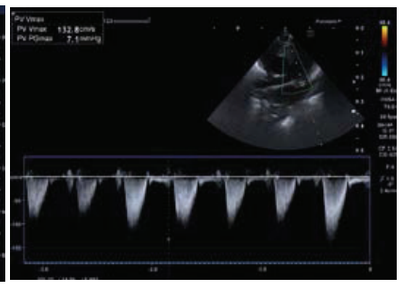


Angiographic PDA measurement.

**Post Closure PDA with Amplatzer Piccolo 4-2 from AO.**

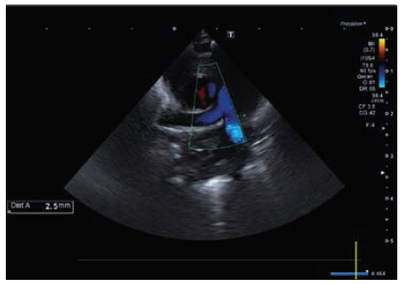


Echocardiographic 2D evaluation.

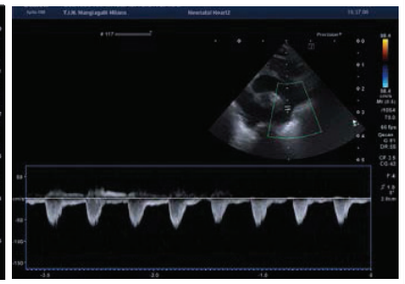


With color Doppler

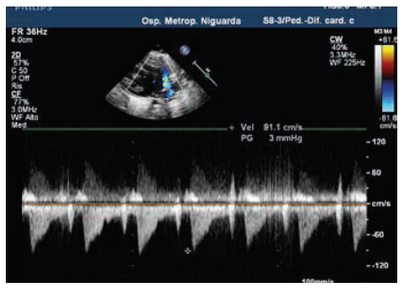
**Post Closure PDA with Amplatzer Piccolo 4-2 from LPA.**




Echocardiographic 2D evaluation.



With color Doppler




With color Doppler

## CONCLUSION

The Amplatzer Piccolo™ Occluder device provide percutaneous closure of the PDA in premature baby reducing time of recovery and invasiveness compared to surgery.

This new device and the modified closing technique can successfully treat almost all premature PDA.

**CASE #8 – ITALY:** LARGE PDA IN EXTREMELY LOW BIRTH WEIGHT INFANT SUCCESSFULLY TREATED

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CASE #9

# SUCCESSFUL PERCUTANEOUS PULMONARY BALLOON VALVULOPLASTY AND CLOSURE OF A PATENT DUCTUS ARTERIOSUS USING THE AMPLATZER PICCOLO™ OCCLUDER IN A PRETERM INFANT WITH A BODY WEIGHT OF 1500G

**Dr. med. Gleb Tarusinov, Dr. Paul Hacke, Dr. Aktham Tannous, Dr. med. Elvira Chrobot**
Klinik für Kinderkardiologie – Angeborene Herzfehler - Herzzentrum Duisburg, Germany

## OBJECTIVES

An eight-weeks old boy, a premature born gemini of 24+5 weeks of gestation with a birth weight of 690 g, was transferred from the neonatal intensive care unit of the maternity hospital to our paediatric cardiac intensive care unit due to a hemodynamic significant patent ductus arteriosus Botalli and a severe valvular pulmonary stenosis for further treatment. On admission he had a body weight of 1500 g. High-flow respiratory support was required. Echocardiography displayed good biventricular function. The left atrium and ventricle were dilated. In loco typico was an elongated PDA with a diameter of approximately 3 mm and continuous left-to-right shunting. An aortic coarctation was excluded. The pulmonary valve appeared dysplastic and stenotic, with a peak Doppler gradient of 60 mmHg and without significant regurgitation. Heart-team consent was balloon valvuloplasty followed by interventional PDA closure.

## PROCEDURE

The procedure was performed in general intubation anaesthesia. Trans-femoral venous access was established and a 4 F Terumo Radifocus® Introducer II short sheath (Terumo, Tokyo, Japan) was inserted. For aortic angiography arterial access was established via A. axillaris, using a 22 gauge peripheral artery catheter (Vygon, Aachen, Germany). The angiography displayed a normal left sided aortic arch, no aortic coarctation and, in loco typco, an elongated and mildly tortuous “Type F” [1] patent ductus arteriosus with a length of 11 mm and a diameter of 3 mm [**Figure 1**]. Via the femoral vein the right ventricle was entered with a 4 F balloon wedgepressure catheter (Arrow, Athlone, Ireland). The dextrocardiogram showed a significant stenotic and dysplastic pulmonary valve [**Figure 2**]. The valve was crossed with a 0.014” balanced middle-weight universal II guide wire (Abbott Vascular, California, USA) and anchored in the periphery of the right pulmonary artery. Over the wire a Tyshak mini 7x20 mm Balloon (NuMED, Ontario, Canada) was advanced into the right ventricular outflow tract and the pulmonary artery. Subsequent the valve was successfully dilated [**Figure 3**], achieving a residual gradient of only 12 mmHg and mild regurgitation. Following the valvuloplasty the 0.014” guide wire was used to antegrade cross the PDA and advanced deep into the descending aorta. For closure an Amplatzer Piccolo™ Occluder 04-04 mm (Abbott Structural Heart, Minnesota, USA) was selected. An Amplatzer™ TorqVue™ LP– Catheter (Abbot Medical, Minnesota, USA) was inserted into the femoral short sheath and advanced over the wire across the PDA into the descending aorta. Here the distal disc was deployed and the system retracted into the ductal ampulla. By further retracting the catheter, while maintaining device position, the waist was deployed within the PDA and the proximal disc at the pulmonary artery end. After an arterial and venous angiography, to confirm correct positioning and to exclude any relevant rest-shunting as well as a potential aortic or pulmonary vessel obstruction, the device was successfully released [**Figure 4 and 5]**.

Dr. Gleb Tarusinov

Dr. Paul Hacke

## POST-INTERVENTIONAL SEQUEL

In the post-interventional echocardiographic control the device was in situ. There was no residual shunt flow and no LPA nor aortic obstruction. Pulsed wave and colour flow Doppler over the pulmonary valve showed a mild flow acceleration of 1,8 m/s and a mild pulmonary regurgitation.

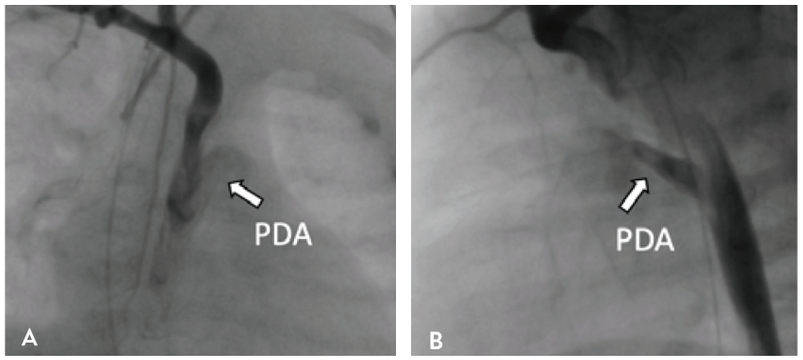


**Figure 1:** Aortic angiogram in A: RAO 18°/ caudal 15° and B: lateral projection, via 22 G peripheral artery catheter in the A. axillaris, shows a large, elongated and mildly tortuous "Type F" patent ductus arteriosus (PDA) (arrow). There is no aortic coarctation. The catheter itself is not radiopaque. The child is intubated and has a naso-gastric tube.

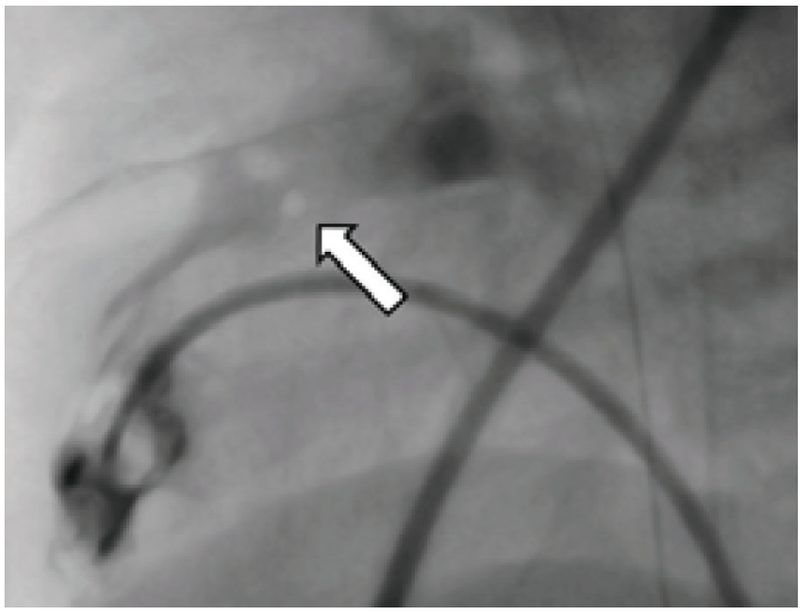

**Figure 2:** Lateral view: a dextrocardiogram via 4 F wedge-pressure- catheter in the right ventricle shows a significant dysplastic pulmonary valve. Relevant valvular stenosis (vPS) can be seen in systole, with only a small jet of contrast medium tracing the dilated main pulmonary artery (arrow).

## DISCUSSION

Our patient, a former extremely low birth weight (ELBW) infant, presented with the combination of valvular pulmonary stenosis and haemodynamic relevant PDA with left-to-right shunting. After PDA closure the gradient over the pulmonary valve would have further increased, therefore both lesions had to be addressed. The surgical option in this fragile child would have been more extensive than a sole PDA ligature and therefore heart team consent was an interventional approach.

Since the first report about transcatheter balloon valvuloplasty of pulmonary valve stenosis by Kan et al. in 1982 [2,3] the interventional procedure evolved into standard therapy. Fortunately the necessity of interventions in preterm and LBW infants are rather infrequent. Successful valvuloplasty in preterm infants with bodyweights of 1.2 to 1.9 kg have been performed before [4,5] and we achieved a good result after the first dilatation, making further attempts unnecessary.

A patent ductus arteriosus Botalli represents the persistence of the fetal connection of the pulmonary artery and the descending aorta and is usually resulting in a left-to-right shunt. In as many as 50 % of premature born children a PDA is present, while in ELBW infants, with a bodyweight less than 1000 g, the persistence increases to over 80 % [2]. Ahemodynamic significant PDA poses a common challenge in extreme premature neonates and is associated with severe respiratory disease, pulmonary and cerebral haemorrhage, necrotizing enterocolitis (NEC) as well as death.

Primary medical treatment consists of cyclooxygenase inhibitors or acetaminophen, but may be unsuccessful in approximately 50 % of ELWB infants and has a significant side-effect profile, including alterations in renal function, gastrointestinal perforation, NEC and impairment of cerebral blood flow [3]. Traditionally, when medical treatment fails, a surgical PDA ligation is attempted in these patients. In larger children and adults however the interventional trans-catheter PDA device closure is now procedure of choice, while lacking suitable devices for smaller children. The Amplatzer Duct Occluder II Additional Sizes (now renamed "Piccolo") obtained the CE-mark in 2011 for PDA closure in infants over 6 kg bodyweight. In January 2019 the Amplatzer Piccolo™ Occluder received effectiveness and safety has been supported by a multicenter trial by Sathanandam et al. [4]. This device can be delivered ante- (trans-venous) and retrograde (trans-arterial), though, due to limited arterial size, femoral artery access is usually avoided in ELBW children [5]. The necessary visual guidance can be achieved by combining fluoroscopy, transthoracic echocardiography and venous angiograms [6,7]. In our case, we used a small peripheral artery catheter in the A. axillaris for angiographic visualization. We find it convenient for safe device positioning and minimizing radiation exposure compared to venous run-through angiograms. The A. axillaris in newborns is larger than the femoral artery and in our single-center experience there were no vascular complications in newborns using this arterial access site.

Piccolo device positioning depends on infant weight: in small infants (< 2 kg) occluder is chosen to achieve intraductal placement, whereas in infants > 2 kg, the device is chosen to achieve an extraductal disc placement. After pulmonary valve intervention and with respect to the well developed pulmonary arteries and aorta in this child, we preferred a secure-fitting extraductal occluder positioning. A minor, hemodynamic insignificant compression of the left pulmonary artery (LPA) was seen in the angiogram, resembling a common and benign finding. Echocardiography showed a normal colour doppler flow and a maximal flow velocity well below 2 m/s, which can be seen a threshold to warrant closer follow-ups concerning development of LPA stenosis.


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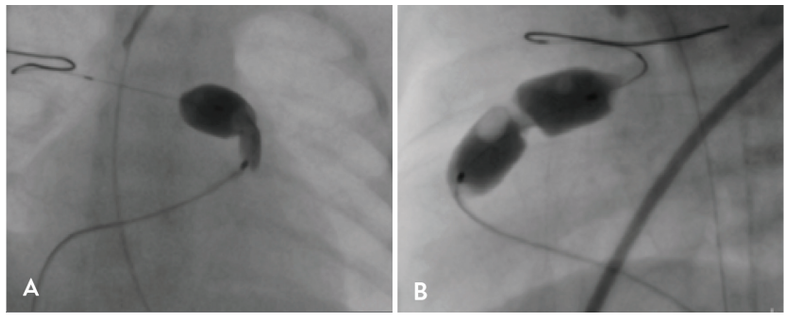


**Figure 3:** A: frontal and B: lateral view. A Tyshak mini 7x20 mm Balloon is used for pulmonary valvuloplasty. The 0.014" guide wire is anchored in the right pulmonary artery. The initial waist of the balloon at the level of the pulmonary valve ring is clearly seen and resolved with increasing pressure.

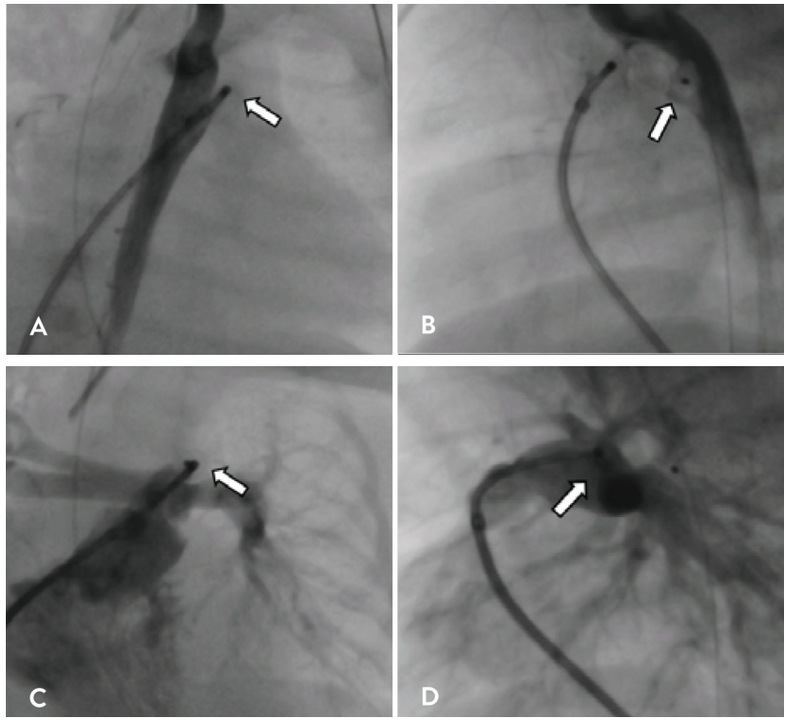


**Figure 4:** Aortic angiogram in an A: RAO 25°/ caudal 15° and B: lateral projection via A. axillaris and pulmonary artery angiogram in a C: LAO 10°/cranial 20° and D: lateral view, via TorquVue LP delivery catheter in the right ventricular outflow tract, for assessment of correct device placement. The occluder itself is still attached to the delivery cable. The distal disc is well placed within the ductal ampulla, there is no aortic obstruction. The waist of the device shows sufficient compression and the proximal disc is deployed at the level of the LPA (extra-ductal occluder positioning). Pulmonary obstruction is ruled out while the left pulmonary artery shows an insignificant and benign compression by the device. Confirming good positioning the device was released.

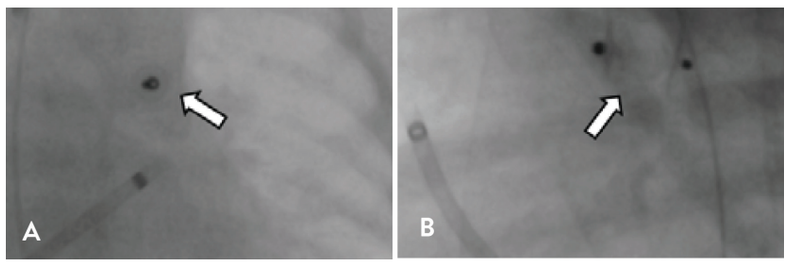


**Figure 5:** A: Frontal projection with a 10 ° cranial tilt and B: lateral. After Piccolo occluder release the device is in situ and well positioned, the devices' waist has the necessary compression (arrow). The delivery catheter is still in the right ventricular outflow tract.

## CONCLUSION

Interventional cardiac catheterization in preterm low birth weight infants can be safely performed. We were able to demonstrate that even a combination of procedures can be successfully achieved and neonatal surgery be avoided. Nevertheless, the aim is not to push the limits of technical feasibility but provide the best possible treatment and therefore heart-team consensus is a conditio sine qua non. Interventional patent ductus arteriosus closure in premature children is a promising and less invasive alternative to ligation. Further studies are urgently needed o assess the benefit of a transcatheter over a surgical or even medical approach. Arterial access should be avoided in all ELBW children, however in "larger" ex-ELWB infants a peripheral artery catheter in the axillary artery can safely be used and may enhance visualization, procedural safety and minimize radiation exposure. Interventions in preterm children requires a dedicated team of paediatric cardiac interventionalists, surgeons, anaesthetists, intensivists, imaging specialists and neonatologists as well as supporting industry partners for development of appropriate devices and delivery systems.

**CASE #9 – GERMANY:** SUCCESSFUL PERCUTANEOUS ULMONARY BALLOON VALVULOPLASTY AND CLOSURE OF A PATENT DUCTUS ARTERIOSUS USING THE AMPLATZER PICCOLO™ OCCLUDER IN A PRETERM INFANT WITH A BODY WEIGHT OF 1500G

All content provided by Dr. Gleb Tarusinov and Dr. Paul Hacke unless otherwise noted.

CASE #10

# TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS WITH AMPLATZER PICCOLO™ OCCLUDER IN AN EXTREMELY PREMATURE NEONATE THROUGH THE UMBILICAL VEIN

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## ABSTRACT

Patent ductus arteriosus (PDA) is common in premature babies. Transcatheter closure of PDA in extremely premature infants remains technically difficult and with many challenges. With the invention of Amplatzer Piccolo™ Occluder, it is possible to do transcatheter closure safely. We report a case of an extremely premature female baby (gestational age 26 4/7 weeks, birth body weight 955 g), who had hemodynamically significant PDA, successfully occluded by an Amplatzer Piccolo™ Occluder via the route of umbilical vein. Neither coarctation of the aorta nor left pulmonary artery stenosis happened at immediate or long-term follow-up. Amplatzer Piccolo™ Occluder is proven safe and effective in premature infants ≥ 700 g. Appropriate size selection is crucial to avoid complications. It is also possible to do PDA closure in extremely premature infants through the umbilical vein.

## INTRODUCTION

Patent ductus arteriosus (PDA) is the most common congenital heart disease among premature babies. Transcatheter closure of PDA is one of the most successful catheter-based procedure, has a long standing history in catheter intervention, and has replaced surgical closure in most circumstances.[1] While transcatheter closure of the PDA in term babies is already proven safe and effective, transcatheter closure of PDA in extremely premature infants remains technically difficult and with many challenges.[2] We report a case of transcatheter closure of PDA with Amplatzer Piccolo™ Occluder in an extremely premature infant through the umbilical vein.

## CASE PRESENTATION

An extremely premature female baby (gestational age 26 4/7 weeks, birth body weight 955 g) was delivered via cesarean section due to preterm premature rupture of membrane with fetal malpresentation. Her Apgar score were 1 (1 min), 3 (5 min), and 7 (10 min). She received endotracheal intubation at the delivery room and was soon admitted to the neonatal intensive care unit. Severe respiratory distress syndrome and persistent pulmonary hypertension of the newborn were diagnosed. We set her on high frequency oscillatory ventilation and inhaled nitric oxide. The baby had pink frothy sputum on postnasal day 5. Cardiomegaly was also evident on chest X-ray. Echocardiography revealed a large patent ductus arteriosus (PDA), size: 3.4 mm in diameter and 9.3 mm in length, with bidirectional, mainly left to right shunt (**Figure 1A and 1B**). Since she had symptoms of necrotizing enterocolitis, oral or intravenous ibuprofen was contraindicated.

As a result, she underwent cardiac catheterization on postnatal day 6 on intravenous conscious sedation by continuous infusion of midazolam and bolus ketamine. The baby was placed on a warm blanket during the procedure.

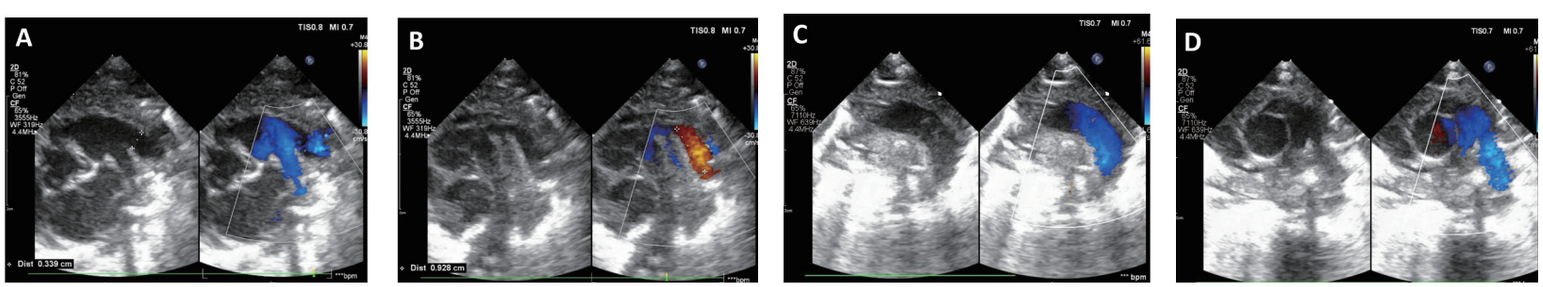
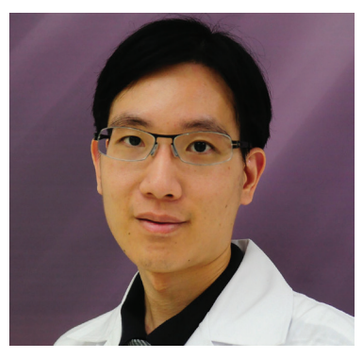



**Figure 1:** Transthoracic echocardiography of the patent ductus arteriosus (PDA) before and after Amplatzer Piccolo occluder deployment. (A) PDA diameter. (B) PDA length. (C) No left pulmonary artery stenosis after APO deployment. (D) No coarctation of the aorta after Amplatzer Piccolo Occluder deployment.



Dr. Hîng-ka Lîm

We cut the indwelling umbilical vein catheter and exchanged to a 4 Fr introducer sheath by a guidewire. We put a 4 Fr Judkins Right 4 diagnostic angiography catheter (Cordis, Miami Lakes, FL, USA) in the right atrium and crossed the PDA with two Sion guidewires (Asahi Intecc Medical, Aichi, Japan) and anchored at the descending aorta. A 4 Fr Amplatzer™ TorqVue™ LP delivery system was then exchanged and was placed at the aortic end of the PDA. Hand injection angiography showed a tubular shaped PDA, 3.5 mm in diameter (Figure 2A and 2B). An Amplatzer Piccolo™ Occluder 5-2 mm was then deployed at the PDA. Subsequent hand injection angiography revealed no obstruction of the left pulmonary artery (Figure 2C and 2D). Immediate transthoracic echocardiography (TTE) revealed neither coarctation nor stenosis of the left pulmonary artery (Figure 1C and 1D). Her blood pressure increased from 55/28 mmHg to 81/38 mmHg. Due to severe bronchopulmonary dysplasia, she had prolonged intubation and mechanical ventilation. She was extubated on postnatal day 68 and was discharged on day 131 (postmenstrual age 45 2/7 weeks). There was neither pulmonary artery nor coarctation of the aorta on the follow-up TTE one year after discharge.

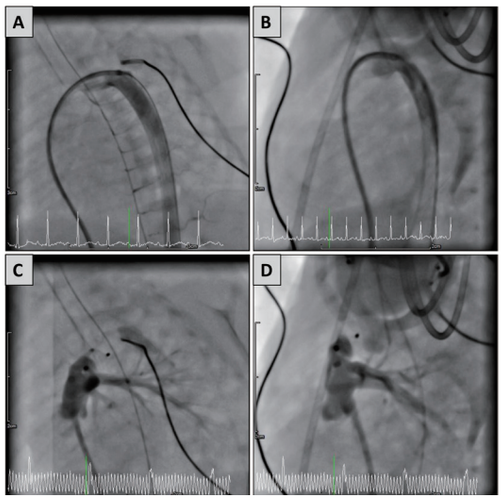



**Figure 2:** Angiography before and after Amplatzer Piccolo™ occluder deployment. (A) Angiography of the patent ductus arteriosus (PDA) with the 4 Fr Amplatzer TorqVue LP delivery sheath at the aortic end of the PDA (four chamber view). (B) Angiography of the PDA with the 4 Fr Amplatzer TorqVue LP delivery sheath at the aortic end of the PDA (lateral view). (C) No left pulmonary artery stenosis shown on angiography of the pulmonary arteries after Amplatzer Piccolo™ Occluder deployment (four chamber view). (D) No left pulmonary artery stenosis shown on angiography of the pulmonary arteries after Amplatzer Piccolo™ Occluder deployment (lateral view).

## CASE DISCUSSION

Amplatzer Piccolo Occluder is currently the first and the only occluder approved for transcatheter closure of premature infants in Taiwan. Previous clinical trial proved its high successful rate and low complication rate in infants between 700 g and 2 kg.[3] However, major procedural complications may still happen, and may be fatal if not optimally managed.[4] Among them, left pulmonary artery stenosis and coarctation of the aorta may not appear immediately
and could progress after the procedure due to device deformation.[5] Appropriate selection of the size of the Amplatzer Piccolo™ Occluder and intraductal placement are crucial to avoid those complications.[4]

Umbilical vein is a natural route for catheterization without an extra puncture wound. If an indwelling umbilical vein catheter is inserted soon after birth, umbilical vein could be a choice for transcatheter closure of PDA.[6] In our experience, it must be very careful while inserting the introducer sheath to make sure not to injure the heart. Since the ductus venosus is draining superoposteriorly, it is less easy for the operator to rotate the catheter anteriorly and direct the guidewire toward the right ventricle than sheath insertion through the femoral vein.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## CONCLUSION

In conclusion, the case presented demonstrates that transcatheter closure of PDA with Amplatzer Piccolo™ Occluder through the umbilical vein is a safe and effective option for premature infants, despite the technical challenges associated with the use of Amplatzer Piccolo™ Occluder in extremely premature infants. Careful selection of the size of the device and intraductal placement are crucial to avoid complications such as left pulmonary artery stenosis and coarctation of the aorta. The use of the umbilical vein as a natural route for catheterization without an extra puncture wound is feasible, but requires careful manipulation to avoid heart injury. Overall, transcatheter closure of PDA with Amplatzer Piccolo™ Occluder through the umbilical vein should be considered as a viable option for premature infants with PDA.

**CASE #10 – TAIWAN:** TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS WITH AMPLATZER PICCOLO™ OCCLUDER IN AN EXTREMELY PREMATURE NEONATE THROUGH THE UMBILICAL VEIN


All content provided by Dr. Hing-ka Lîm*, Hsi-Chuan Hung unless otherwise noted.





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CASE #11

# TRANSCATHETER CLOSURE OF LARGE CONICAL-SHAPED PATENT DUCTUS ARTERIOSUS USING AMPLATZER PICCOLO™ OCCLUDER IN A YOUNG INFANT: TIPS AND TRICKS

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## ABSTRACT

In young infants with large conical-shaped PDA, device closure can be challenging. Amplatzer Piccolo™ Occluder, which is an ideal device for preterm infants with tubular-shaped PDA, can also be used in selected infants with large conical-shaped PDA. In this report, I would like to share one of my previous case experiences, as well as the process of decision-making related to the intervention.

## INTRODUCTION

Device closure of large PDA in full-term infants can be even more challenging than the procedures performed in preterm neonates. Comparing to the PDA in preterm neonates, whose PDA is usually tubular-shaped, PDA in full-term young infants can vary widely. Many of them had a conical-shaped PDA, while the aortic and pulmonary ampulla were not large enough to accommodate the retention discs of Amplatzer™ Duct Occluder I (ADO I) or Amplatzer™ Duct Occluder I II (ADO II). Based on manufacturer's recommendations, neither ADO I nor ADO II were suitable for the use in infants < 6 months and weighing < 6 kg. The availability of Amplatzer Piccolo occluder (Abbott Structural Heart, Plymouth, MN) has not only pushed the boundaries of transcatheter closure of PDA to low-weighed preterm infants, but also provided new treatment options for full-term young infants with large PDA, even when the shape of PDA does not perfectly fit the device.[1]

## CASE PRESENTATION

A 2-month-old, full-term baby girl was referred to our hospital because of intractable PDA-related heart failure.

She was only 4 kg at the time of admission (< 3rd percentile). Cardiac examinations revealed a grade 3/6 continuous murmur at left upper sternal border with marked bounding femoral pulse. Echocardiography showed a conical-shaped PDA with narrowest diameter at pulmonary end of 3.5 mm in diameter (**Figure 1A**). The pressure gradient of the tricuspid regurgitation was 91 mmHg, suggestive of significant pulmonary hypertension.

She was brought to the cardiac catheterization laboratory attempting for transcatheter PDA closure. Under general anesthesia and endotracheal intubation, both femoral artery and vein were cannulated and 4Fr sheaths were placed. Descending aortogram showed a long and conical-shaped PDA. The length was 9.2 mm, and the diameters at pulmonary end, mid-portion, and aortic ampulla were 3.2 mm, 4.0 mm, and 5.5 mm, respectively (**Figure 1B**).

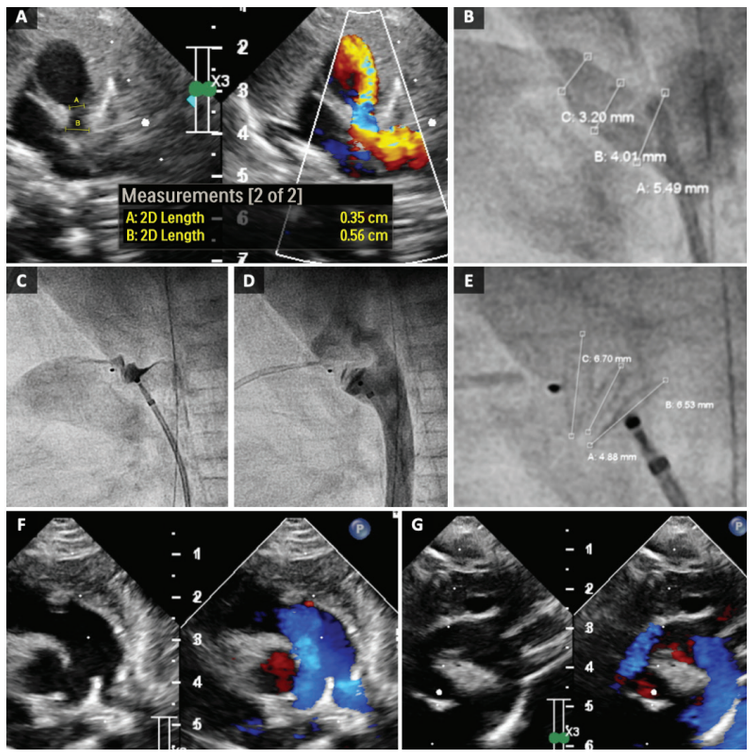


**Figure 1:** (A) Transthoracic echocardiography showed a large conical-shaped PDA. (B) The morphology and the measurements of the PDA on descending aortogram. (C) Before detaching the Piccolo occluder (5/2), manual injection of the contrast confirmed that the entire device was placed inside the ductus. (D) There was no residual shunt immediately after device detachment. (E) The device kept its nominal diameters inside the ductus.

Dr. Chen Chun-An

There was a small and short pulmonary ampulla.
The pulmonary-to-aortic flow ratio was estimated at 4.9.
To ensure that the entire device was well packed inside the PDA (rather than retention disc protruding to the pulmonary ampulla), we used retrograde approach.
A 4Fr Amplatzer™ TorqVue™ LP Catheter was inserted through the femoral artery sheath, and advanced across the PDA over 0.035 Terumo guidewire. Then the delivery catheter was pulled back slowly till the tip of the catheter passed the narrowest part of the PDA (pulmonary end).
An Amplatzer Piccolo™ Occluder 5/2 was placed.
Before release, echocardiography and manual injection of contrast through the TorqVue LP catheter both revealed the device sitting nicely at the desired position (**Figure 1C)**. There was immediate occlusion of the ductus after detaching the device (**Figure 1D**), without any compromise to the aortic or left pulmonary artery blood flow. Interestingly, although we oversized the device and put the entire device inside the ductus, the device still kept its nominal diameters of retention discs and central lobe (**Figure 1E**).

The patient was discharged home uneventfully 3 days after the procedure. She experienced marked catch-up in somatic growth in the next few months. After 2 years of follow-up, the aortic arch and left pulmonary artery remained fully patent (**Figure 1F and 1G**).

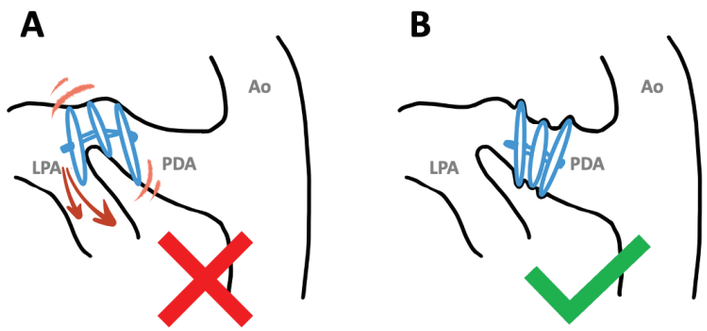


**Figure 2:** A) In conical-shaped PDA, protrusion of the retention disc of Piccolo occluder (blue) to the pulmonary artery might increase the risk of device embolization, and obstruction to the left pulmonary artery (LPA) blood flow. (B) Packing the entire device inside the PDA could minimize the risks of procedural complications. Ao=aorta.

## CASE DISCUSSION

In my personal practice, if the preterm infant was < 2.5 kg and the PDA was long and straight on procedural echocardiographic assessment, placement of Amplatzer Piccolo occluder is always conducted exclusively from venous approach (no arterial puncture).
Sometimes the whole procedure can be guided solely by echocardiography and fluoroscopy without using any contrast agents. However, for full-term infants with large and nontubular PDA, my personal preference is to get a descending aortogram with the catheter tip placed at aortic isthmus to have a better understanding about the exact morphology of PDA.

The retention discs of Amplatzer Piccolo occluder were much smaller than ADOI and ADO II, and the Piccolo occluder comes with various length selections.
Considering about patient's weight and a relatively small aortic ampulla, arch obstruction should not be a problem if a short Piccolo occluder was used. However, left pulmonary artery obstruction remained a concern if the device is placed across the narrowest part of the PDA (Figure 2A). Furthermore, the major disadvantage of using Piccolo occluder in conical-shaped PDA is insufficient device stability. Therefore, we chose the shortest Piccolo occluder (2mm long) and packed all three parts of the device inside the PDA (Figure 2B), like the way we used in preterm neonates with tubular PDA.[2] In addition, we purposely oversized the device in order to maximize the device stability. Delivery from femoral artery further ensured the position of pulmonary retention disc, which is the major determinant of final device position.


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## CONCLUSION

In selected infants with large conical-shaped PDA, device closure using Amplatzer Piccolo occluder can be a feasible option. In contrast to relatively standardized procedures in preterm PDA closure, modifications in landing zone selection, device size selection, and deployment technique might be required in each individual case to minimize the risk of adjacent vessel obstruction and device embolization.



All content provided by Dr. Chun-An Chen unless otherwise noted.

CASE #12

# TRANSCATHETER CLOSURE OF DUCTUS ARTERIOSUS WITH AN AMPLATZER PICCOLO™ OCCLUDER IN A PREMATURE INFANT WITH ACUTE PULMONARY HEMORRHAGE AND COMPLICATED WITH PNEUMOTHORAX

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National Cheng Kung Hospital, Taiwan

## INTRODUCTION

Patent ductus arteriosus (PDA) among premature infants plays a role in hemodynamic instability and may be responsible for prematurity-related complications. Supportive therapy or medical therapy is the initial strategy for PDA management. However, invasive interventions have been required for hemodynamic-significant PDA (HS-PDA) when medical treatment has failed. To date, invasive interventions for PDA have included surgical ligation or transcatheter closure. Although surgical ligation via lateral thoracotomy has been a well-established procedure for decades, yet several adverse impacts on ventilator dependency and correlation to a higher incidence of severe bronchopulmonary dysplasia were reported [1]. The pulmonary benefits of transcatheter occlusion deserve more clinical attention. We therein reported our experience in transcatheter closure of PDA in a premature baby with acute pulmonary hemorrhage and complicated with pneumothorax, highlighting the procedure's potential as an alternative to surgery.

## CASE PRESENTATION

We present the case of a premature baby born at the gestational age of 26 weeks weighing 766 grams at birth. The baby had been having the problem of respiratory distress syndrome (RDS) status post intubation with mechanical ventilator then nasal continuous positive airway pressure (CPAP) on day 23 (**Figure 1A**). PDA (diameter size 0.26 cm) was found and indomethacin was given for 3 courses but still persisted hemodynamic significant. On day 24, acute pulmonary hemorrhage with desaturation was noted (**Figure 1B**), and the pulmonary hemorrhage improved after supportive management on day 26 (**Figure 1C**). Acute desaturation was noted again on day 27, and chest X-ray revealed left pneumothorax (**Figure 1D**), therefore pigtail catheter drainage was done (**Figure 1E**). After supportive management, the chest X-ray still revealed coarsening of bilateral bronchovascular bundle with fine granulation of lung parenchyma (**Figure 1F**). Repeated echocardiogram also revealed hemodynamic significant PDA (diameter size: 0.34 cm) (**Figure 2**). Due to poor lung condition with extremely high setting of the ventilator and failure of response to medication, our team suggested PDA closure by transcatheter approach or surgical closure. However, neonatologists and cardiac surgeons both considered the difficulties in ventilation during surgical ligation. Transcatheter approach was chosen after shared decision-making. On the day 36, the body weight was 836 grams. This patient was transported to catheterization room, and the procedure was done as our previous report [2]. In brief, we set up one route from left femoral vein via a 4F Merit Prelude sheath (Merit Medical Systems Inc., South Jordan, UT, USA) sheath. A 4F Judkins right (JR) coronary catheter (Cordis, Fremont, CA, USA) was positioned at the inferior vena cava and right atrial junction. We steered a 0.014-inch Runthrough™ floppy guidewire (Terumo, Tokyo, Japan) across the right heart and placed it in the descending aorta to guide the JR catheter into the descending aorta. Hand injection ductal angiograms were performed in the lateral view and right anterior oblique views through the catheter positioned at the aorta end of PDA to define the PDA size. The PDA size measured by angiogram was 3.1 mm in width, and 6.8 mm in length (**Figure 3A & B**). An Amplatzer Piccolo™ Occluder (4x4mm) occluder was deployed (**Figure 4A & B**). Follow up echocardiogram also revealed minimal residual shunt without pulmonary artery or aorta obstruction (**Figure 5A & B**). After the procedure, endotracheal tube was removed at day 40, and discharge without oxygen supplement. This patient now is 6 years old with normal cardiopulmonary status.

Dr. Jieh-Neng Wang

## CASE DISCUSSION

Performing transcatheter PDA closure in symptomatic premature infants weighing more than 478 g is feasible using currently available devices [2]; moreover, the procedure serves as an alternative to surgery. The several potential benefits of transcatheter occlusion should be addressed, as it is less complicated than surgical ligation. Our data had shown the tendency toward earlier improvement in the respiratory trajectory could still be observed when compared with surgical ligation [3].
As a result of PDA ligation's adverse impact on ventilator dependency and correlation to a higher incidence of severe bronchopulmonary dysplasia (BPD), infants receiving this treatment have been reported to suffer from diaphragmatic paralysis due to phrenic nerve injury. Therefore, compared with the transcatheter approach, surgery for PDA in extremely preterm infants is associated with severe BPD at discharge [4]. However, the transcatheter technique has been associated with some potential risks, including hypothermia, device migration, vascular injury, left pulmonary artery stenosis, and the coarctation of the aorta [5]. Future research with larger case numbers should be conducted to address the role of transcatheter approach in more detail.

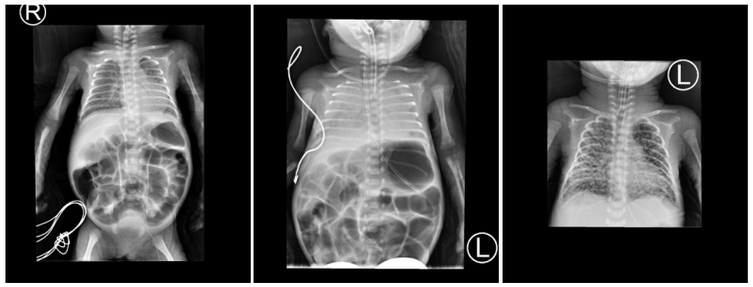


Figure 1A | Figure 1B | Figure 1C

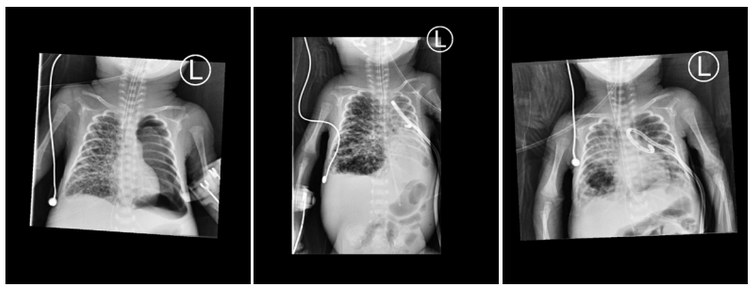


Figure 1D | Figure 1E | Figure 1F

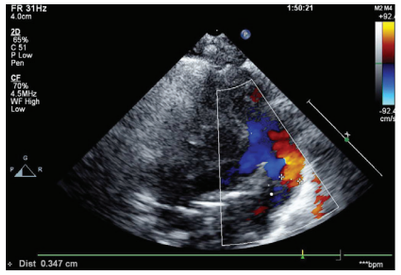


Figure A

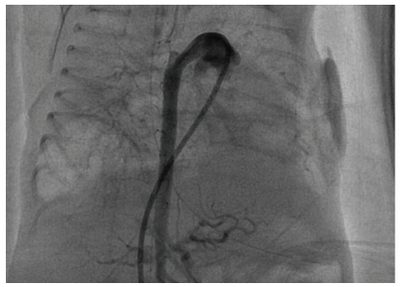

Figure 3A

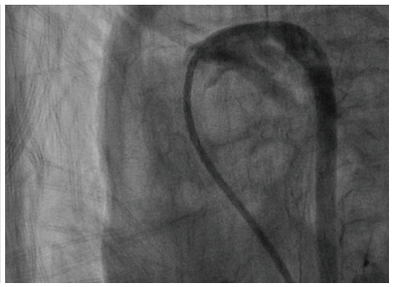

Figure 3B

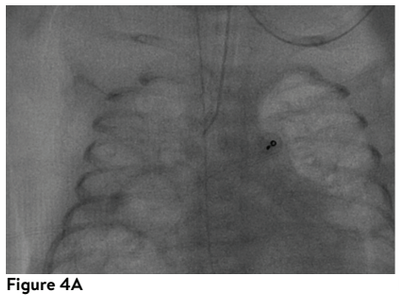

Figure 4A

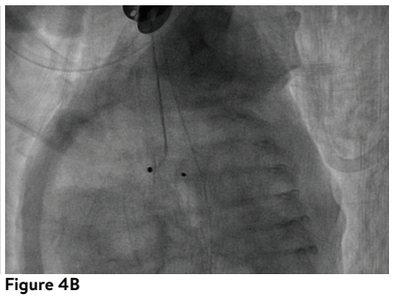

Figure 4B

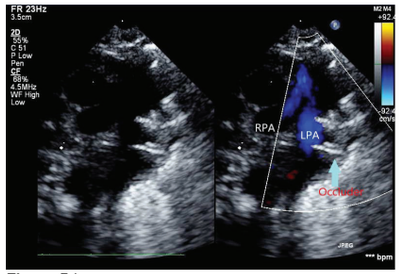


Figure 5A

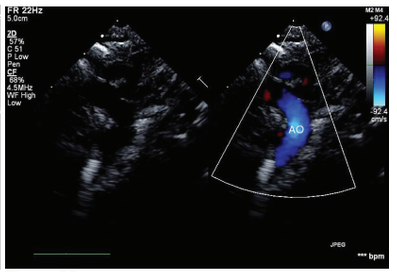


Figure 5B


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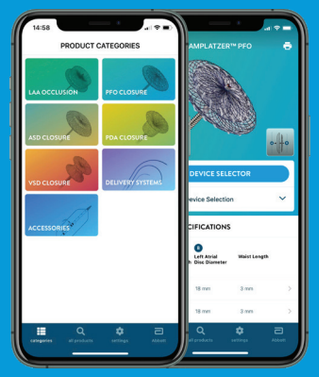
## CONCLUSION

Transcatheter PDA closure in symptomatic premature infants is feasible using the Amplatzer Piccolo™ Occluder. A tendency toward earlier improvement in the respiratory trajectory could be observed. However, case by case evaluation and team approach could be the best benefits for the premature babies.

**CASE #12 – TAIWAN:** TRANSCATHETER CLOSURE OF DUCTUS ARTERIOSUS WITH AN AMPLATZER PICCOLO™ OCCLUDER IN A PREMATURE INFANT WITH ACUTE PULMONARY HEMORRHAGE AND COMPLICATED WITH PNEUMOTHORAX

All content provided by A/Prof. Jieh-Neng Wang unless otherwise noted.

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