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Review

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Transcatheter closure of patent ductus arteriosus: review of author's experiences and observations

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Abstract

Patent ductus arteriosus (PDA) is a congenital cardiac defect (CCD) and comprises 8% to 10% of all CCDs. Following the description of surgical closure by Gross and colleagues in the 1930s, it has become a standard mode of therapy and remained so until the description of transcatheter techniques to occlude PDA by Porstmann, Rashkind and their associates in the late 1960s. This review paper discusses transcatheter occlusion techniques with buttoned devices, *Giantuco coils*, and Amplatzer devices with particular attention to author's contributions to these methods.

Keywords: Patent ductus arteriosus, transcatheter occlusion, buttoned device, *Gianturco coil*, Amplatzer duct occluder, residual shunts, aortic coarctation

INTRODUCTION

The ductus arteriosus is a vascular muscular channel connecting the pulmonary artery (PA) with the descending aorta (DAo) at the level of the left subclavian artery (LSA). It facilitates the transport of the unoxygenated blood from the PA into the placental circulation for picking up oxygen in the fetus[1-4]. It obliterates naturally shortly following birth[1-4]. If this structure is patent beyond 72 h after birth, it is defined as patent ductus arteriosus (PDA)[5]. Although other shapes[6] are also well recognized, most often the PDA is conical in shape and is broader on the aortic end (ampulla) and smaller on the pulmonary end [Figure 1].

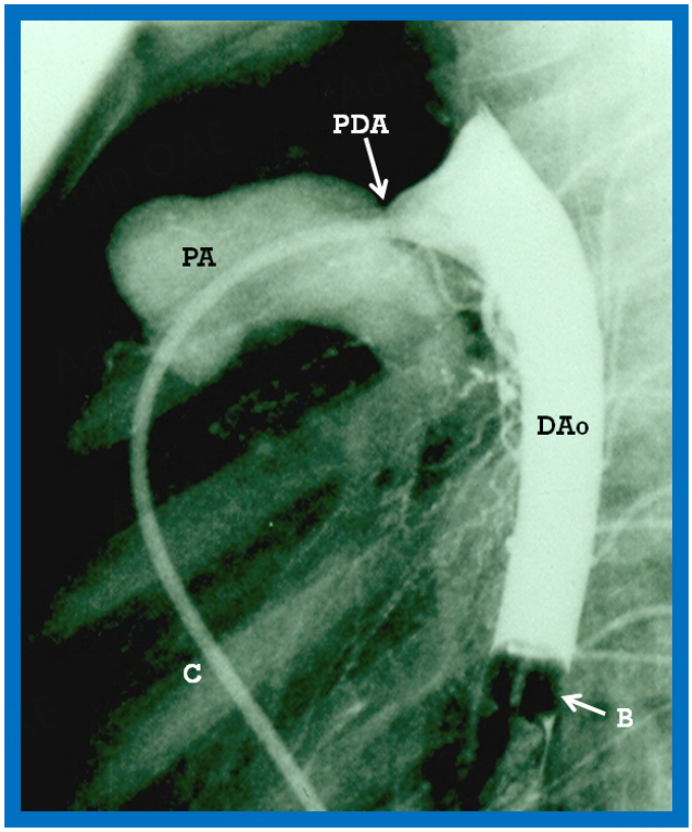

Figure 1. Selected frame from a cine-angiogram in the lateral view by balloon (B) occlusion (lower arrow) aortography, demonstrating patent ductus arteriosus (PDA). The catheter (C) is placed into the descending portion of the aorta from the main pulmonary artery (PA) via the ductus. Note conical or funnel shape of the PDA with a wider aortic end (ampulla) and smaller pulmonary end (upper arrow). DAo: Descending aorta. Reproduced from Ref.[7].

The prevalence of isolated PDA is approximately 0.05% of full term live births and the condition is found in 8%-10% of patients with congenital cardiac defects (CCDs), although a much higher incidence is seen in the premature babies[5]. Shunting from the aorta to the PA occurs through the PDA which causes dilatation of the left heart. The degree of hemodynamic abnormality is closely proportionate to the minimal ductal diameter and inversely related to the length of the PDA. The main and branch PAs are also dilated. A review of the pathology and pathophysiology as well as clinical presentation including characteristic findings in chest roentgenogram, electrocardiogram, echocardiogram, and angiogram of PDA were reviewed previously[8-10] and will not be discussed here except for demonstrating echo-Doppler features of the PDA [Figure 2].

Surgical closure was the conventional treatment of choice for PDAs since its description by Gross and Hubbard in 1938[12] and stayed so till the general acceptance of the transcatheter methods devised by Porstmann and his associates as well as by Rashkind and his colleagues[13-16] became clinically applicable[17]. In this paper, issues related to transcatheter occlusion of PDAs, with a particular focus on author's contribution to this procedure, will be reviewed.

INDICATIONS FOR PDA CLOSURE

The indication for the occlusion of a ductus is the existence of a continuous murmur indicative of a patent ductus, along with substantiation by echocardiography. PDA closure is not advised in patients with "silent

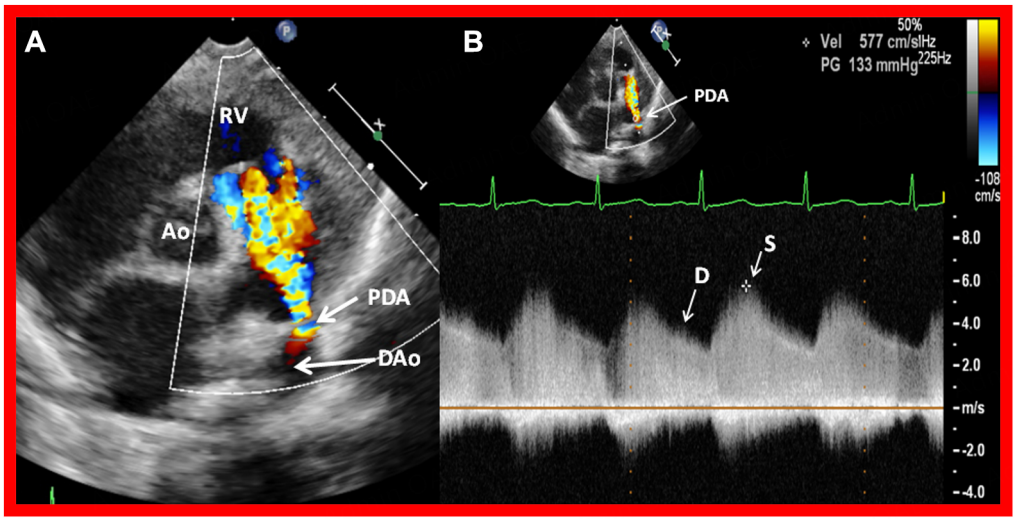

Figure 2. Echocardiographic study demonstrating various features of a medium-sized patent ductus arteriosus (PDA). (A) shows shunting from the descending aorta (DAo) into the pulmonary artery across the ductus. (B) shows Doppler features of the PDA. Note high Doppler velocity of approximately 4 m/s by continuous wave Doppler, suggesting that the pressure in the pulmonary artery is low. Ao: Aorta; D: diastolic; RV: right ventricle; S: systolic. Reproduced from Ref.[11].

ductus" found by chance without classic auscultatory findings. It is agreed that very small and small PDAs [Figure 3][18] without a hemodynamic burden ought to be occluded to avoid infective endocarditis. PDAs which are moderate to large [Figure 3][18] are also candidates for closure to avoid additional volume overload of the left heart, provide treatment of heart failure, and to avert development of pulmonary hypertension, as well as to eliminate the risk of endocarditis.

Catheter-based PDA occlusion in premature babies has not been regularly undertaken previously secondary to dimension of the device delivery catheter (sheath) restraints and the possibility of dislodgment of the device. Many of these problems have been solved to a great degree, facilitating transcatheter closure in this group of patients. Premature infants with medium to large PDAs by echocardiographic criteria[5,10] with deterioration in clinical status, who increasingly need additional intensive management of ventilatory status and require frequent therapy with diuretic medications, or who are failing to wean from ventilatory settings (hemodynamically significant PDAs) are initially managed with fluid restriction and other conservative measures, followed by therapy with Prostaglandin E_1 (PGE_1) inhibitors such as ibuprofen or indomethacin. A failure of these interventions to close the PDA calls for surgery (thoracotomy in the operating room or bedside or by video-assisted thoracoscopic [VATS]) or percutaneous closure of the PDA, largely based on the expertise at a given institution.

HISTORICAL ASPECTS OF PDA OCCLUSION

Following the initial report by Gross of surgical occlusion of PDA in 1939[17], surgical intervention was utilized in the management of patent ductus. Surgery met the standards of safety and effectiveness with rare problems. Surgery has remained treatment of choice until the wider application of transcatheter closure methods proposed by Porstmann, Rashkind and their associates[13-16]. The historical aspects of transcatheter closure of PDAs were examined by the author previously[19-22]. A summary will be presented here. Porstmann[13,14] devised a PDA closing technique in the late 1960s in a pioneering effort. His efforts stimulated other investigators in developing other transcatheter methodologies for PDA occlusion. Porstmann's device consists of an Ivalon foam plug which is conical in shape [Figure 4A]. The foam plug is custom made for each patient based on the angiographic appearance (in the lateral view) of the PDA. A

Type	Description
Silent PDA	Usually less than 1.5 mm* without audible murmur of PDA
Very small PDA	≤1.5*; a murmur of PDA is present
Small PDA	1.5-3.0 mm*; a murmur of PDA is present
Moderate PDA	3-5 mm*; a murmur of PDA is present
Large PDA	>5 mm*; a murmur of PDA is present

*minimal ductal diameters on lateral cineangiographic view.
PDA = patent ductus arteriosus.

Figure 3. Categorization of ductus arteriosus based on its size. PDA: Patent ductus arteriosus. Modified from Ref.[18].

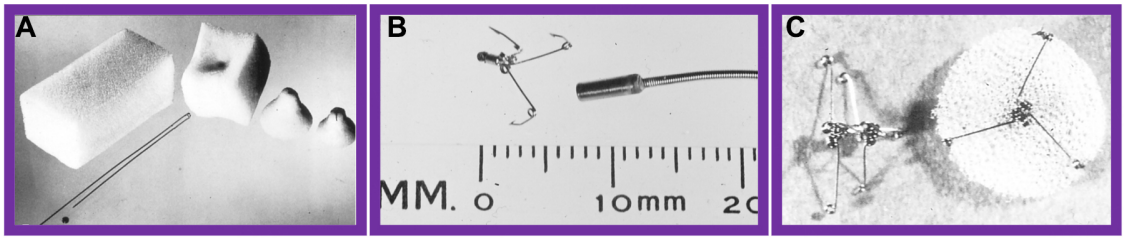

Figure 4. (A) Photograph of Porstmann's Ivalon foam plug. (B) Photograph of Rashkind's hooked patent ductus arteriosus device. (C) Photograph of twin umbrella occluder of Rashkind.

little more than a decade later, Rashkind[15] described another PDA-occluding device which consists of an umbrella-like skeleton covered with polyurethane foam; miniature fish hooks were attached to the arms of the stainless steel skeleton [Figure 4B]. Because of several difficulties with this hooked PDA occluder, Rashkind addressed these problems by changing it into a two-disc device and by eliminating the hooks[16,23,24]. The re-designed device is made up of two umbrellas with three stainless steel arms covered with polyurethane foam [Figure 4C]. This PDA occluder is implanted via femoral venous route. The first umbrella is positioned on the aortic side of the ductus while the second umbrella is positioned on PA side of the PDA. Preliminary experiments in calf models by Rashkind[16] and subsequent multicenter FDA clinical trial[24] seem to yield relatively satisfactory outcomes. But the FDA did not eventually approve the device for clinical use.

Several additional ductal occluding devices were fabricated and utilized in animal experiments, but without undergoing human trials; these were tabulated elsewhere[21] for the interested reader. Many other devices have undergone clinical trials in patients, and most of the devices were evaluated in animal experiments before human trials began. These are listed in Table 1.

DEVICE CLOSURE OF PDAS WITH BUTTONED DEVICE

Introduction

Buttoned device for PDA occlusion (Custom Medical Devices, Athens, Greece and Amarillo, Texas) was initially described by Sideris and his associates in 1990 including its use in piglets to close PDAs[26]. PDA closure with this device in children was first reported by Rao and associates in 1991[27]. Subsequently clinical

Table 1. PDA occluding devices which have undergone clinical trials

Name of the device	Author(s) and ref.	Year of publication
Ivalon foam plug	Porstmann *et al.*,[13,14]	1967, 1971
Umbrella covered with polyurethane foam and miniature fish hooks	Rashkind and Cuaso[15]	1979
Rashkind's double umbrella device	Rashkind[16]	1983
Botalooccluder	Savel'ev *et al.*,[25]	1984
Buttoned device	Sideris, Rao *et al.*,[26-28]	1990, 1991, 1993
Clamshell septal umbrella	Bridges *et al.*,[29]	1991
Gianturco coil	Cambier *et al.*,[30]	1992
Duct occlud pfm	Lê *et al.*,[31]	1993
Cook and Flipper detachable coils	Cambier, Uzun, Tometzki *et al.*,[32-34]	1994, 1996
Gianturco-Grifka vascular occlusion device	Grifka *et al.*,[35]	1996
Infant buttoned device	Sideris *et al.*,[36]	1996
Polyvinyl alcohol (Ivalon R) foam plug	Grabitz *et al.*,[37]	1997
Amplatzer duct occluder	Masura *et al.*,[38]	1998
Folding plug buttoned device	Rao *et al.*,[39]	1999
Wireless PDA devices	Sideris *et al.*,[40,41]	2007, 2001
Reinforced duct-occlude pfm	Lê *et al.*,[42]	2001
Amplatzer muscular ventricular septal defect occluder	Thanopoulos *et al.*,[43]	2002
Amplatzer vascular plug	Hoyer[44]	2005
Nit-Occlud coils	Celiker *et al.*,[45]	2005
Inoue single-branched stent graft	Saito *et al.*,[46]	2005
Nonferromagnetic Inconel MReye embolization coils	Grifka *et al.*,[47]	2008
Amplatzer vascular plug with prefilled embolization coils	Glatz *et al.*,[48]	2008
Self-expanding platinum-coated Nitinol device (Cocoon device)	Lertsapcharoen *et al.*,[49]	2009
Chinese self-expandable occluder, like the Amplatzer occluder	Yu *et al.*,[50]	2009
Amplatzer vascular plug II	Cho *et al.*,[51]	2009
Cardio-O-Fix occluder	Białkowski *et al.*,[52]	2010
Nit-Occlud PDA-R (reverse) device	Peirone *et al.*,[53]	2011
Amplatzer vascular plug IV device	Prsa and Ewert[54]	2011
Amplatzer duct occluder II	Karagöz *et al.*,[55]	2012
Amplatzer duct occluder II -additional sizes (also called ADO II AS and Amplatzer Piccolo Occluder)	Agnoletti *et al.*,[56]	2012
TAG stent graft	Fujii *et al.*,[57]	2012
Amplatzer septal occluder	García-Montes *et al.*,[58]	2015
Occlutech duct occluder	Abdelbasit *et al.*,[59]	2015
Cera PDA occluder	Rohit and Gupta[60]	2017
Fenestrated muscular VSD occluder	Güvenç *et al.*,[61]	2017
MedtronicMicro vascular plug	Wang-Giuffre *et al.*,[62]	2017

PDA: Patent ductus arteriosus.

trials of PDA occlusion with this device both in children[28,39] and adults[63,64] were published. These will be reviewed in brief.

Some of the more commonly used PDA occluding devices are shown in Figure 5.

Device description

The PDA buttoned device is made up of three parts, namely, occluder, counter-occluder and delivery arrangement [Figure 6].

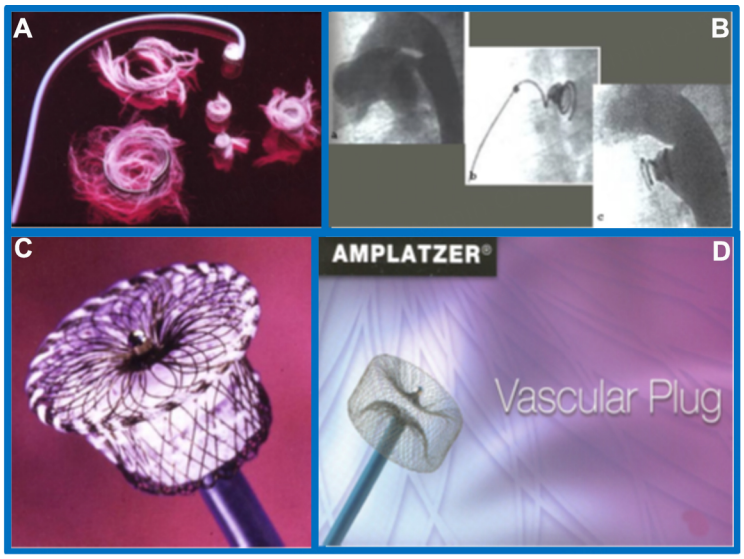

Figure 5. Photographs of Gianturco coils (A), Nit-Occlud (B), Amplatzer duct occluder (C), and Amplatzer vascular plug (D) are shown.

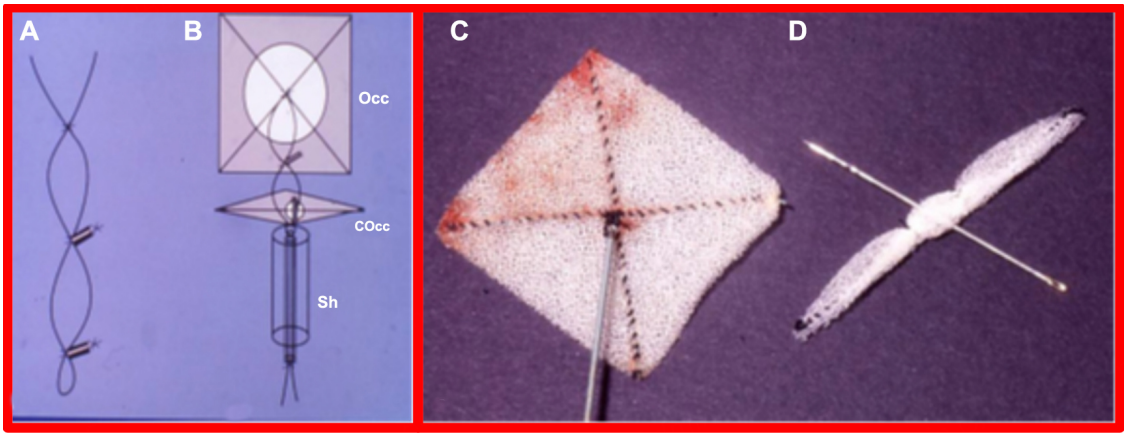

Figure 6. (A and B) Cartoon of the buttoned device. (C and D) Photograph of the buttoned device. (A) shows button loop. (B) details components of the device. © shows occluder (Occ), (D) depicts counter-occluder (COcc). Sh: sheath.

The occluder comprises of X-shaped stainless steel arms coated with Teflon. Polyurethane foam (1/16″ thick) covers the wire skeleton [Figures 6B and C]. An eight mm string loop is connected to the middle of the occluder [Figure 6A and B]. The string loop has two spring buttons (knots), four mm and eight mm from the occluder [Figures 6A and B]. Radiopaque material is incorporated into both buttons. The counter-occluder is made up of one stainless steel arm which is coated with Teflon and covered with polyurethane foam. A latex rubber material is sewn into the center of the counter-occluder which turns into a buttonhole [Figure 6B]. The device is delivered with the aid of (1) A 0.035″ Teflon-coated wire (Cook, Inc., Bloomington, IN) with its core taken out; (2) A folded 0.008″ nylon thread that goes through the wire described in item 1. The nylon thread also goes through the lower section of the button loop fastened to the middle of the occluder [Figure 6B]; (3) A 7-French marker blue Cook sheath (Cook, Inc.) through which the device is delivered; and (4) A #6F or #7F catheter that is utilized to push the occluder and counter-occluder through the long sheath.

Technique of device implantation[28,39]

Following cardiac catheterization, aortography is undertaken in lateral and 30° right anterior oblique (RAO) projections to delineate the minimal ductal diameter and shape of the ductus. Either a pigtail catheter (Cook Inc.), introduced retrogradely via the femoral artery, or balloon occlusion angiography [Figure 1] are used for this purpose. Heparin (one hundred units/Kg) is administered after percutaneous insertion of catheters and activated clotting times (ACTs) exceeding 200 s are maintained by additional doses of heparin, as necessary. A #5F multipurpose catheter (Cordis Corp., Miami, FL) is placed trans-venously thru the ductus into the descending portion of the aorta. An exchange-length (0.035″), extra-stiff Amplatz guide wire with a J-tip (Cook Inc.) is placed in the DAo, and the catheter is taken out. A #7-French long blue Cook sheath (Cook Inc.) is threaded over the guide wire and its tip sited in the DAo. The sheath is flushed. If the device is bigger than 20 mm, a #8F sheath is utilized instead. Detailed description of the device delivery across the ductus is described in our prior publications[27,28,39,63,64] and will not be reviewed here, given the fact that the device is no longer accessible for medical use as stated in the "Status of the Buttoned Device" section.

Outcomes of buttoned device closure of PDA

The first successful use of buttoned device to occlude a ductus was in a child aged five years, demonstrated both by angiography as shown in Figure 7 and by echo-Doppler study as illustrated in Figure 8[27].

In the initial clinical trial involving fourteen patients[39], equally impressive results were observed; some examples are illustrated in Figure 9.

In a larger multi-institutional study involving 284 patients[40], effective device insertion was accomplished in 98% of patients (278 of 284). At a follow-up of 2 years (median), re-intervention was required in 2.5% of the cases. Residual shunts were seen in some patients, but they disappeared spontaneously over time [Figure 10]. Comparable results were observed in adult subjects[63,64].

To address the residual shunts, buttoned device was redesigned by incorporating polyurethane foam folding plug to cover the button loop [Figures 11 and 12]; this resulted in complete PDA occlusion [Figure 13][39].

International clinical trial with folding plug buttoned device was undertaken in twenty patients[65]. Full occlusion of PDA was observed in 17 (85%) of twenty patients by echocardiographic examination performed on the next day after the occlusion. In the left over three subjects, residual shunts were trivial. Data on follow-up was available from 3 months to 2 years following device delivery. The data showed no evidence of complications. Full closure was seen in 95% of patients (19 of 20). We suggested that studying of a bigger cohorts of PDA subjects with a lengthier follow-up period is required to validate the preceding findings[65].

Status of the buttoned device

The results of buttoned device closure of PDAs look adequate and are akin to the other PDA occlusion devices. After the conclusion of FDA-supported medical testing, the designer of the device opted not to pursue pre-market approval (PMA) and consequently, the buttoned device was not accessible for use in patients. Based on informal discussions with the inventor of the device, the author was given to understand that it is expensive to seek PMA from the FDA (approximately one million dollars in early 2000); the inventor is a physician, not a device-manufacturing company. And, finally, the inventor's interest is purely scientific, not financial.

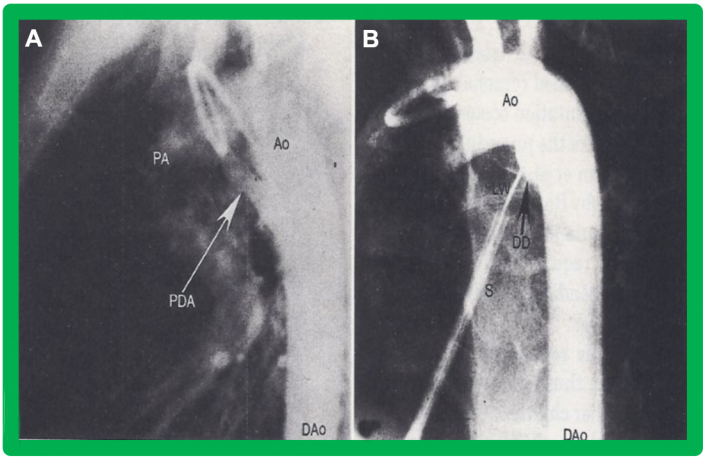

Figure 7. Lateral view angiographic frames illustrating occlusion of a ductus. In (A), aortogram performed before occlusion. The PDA is clearly seen (long arrow). In (B), after buttoned device closure, but prior to detaching the loading wire, complete closure of the PDA was demonstrated. Aorta (Ao), ductal diverticulum (DD), descending aorta (DAo), pulmonary artery (PA), patent ductus arteriosus (PDA), and sheath (S) are marked. Replicated from Ref.[27].

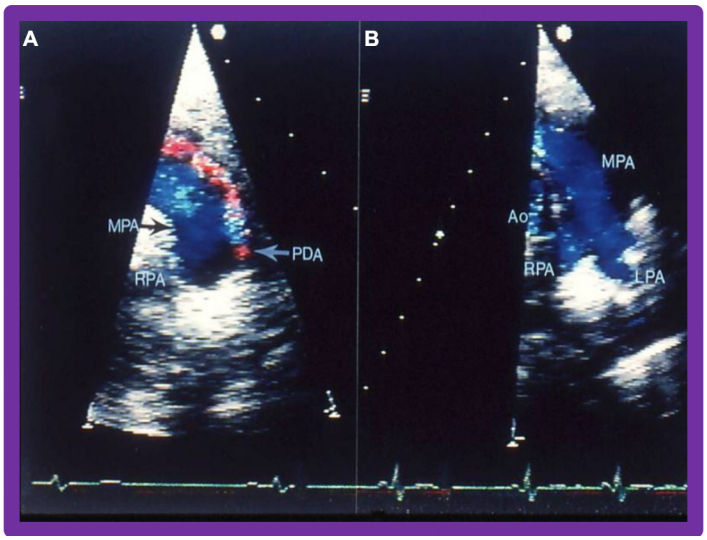

Figure 8. Echo-Doppler images illustrate complete conclusion of a patent ductus arteriosus (PDA) following placement of a buttoned device across the PDA. (A) shows PDA (blue arrow). (B) demonstrates no residual PDA with laminar flow in the main (MPA), left (LPA) and right (RPA) pulmonary arteries. Ao: Aorta. Reproduced from Ref.[27].

CLOSURE OF PDAS WITH GIANTURCO COILS

Introduction

Gianturco steel coils were originally described in 1975 for the occlusion of blood vessels supplying the kidneys[66] and have undergone several modifications. Currently, the Gianturco coils consist of stainless steel material to which Dacron material is incorporated to increase thrombogenicity [Figure 5A]. Following the first report by Cambier and colleagues in 1992[30], the occlusion of small PDAs with Gianturco coils became popular. Gianturco coils are accessible for use in patients in multiple wire sizes, lengths, and coil diameters (Cook Inc., Bloomington, IN). The manufacturer listing of the coil includes the wire diameter and length, and diameter of the coil, in that sequence. The manufacturer does not list the number of coil loops, but this can be computed by dividing the length of the coil by πD where D is the diameter of the coil loop.

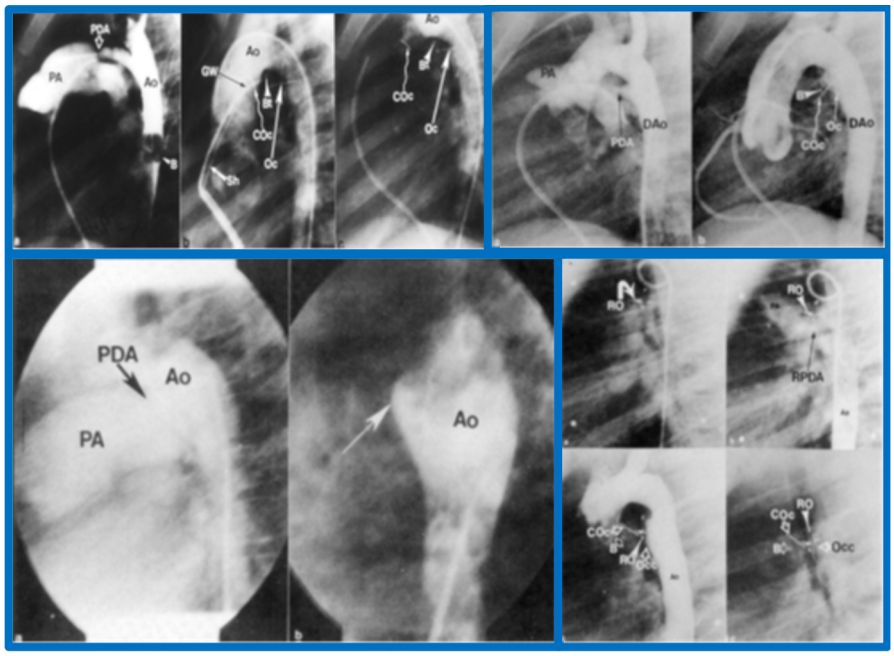

Figure 9. Selected cine frames from buttoned device occlusion of small (top left frames), medium (top right frames), and big (bottom left frames) PDAs and that following prior occlusion with Rashkind's PDA occluder (bottom right panel) are shown. PDA: Patent ductus arteriosus. Adopted from Ref.[28].

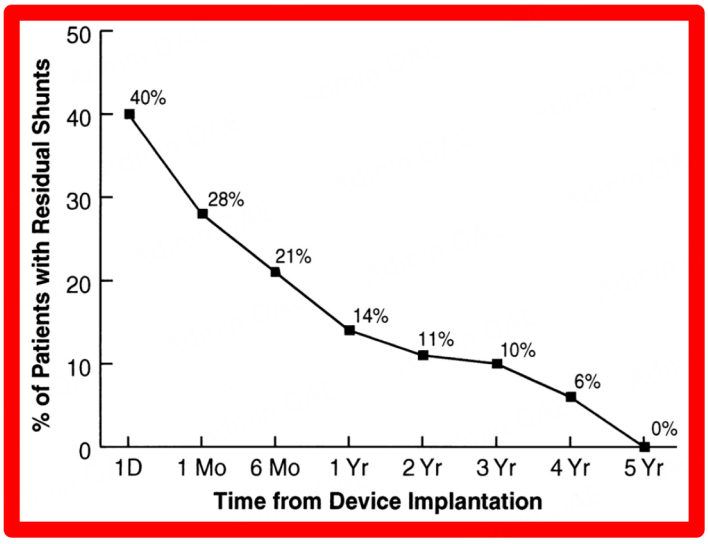

Figure 10. This graph illustrates disappearance of residual shunts in an actuarial fashion ($P < 0.01$) after occlusion of ducti with buttoned devices. Reproduced from Ref.[39].

Initially the coils were used in an off-label manner, but afterwards received approval by the FDA for closing PDAs. Gianturco coil of 0.038″ wire diameter is most utilized for PDA occlusion. Some workers, including our group used 0.052″ coils for the occlusion of moderate-sized PDAs.

Patient selection

The patient selection was like that described in the buttoned device section above. Initially, small, medium,

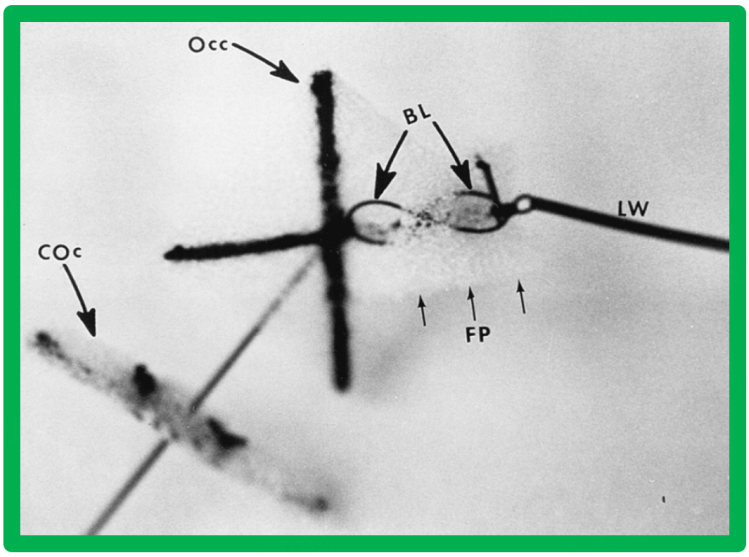

Figure 11. Picture of the re-designed buttoned device (Folding Plug Device). BL: Button loop; Coc: counter-occluder; FP: polyurethane folding plug (arrows) surrounding the BL; LW: loading wire; Occ: occluder. Reproduced from Ref.[39].

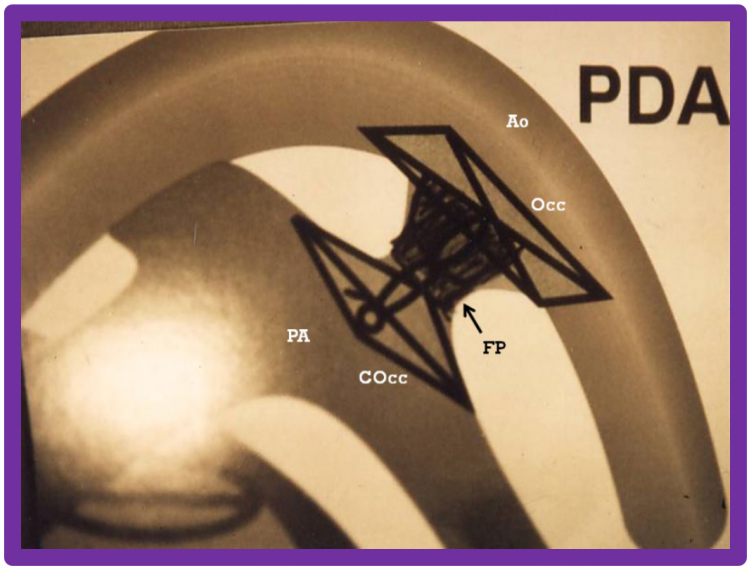

Figure 12. Artist's rendition of the folding plug (FP) buttoned device. The FP is situated within the ductus while the occluder (Occ) is on the aortic (Ao) side of the patent ductus arteriosus (PDA) and the counter-occluder (COcc) is situated on the pulmonary artery (PA) side of the PDA. Amended from Ref.[42].

and large PDAs were selected for coil occlusion. The medium-to-large PDAs required multiple coils or thicker (0.052″) coils. Since the availability of other PDA occluding devices, Gianturco coils are primarily used for small and very small PDAs [Figure 3].

Technique of coil implantation

The procedure of coil implantation was detailed in our prior papers[17,18,67] and the relevant features will be reviewed. Percutaneous hemodynamic study to validate the previously made diagnosis of PDA is executed. Aortogram in 30° RAO and lateral views is accomplished using #4F to #6F marker pigtail catheters. Minimal

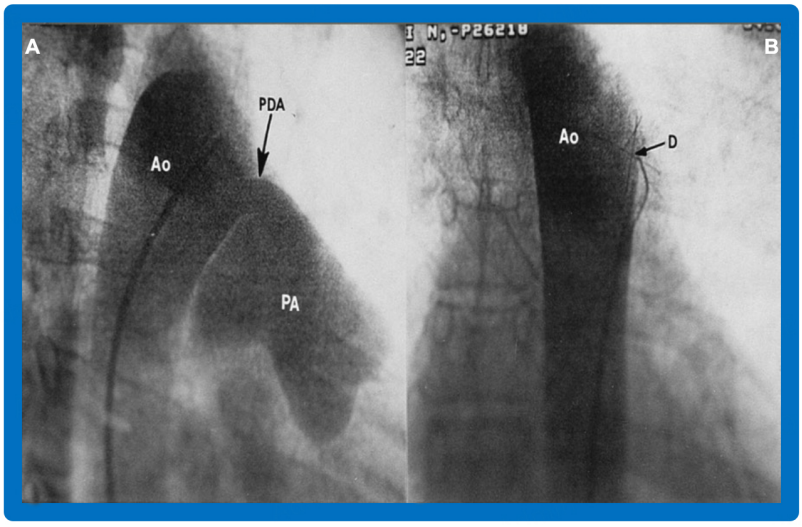

Figure 13. Chosen cine-angiographic images illustrating complete occlusion of a large ductus. In (A), a large PDA is seen. In (B), after placement of a folding plug buttoned device (D), there is complete closure of the PDA. aorta (Ao), patent ductus arteriosus (PDA), and pulmonary artery (PA) are labelled. Reproduced from Ref.[39].

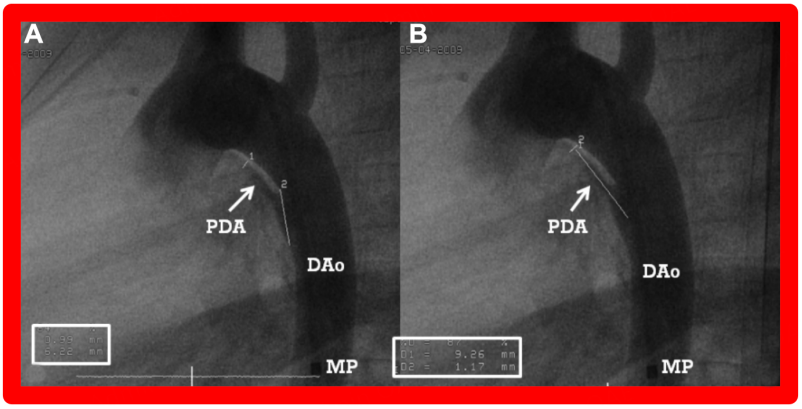

Figure 14. Selected aortic arch cine-angiographic images in lateral projections illustrating different PDA dimensions in a child with a small patent ductus arteriosus (PDA). Measurements of smallest PDA diameter in (A and B), ductal ampulla in (A), and the length of the patent ductus arteriosus (PDA) in (B) are demonstrated. DAo: Descending aorta; MP: marker pigtail catheter. Reproduced from Ref.[67].

ductal diameter, typically at the pulmonary side; dimension of the ampulla, at the aortic side; and the length of the PDA are computed [Figure 14] in both projections and averaged. These dimensions serve as a guide in the choice of the coil diameter utilized for PDA closure. The author prefers 0.038″ Gianturco coils[17,18,67-71] because they result in better occlusion when compared with 0.035″ coils.

A #4F to #6F coil delivery catheter (right coronary artery {RCA} catheter {Cordis, Miami, FL}, Glidecath catheter {Meditech, Watertown, MA}, or a similar catheter) is positioned in the main PA from the DAo through the ductus. If that is not possible, the flexible end of a 0.035″ straight guide wire (Benston {Cordis, Miami, FL}, Teflon-coated Amplatz {Cook, Bloomington, IL}, angled floppy {Meditech, Watertown, MA}, or a similar guide wire) is utilized to traverse the PDA. Once this is accomplished, the catheter is threaded over guide wire across the PDA into the PA, and the guide wire is withdrawn. The location of the catheter in the main PA is verified by measurement of pressure in the PA and, if required, a test angiogram. Angio

images secured in the straight lateral [Figure 14] and RAO projections are utilized as a reference/guide during coil implantation. The position of the tracheal shadow relative to smallest PDA diameter is also utilized to place the coil within the PDA.

The diameter of the coil that we select for implantation is two to three times that of the minimal ductal diameter. The coil length that most workers choose[17] is one that is sufficient to produce three coils, once the coil is delivered. However, we prefer a coil that has at least five loops[68,69]. The selected Gianturco coil is inserted into the coil delivery catheter with the aid of the stiff end of a 0.038″ guide wire, but is pushed forward with the soft end. While the procedure is monitored on fluoroscopy in the lateral view, one loop of the coil is placed into the PA [Figure 15A]. The guide wire is partly withdrawn, and the coil/catheter assembly is gradually withdrawn such that already delivered coil loops are drawn into the PA end of the PDA. The catheter is then withdrawn slowly into the aortic end of the ductus. The guide wire is pushed forward till it contacts the coil. The guide wire is fixed in place and the catheter is gently pulled back over the guide wire into the descending aorta, thus squeezing out the left over coil loops into the ampulla of the ductus. As a result, the implanted coil straddles the minimal diameter of the PDA. Aortography is performed fifteen minutes after coil implantation [Figures 15B]. The sequence of coil insertion in another patient is illustrated in Figure 16.

Pressure tracings across the aortic arch and oxygen saturations from the right ventricle, main PA, and the aorta are recorded. The administration of heparin (one hundred units/kg) and checking ACTs and keeping them more than two hundred seconds, and giving Ancef or a comparable antibiotic are routinely practiced for all coil implantations. No aspirin or Clopidogrel (Plavix) is administered during follow-up. Assessment of clinical features, chest roentgenogram, and echo-Doppler studies on the day following coil occlusion and at 1, 6, and 12 months after coil insertion, and yearly afterward are performed.

Several refinements and modifications of the coil occlusion procedure have taken place over time, and these are anterograde coil delivery, multiple coil implantation, snare or bioptome-assisted coil placement, the momentary occlusion of the PDA by a balloon positioned on the aortic or PA side of the ductus, the insertion of coils with five loops, coil delivery via catheters with tapered tips, PDA closure with 0.052″ coils, coil placement without administering heparin, and the use of detachable coils. These techniques are referenced elsewhere[67,70,71] for the interested reader. Several of these methods have advantages when compared with the standard free coil placement described above. However, most of the described modifications increase the complexity of coil insertion, extend the duration of the procedure including fluoroscopy time, and increase the expense. These factors should be investigated when deciding to use these modified practices. The author's opinion is that standard retrograde implantation of 0.038″ coils for very small ducti is most appropriate[7,67,70,71]. In addition, the availability of devices to occlude medium and large PDAs more effectively than with coils, delegates coil usage only for very small PDAs, as defined in Figure 3.

Advocacy for use of five loop coils

Since the report by Cambier and associates in 1992[31], several cardiologists as referenced in our paper[68], adopted this method of PDA occlusion. A review of these studies indicated occurrence of dislodgment/embolization of the coil in 1.5% to 29% patients and residual shunts in 6% to 41% of procedures[70]. We hypothesized that five-loop Gianturco coils are likely to decrease and/or avoid dislodgment of coils and residual shunts. To evaluate such a hypothesis, we reviewed the results of ten successive duct closures using five-loop coils during a six-month duration. All subjects with PDAs sent to our practice for diagnosis and management during April to September 1996 were entered in the study. Additional follow-up data on thirty patients who had five-loop coil occlusion[69] will also be presented in support of this hypothesis.

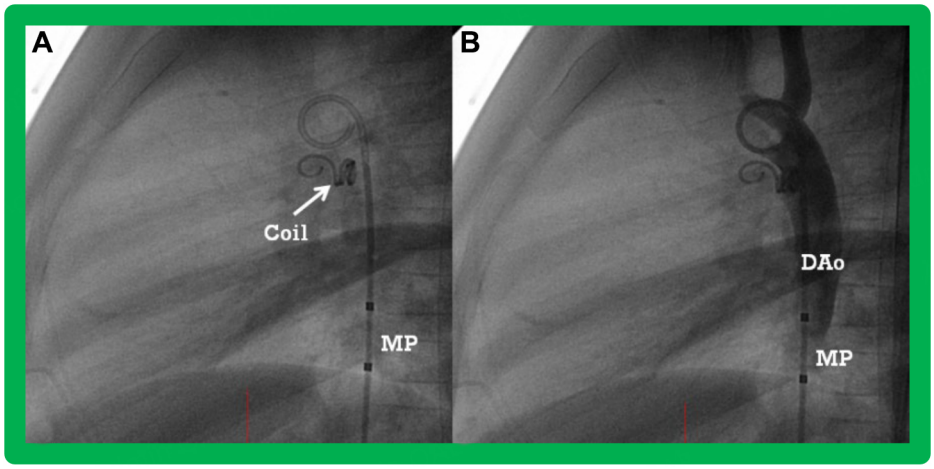

Figure 15. Selected aortic arch cine images in lateral projections demonstrating coil occlusion of a ductus in a child. (A) shows the position of a Gianturco coil (arrow) placed across a patent ductus arteriosus (PDA). (B) is an angiographic frame demonstrating complete closure of the PDA. DAo: Descending aorta; MP: marker pigtail catheter. Reproduced from Ref.[67].

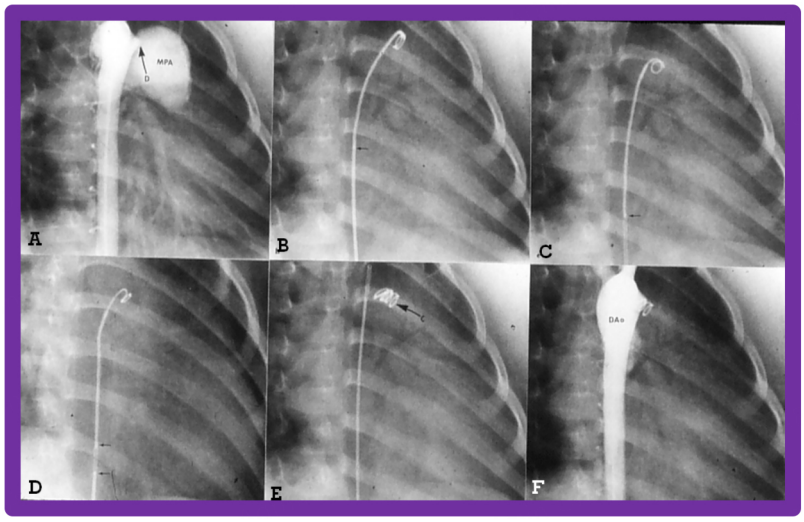

Figure 16. Aortic arch cine images in right anterior oblique projections illustrating the sequence of coil implantation. (A) Aortogram prior to coil occlusion demonstrating patent ductus arteriosus (arrow, D). (B) Radiogram showing the initial delivery of coils across the ductus. (C and D). The catheter is gradually retracted after the loading wire is pulled back (see arrows). (E) Once the catheter tip reaches the descending aorta (DAo), the loading guide wire is positioned against the coil wire and the catheter is pulled back while the guide wire is kept stable, thus delivering the remaining coils across the ductus. (F) Cine-angiogram showing full closure of the ductus. See that there is one coil loop in the main pulmonary artery (MPA) while the left over loops are in the ampulla of the ductus. Reproduced from Ref.[7].

The indications and selection of patients in both studies[68,69] were the same as those described in the preceding sections. The procedure of coil implantation is as described above [Figures 15 and 16]. We utilized 0.038″ wire diameter Gianturco coils with a coil helical diameter of 1.5 to 2 larger than that of the minimal ductal diameter, assessed on a lateral projection cine-angiogram. A length of the coil adequate to result in five coil loops was selected for placement. Since such coils were not in the Cook's inventory, they were custom designed for our specifications. The method of calculation of the number of coil loops is indicated in the above section describing Gianturco coils. The method of coil placement, including the post-coil data secured is as described in the section on "Technique of Coil Implantation". Examples of

angiograms from the aorta and PA are shown in Figures 17 and 18.

In the first cohort, the PDAs were 1.8 to 4.5 mm in diameter with a median of 3.0 mm. The blood flow to the lungs was increased with the ratio of pulmonary to systemic blood flow (Qp:Qs) of 1.9 ± 0.6 ranging from 1.3 to 3.3. The shape of the PDA was conical in all patients (type A in eight and type E in two by Krichenko classification[6]). Eight patients had no other heart abnormalities and one child had stenosis of the left PA; this was addressed by placement of a stent previously. The final subject is an adult who had had a prior unsuccessful surgical occlusion of the ductus at a different hospital. All coils were 0.038″ Gianturco coils with five loops. The coil diameter used was 3 mm in three children, 5 mm in six children, and 8 mm in the final patient. Coil placement across the PDA was effective in all ten patients. No displacement or migration of the coils was seen. Following coil implantation, no shunt was observed by sampling of blood for oxygen saturation in the main PA. The Qp:Qs was reduced (1.9 ± 0.6 *vs.* 1.0 ± 0; $P < 0.001$). Aortography following coil insertion did not show residual shunt in nine subjects [Figure 17], while a trivial shunt was observed in one subject. Cine-angiograms from the PA [Figure 18] did not reveal any obstruction in the left PA. No systolic pressure gradients were documented across the aortic arch. No cardiac murmurs were heard in eight patients. A grade 1/6 short ejection systolic murmur was auscultated in two patients. Please note that all patients had continuous murmurs of open ductus prior to coil occlusion. Echocardiographic examination including color Doppler did not reveal residual shunt across the coil-occluded PDA [Figure 19] in nine patients. A tiny shunt was seen in one patient - the same patient who had a trivial shunt on post-coil angiogram. Doppler examination of the main and left PAs and the DAo [Figure 20] did not demonstrate narrowing and had laminar flow across these sites by color Doppler. There was also no elevation in peak Doppler velocity. The diameter of the LA decreased from 24 ± 2 to 20 ± 2 mm; $P < 0.01$. Similarly, the LA to aorta (Ao) ratio was reduced from 1.5 ± 0.3 to 1.15 ± 0.1 ($P < 0.01$). All subjects were discharged on the day after PDA closure. Also, no complications were observed.

Follow-up data (6 to 12 months) subsequent to coil closure revealed that all the patients were symptom-free. Cardiac murmurs were absent in nine patients and a grade 1/6 ejection systolic murmur suggestive of peripheral PA stenosis was auscultated in remining patient, who is known to have had a prior branch PA stent. Chest X-rays showed coil position to be stable. Reduction in cardiac size was observed in three patients who had sizable PDAs. Echocardiographic examination showed absence of residual shunt in all patients. Scrutiny for obstruction in the left PA and DAo was negative. The dimension of the LA (18 ± 2 mm) and LA:Ao ratio (1.1 ± 0.1) continued to get better ($P < 0.01$). Complications were not observed in the follow-up.

With the use of conventional three-loop coil occlusion, the incidence of coil displacement of residual shunts was high[68]. Some of these patients needed implantation of another coil to manage the residual shunt. With the five-loop coils that we used, examples of coil displacement were not seen, and full closure of the PDA was accomplished in all subjects. We speculated that a larger amount of thrombus formation was achieved within the PDA secondary to use of five-loop coils in place of coils with three or four loops[70]. On the basis of the data depicted, we determined that percutaneous closure of the ductus with five-loop coils is safe and effective. Five-loop coils appear to prevent coil dislodgement and reduce residual shunts. We suggested that a study using larger patient cohorts with more morphologic and size variations of the PDA with a lengthier follow-up time are necessary to further validate these studies[68].

Further evaluation of five-loop coils

In a subsequent study[69], thirty patients were studied. Their ages ranged from 5 months and 67 years with a median of 4.5 years. The patient weights varied from 4.9 to 66.6 kg (median - 17.0 kg). Twenty-two were

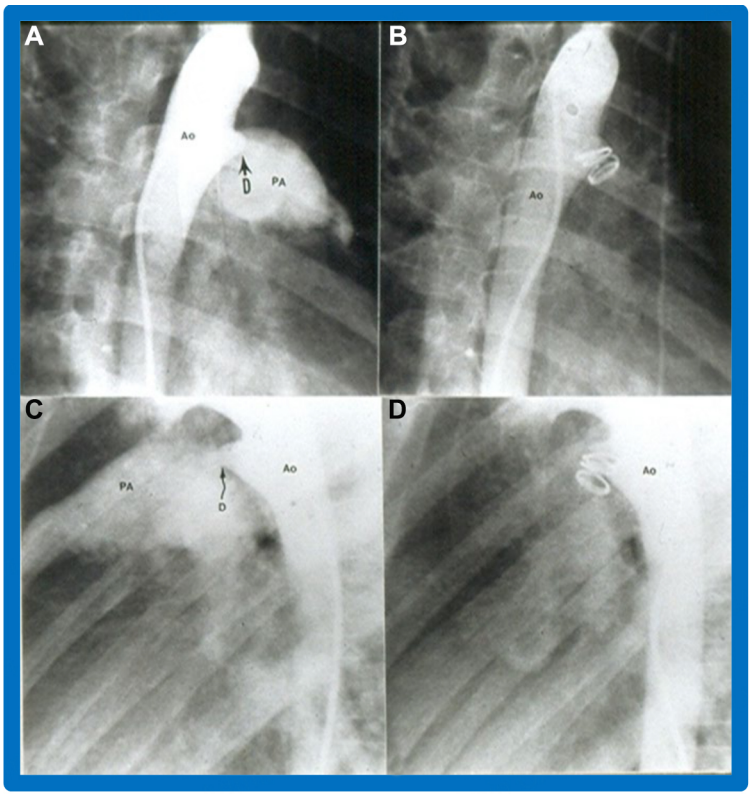

Figure 17. Aortic arch cine images in 30° right anterior oblique (A and B) and lateral (C and D) projections illustrating the results of coil implantation. (A and C) demonstrate the ductus (D) prior to coil placement. (B and D) show complete closure of the D following coil implantation. Ao: Aorta; PA: pulmonary artery. Reproduced from Ref.[68].

females and eight were males. The minimal diameter of the ductus varied between 1.2 and 4.5 mm (mean - 2.2 mm). The lengths of the PDAs were between 3.2 and 18.9 mm (median - 9 mm). Their shapes by Krichenko's classification[6] were Type A - 21; B - 4; D - 3, E - 2. The Qp:Qs varied between 1.2 to 2.4 (mean ± SD - 1.5 ± 0.4). All ducts were closed with a single coil with wire diameter of 0.038″ containing five-loops. The ratio of coil loop to PDA width varied between 1.5 and 3.0 (median - 2.1). The coil diameters were 3 mm in eight subjects, 5 mm in nineteen, and 8 mm in the remaining three subjects. The coils were implanted across the PDA with several types of catheters (#4F Glidecath {Meditech, Watertown, MA, n = 23}, #5F [n = 6] or #6F [n = 1] Judkins RCA {Cook}). As shown in Figure 21, 30 patients with complete occlusion of PDA by echocardiographic study the day after coil closure were selected for follow-up evaluation.

In these 30 patients, the Qp:Qs was reduced (1.5 ± 0.4 *vs.* 1.02 ± 0.05; $P < 0.001$) following coil implantation. No angiographic evidence for narrowing of the left PA or the DAo was discovered both by echocardiograms and angiograms. The LA dimension decreased from 26 ± 7 to 22 ± 6 mm ($P < 0.02$) and the LA/Ao ratio declined from 1.38 ± 0.22 to 1.12 ± 0.11 ($P < 0.001$) [Figure 22]. The LV dimension (37 ± 6 *vs.* 33 ± 6 mm; $P < 0.02$) was reduced without an alteration in the LV fractional shortening (37% ± 4% *vs.* 37% ± 5%). No major complications were encountered.

Data was obtained from all patients after a follow-up interval of six to 30 months (median - 12 months) after the five-loop coil occlusion. There were no symptoms in any patient. No cardiac murmurs were auscultated in twenty-six subjects. Functional murmurs were heard in three patients. One patient had a

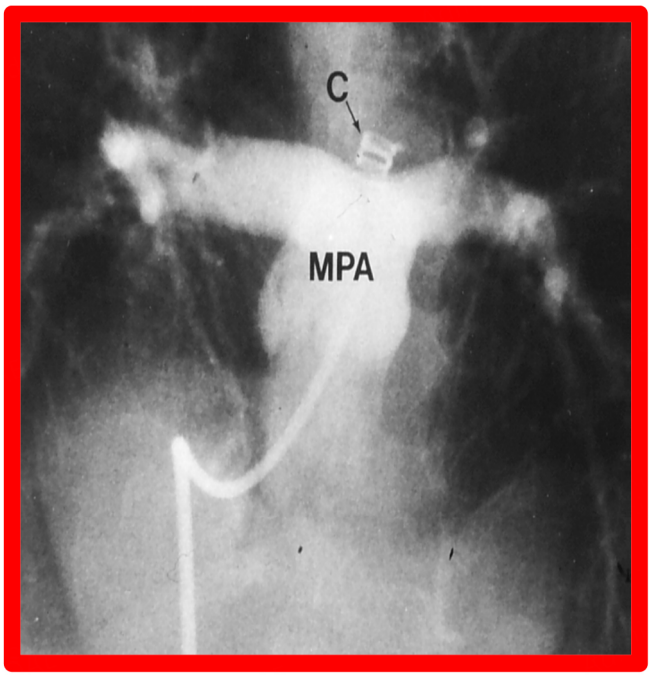

Figure 18. Cine image demonstrating the position of the coil (C) implanted for occlusion of a patent ductus arteriosus. Note that there is no evidence for branch pulmonary arteries. The main pulmonary artery (MPA) cine was performed in a sitting-up view. Reproduced from Ref.[68].

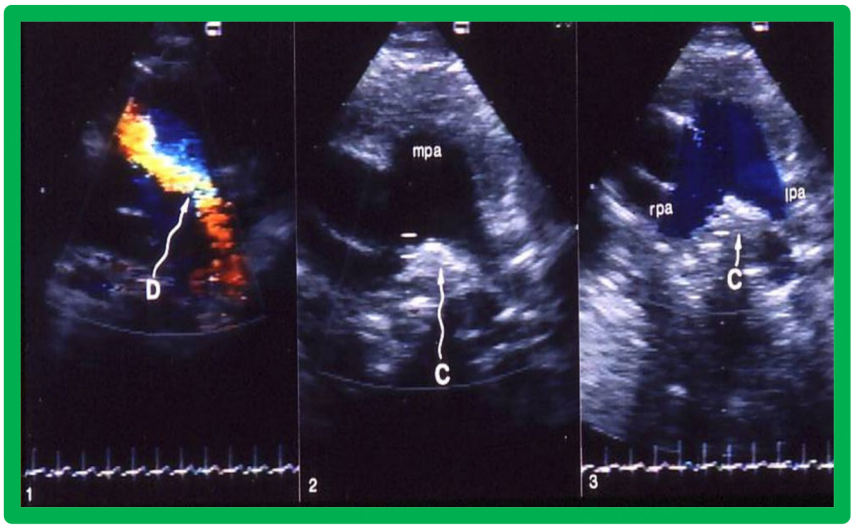

Figure 19. Echocardiographic examination to illustrate successful coil occlusion. (1) Demonstrates a patent ductus (D) prior to coil occlusion. (2 and 3) Show the position of the coil (C) within the ductal structure in between pulmonary arteries. Also note laminar flow in the main (mpa), left (lpa), and right (rpa) pulmonary arteries. as shown in (3). This study demonstrates the complete occlusion of the ductus. Replicated from Ref.[7].

grade I/VI systolic ejection murmur related to branch PA stenosis. No patient exhibited continuous murmur suggestive of clinical reopening of the ductus. Chest X-rays showed stable coil position. In seven patients who had large shunts prior to PDA closure, the heart size was diminished at follow-up chest X-ray. Detailed echocardiographic studies revealed no evidence for a residual shunt in any patient. Therefore, there is no indication for reopening of the ductus in any patient. Also, DAo narrowing was not observed.

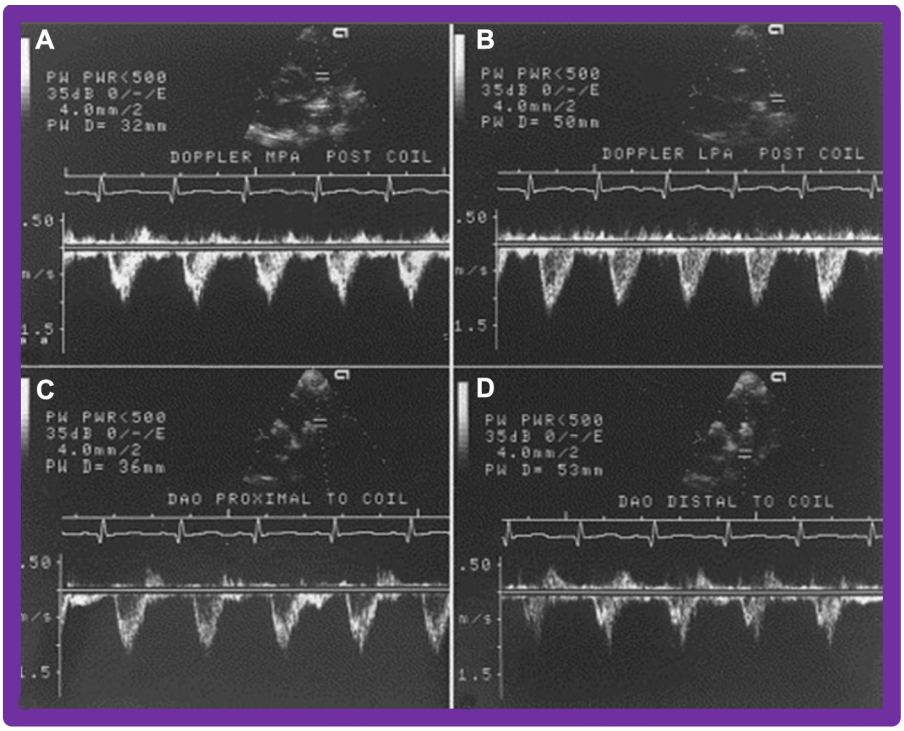

Figure 20. A composite of video images is put together to illustrate the technique of Doppler sampling to detect obstruction in the pulmonary artery on the left side and descending aorta following five-loop coil closure of ductus arteriosus. (A) shows Doppler sampling of the main pulmonary artery (MPA) while (B) illustrates sampling from the left pulmonary artery (LPA). Similar Doppler velocity magnitudes in (A and B) suggest that there is no obstruction in the LPA. (C) shows Doppler sampling of the descending aorta (DAO) proximal the coil while (D) samples DAO distal to the coil. Equal Doppler velocity magnitudes in (C and D) indicate no obstruction in the DAO. Color flow and continuous wave Doppler recordings through the LPA and DAO were also secured in each patient (not shown). No abnormalities in the color Doppler flow were seen (not shown). Reproduced from Ref.[68].

Minimal elevation of Doppler flow velocity magnitude in the left PA was seen in two subjects at one year follow-up evaluation. Quantitative lung perfusion scans were performed on both patients. The flow distribution in the first patient was right lung at 56% and left lung at 44%. In the second patient, right lung perfusion was 54% and left lung was 46%. Both were near normal. The LA size (LA diameter - 22 ± 7 mm; LA/Ao ratio - 1.05 ± 0.17) [Figure 22] decreased and the left ventricular dimension (35 ± 7 mm) and fractional shortening (37% ± 4%) did not alter. No evidence for development of findings suggestive of thrombus formation was seen. The data presented indicate that the full closure of PDAs occurred when five-loop coils were used. Our speculation that a higher degree of thrombosis is generated in the PDA when five-loop coils are used seems to be supported by these observations. The author continues to advocate using coils with five-loops in place of coils with three-loops for percutaneous closure of the ductus. It is possible that follow-up data over a longer period (2 to 5 years) may be needed to confirm these observations[69].

COIL CLOSURE OF PDA IN PATIENTS WITH RIGHT AORTIC ARCH

Introduction

The aortic arch descends on the left side of the spine in most subjects with an open ductus, and the anatomy of such PDAs is familiar to interventional cardiologists. However, the ductal location is variable in subjects who have their aortic arch on the right. Variations of the right arch and the associated PDAs are listed in Table 2[72-74].

Table 2. Variations in right aortic arch and ductus (ligmentum) arteriosus*

Type	Potential for forming vascular ring	Relative frequency
Mirror image brachiocephalic vessels (22)[a]		
A1. Left ductus arteriosus (18)		
A1a. Left subclavian-to-LPA (18)	No	Common
A1b. Upper descending aorto-to-LPA (0)[b]	Yes	Rare
A2. Right ductus arteriosus (3)	No	Uncommon
(undersurface of aortic arch-to-RPA)		
A3. Bilateral ductus (1)		
A3a. Left ductus (left subclavian-to-LPA) (1)	No	Rare
Right ductus (as in A2)		
A3b. Left ductus (upper descending aorto-to-LPA) (0)[c]	Yes	Not reported
Right ductus (as in A2)		
Abnormal origin of left subclavian artery (15)		
B1. Left ductus arteriosus (15)	Yes (loose)	Common
(Left subclavian-to-LPA)		
B2. Right ductus arteriosus (0)[d]	No	Rare
B3. Bilateral ductus (0)[c]	Yes	Not reported
Aberrant left innominate artery (0)[b]		
C1. Left ductus arteriosus (0)[b]	Yes	Rare
(Undersurface of left innominate-to-LPA)		
C2. Right ductus arteriosus (0)[c]	No	Not reported
C3. Bilateral ductus (0)[c]	Yes	Not reported
Isolation of left subclavian artery (2)		
D1. Left ductus arteriosus (1)	No	Rare
D2. Right ductus arteriosus (0)[d]	No	Not reported
D3. Bilateral ductus (1)	No	Rare

*Modified from Stewart *et al.*[73] and Shuford *et al.*[74];LPA and RPA indicate left and right pulmonary arteries respectively; [a]The figure in parentheses following each item is the number of cases found in the material documented by Stewart *et al.*[73]; [b]No cases of this type were found in the cases of Stewart *et al.*,[73] but isolated cases were reported by others; [c]To our knowledge, patients of this type have not been described in the literature as of 2001; [d]A hypothetical abnormality, unlikely to exist, and not reported to the best of our knowledge as of 2001; Reproduced from Ref.[72].

We presented examples of two distinct types of PDAs in patients with right aortic arches in whom we successfully coil-occluded the PDA with Gianturco coils[72]. The PDA site is different from that observed in patients with left sided aortic arch. After defining the exact location of the PDA, coil occlusion was undertaken similar to that explained in the prior paragraphs.

Closure of PDAs with right aortic arch

The first youngster was a male Down syndrome subject aged sixteen years. He had prior surgical correction of a common atrioventricular septal defect. There were no symptoms of dysphasia, stridor, or difficulty in breathing. On auscultation, a grade II/VI holosystolic murmur was auscultated at the apex indicating mild mitral insufficiency. Also, a continuous murmur of grade II/VI intensity was appreciated at the left upper sternal region suggestive of a PDA. Echo-Doppler studies revealed mild mitral insufficiency and a small PDA with shunting left-to-right. Aortogram revealed an aortic arch on the right side and a small PDA with smallest ductal dimension of 1.5 mm. The ductus arose from the undersurface of the anomalous LSA. It was occluded with a 0.038″, 5-mm-loop, five-loop Gianturco coil (MWCE-38-8-5; Cook, Bloomington, IN), delivered via a #5F RCA catheter (Cordis, Miami, FL). Following PDA occlusion, no residual shunt was detected on oximetry or by angiography [Figure 23A]. No evidence for obstruction in the left PA was seen

Figure 21. Chart of subjects who had coil occlusion of patent ductus arteriosus from April 1996 through December 1998. Of the total of thirty-eight patients, five patients were excluded because the patent ductus arteriosus (PDA) was closed with two or more coils (in three patients), or with a wire thickness of the coil other than 0.038" (in two patients). Of the remaining thirty-three subjects, thirty patients were shown to have full closure of the PDA by echo-Doppler study on the day after Gianturco coil placement, and are the subjects of this investigation. Modified from Ref.[69].

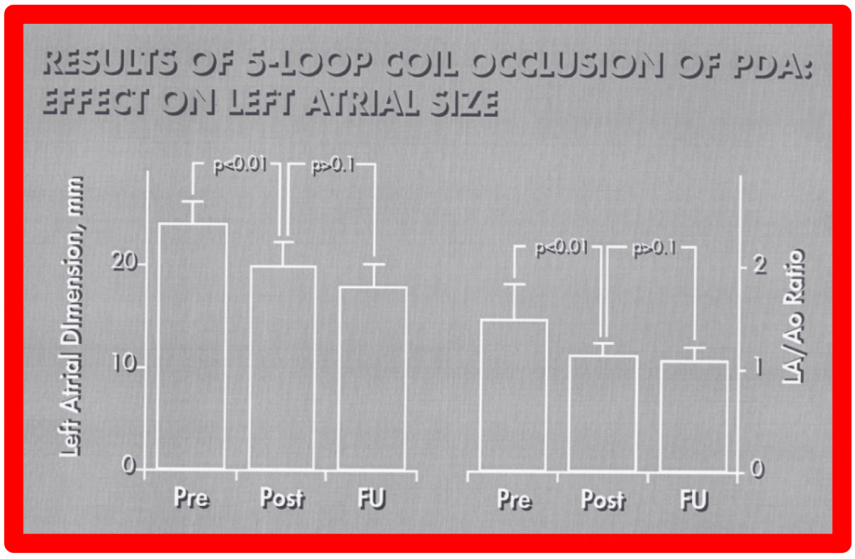

Figure 22. Diagram demonstrating the reduction ($P < 0.001$) in the dimension of the left atrium (left panel) and left atrium to aortic root ratio (right panel) on the day after occlusion of the ductus arteriosus. During follow-up (FU), there was no further change ($P > 0.1$); these values continued to be decreased ($P < 0.01$) when compared to those before (Pre) ductal closure. LA/Ao: Left atrium to aorta; Post: on the day following ductal closure. Reproduced from Ref.[7].

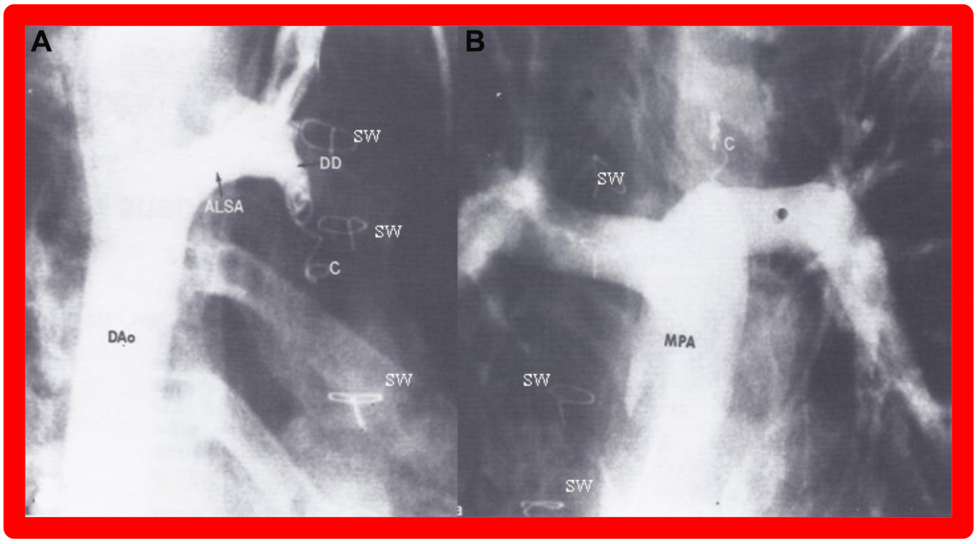

Figure 23. (A) Selected cine-angiographic frame from the first case showing the coil-occluded ductus arteriosus. The anomalous left subclavian artery (ALSA) takes off abnormally from the descending aorta (DAo) and supplies blood to the left arm. Note the origin of the ductal diverticulum (DD) from the undersurface of the ALSA. The coil (C) is seen within the ductal structure and residual shunt was not observed. (B) Selected cine angiogram of the pulmonary artery in an axial view demonstrating the location of the coil (C) within the ductal structure. There is no demonstrable narrowing of the pulmonary artery. Sternal wires (SW) from prior cardiac surgery are marked. MPA: Main pulmonary artery. Modified from Ref.[72].

[Figure 23B]. Follow-up echocardiographic examination on the morning after the coil occlusion did not show any residual shunt. Repeat echo studies at 1, 6, 12, and 24 months after the procedure continued to reveal no ductal shunt and no left PA obstruction. No symptoms suggestive of an obstructed vascular ring were noted.

The next is a four-year-old female who had been followed at our institution since early infancy with a clinical and echocardiographic diagnosis of a small defect in the ventricular septum and a small PDA. An examination shortly before the intervention revealed no evidence for a murmur suggestive of a ventricular septal defect (VSD), but a continuous murmur of grade II/VI intensity suggestive of a PDA was auscultated both at the left and right upper sternal margins. A chest X-ray showed the heart size to be normal, a slight increase in pulmonary blood flow, and a right aortic arch. An echo-Doppler study revealed no evidence for a VSD, but a small PDA was visualized. The PDA was long, and it appeared to enter the right PA. Angiography revealed right sided aortic arch and the brachio-cephalic vessels arose in a mirror image pattern. The PDA arose from the underside of the aortic arch and emptied into the right PA. The minimal ductal diameter was 1.5 mm. It was occluded with a 0.038″, 5-mm-loop, five-loop Gianturco coil (MWCE-38-8-5; Cook, Bloomington, IN), delivered via a #4F Glidecath catheter (Meditech, Boston, MA). Repeat oxygen saturation measurements and angiograms [Figure 24A] revealed no evidence for a residual shunt. A PA angiogram [Figure 24B] showed excellent location of the coil without narrowing of the right PA. Echo-Doppler studies in the morning after the coil occlusion and at one and six months later did not demonstrate residual shunting, nor was there any evidence for right PA or DAo obstruction.

DISCUSSION

Since the anatomy of the right-sided aortic arch and of the PDA is variable, the nature of the right arch and the structure of the ductus [Table 2] should first be identified and recognized prior to coil occlusion of a PDA. The most frequent category of right-sided aortic arch is that with brachio-cephalic vessels arranged in a mirror-image fashion. In such patients, the PDA connects the left subclavian artery with the left PA (Type

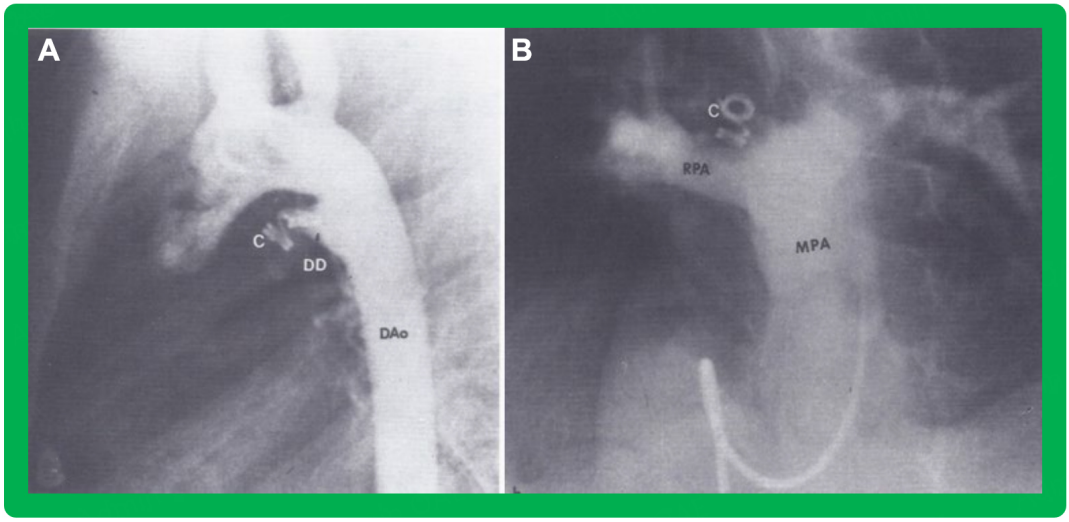

Figure 24. (A) Selected cine-angiographic frame from the second case, showing the coil-occluded ductus arteriosus. The origin of the ductus is from the bottom of the aortic arch. Note complete closure of the ductal structure with a coil. (B) Selected cine pulmonary angiographic frame in a long axial oblique view, displaying the location of the coil (C) in the ductus. Note the position of the coil above the right pulmonary artery (RPA). There is no evidence of obstruction in the RPA. DAo: Descending aorta; DD: ductal diverticulum; MPA: main pulmonary artery. Modified from Ref.[72].

A1a); this category is usually associated with cyanotic CCDs and does not produce a vascular ring. Such PDAs do not need coil occlusion.

In Type A2 (our second patient), the PDA originated from the underside of the right aortic arch and empties into the right PA. The Gianturco coil conclusion of the PDA in these cases is not substantially different from that of the ductus in subjects with a normal left-sided aortic arch.

The PDA in Type B1 (our first patient) originates from the undersurface of the anomalous LSA and empties into the left PA. This type is usually associated with a loose vascular ring. If there are symptoms of an obstructive vascular ring, such as dysphasia, dyspnea, or stridor, surgical interruption of the vascular ring should be undertaken, rather than coil occlusion of the PDA. In our case, there were no signs suggestive of an obstructive vascular ring and therefore, coil occlusion was performed. During observation for two years following coil occlusion, the patient did not present any symptoms of a vascular ring.

Other rare forms, namely, Types A1b, A3b, B3, C1, and C3, produce obstructive vascular rings, and relief of obstruction rather than coil occlusion of the PDA is most appropriate for these patients.

In summary, we presented two children with PDA in association with right aortic arch who had effective percutaneous coil closure of their PDAs. It was stressed that the anatomy arch of the aorta and ductus should be demarcated clearly to ensure the absence of a symptomatic vascular ring, before proceeding with PDA closure. The conclusion was that coil closure of a PDA in subjects who have a right aortic arch is successful and safe, although the described number of cases is limited.

CLOSURE OF PDAS WITH AMPLATZER FAMILY OF DEVICES

Amplatzer duct occluder

The Amplatzer duct occluder (St. Jude Medical, Inc., St. Paul, MN) was originally described in the late 1990s[38,75] and subsequently the FDA approved the device for ductal occlusion. The Amplatzer duct occluder

(ADO) is put together with 0.004″ Nitinol wire material, is mushroom in shape [Figure 5C], and is self-expandable[75]. The ADOs are seven mm in length except for the 5/4 ADO which has a length of 6 mm. The aortic side is two mm wider than the PA side of the device, and it progressively becomes narrower from the aortic to the pulmonary side [Figure 15C]. A skinny retaining disc is incorporated at the aortic end of the device; this disc is four mm bigger than the aortic end. A depressed screw is built into the PA end and can be attached to a wire through the process of device delivery and implantation. Thrombogenic polyester fibers are incorporated into the ADO to increase thrombus formation after the placement of the device. The ADOs can be deployed through #6F to #8F size sheaths, which are also supplied by the device's manufacturer. The ADO is easily inserted into the delivery sheath, and can be easily recaptured, as necessary. Multiple sizes (5, 6, 8, 10, 12, and 14 mm) are produced. Currently the Amplatzer is the most used device around the world for the closure of patent ducti.

Patient selection

The patient selection is like that described for the buttoned device and *Giantuco coil*, although, the ADO is commonly used in medium to large PDAs as described in Figure 3.

Technique of device implantation

The technique of ADO implantation was reviewed in detail in our prior publications[67,76,77] and the salient features will be reviewed here. Percutaneous hemodynamic study is performed to validate the diagnosis of PDA. Angiograms from the aortic arch, usually in 30° RAO and straight lateral projections are conducted using a #4F or #5F marker pigtail catheter, inserted in the femoral artery. The minimum dimension of the ductus (typically at the pulmonary side), dimension of ampulla (at the aortic side), and ductal length are determined [Figure 25] in both projections and an average is calculated. These data serve as guide in the selection of the device size used for closure.

The technique of crossing the ductus is as explained in the "Technique of Device Implantation" of the "Buttoned Device". Once the guide wire is in position in the descending aorta, a suitable-sized ADO device implantation sheath is threaded over the guide wire through the right atrium, right ventricle, PA, and PDA, and its tip is placed in the DAo. The dilator and the guide wire are withdrawn and the delivery sheath is flushed.

An Amplatzer PDA device that is somewhat bigger (by 1 to 2 mm) than the minimal dimension of the PDA is selected. The chosen ADO is de-aerated and fastened to the delivery wire. The ADO is unscrewed by a turn or so after completely screwing the device. This is to help the un-screwing and release of the ADO following its insertion across the ductus. The ADO is retracted underneath saline into the loading sheath while saline flushing of the ADO loading sheath to prevent entry of air into the device delivery system. The ADO is advanced forward through the sheath while being monitored with fluoroscopy. When the end of the ADO arrives at the delivery sheath tip, the whole assembly is pulled back till the sheath tip is in the descending part of the aorta just beyond the ductal ampulla. While the ADO is held in place, the delivery sheath is withdrawn to uncover and deploy the aortic disc of the ADO. The complete device/sheath assembly is gradually pulled back into the ductal ampulla and if feasible into the middle of the ductus. At this point, an aortography is done to assess the location of the aortic disc of the ADO [Figure 26A]. If the ADO's position is acceptable, the delivery sheath is further withdrawn, whilst the ADO is held in position to un-sheath the outstanding part of the ADO, across the narrow PA end of the ductus. A repeat aortogram [Figure 26B] is accomplished to confirm the location of the device. This is to confirm that (1) The aortic disc is within the PDA devoid of significant protrusion into the aorta; (2) The location of the PA end of the ADO is across the narrow portion of the PDA (determined by its relationship with the tracheal shadow); and (3) No residual shunt exits surrounding and parallel to the ADO.

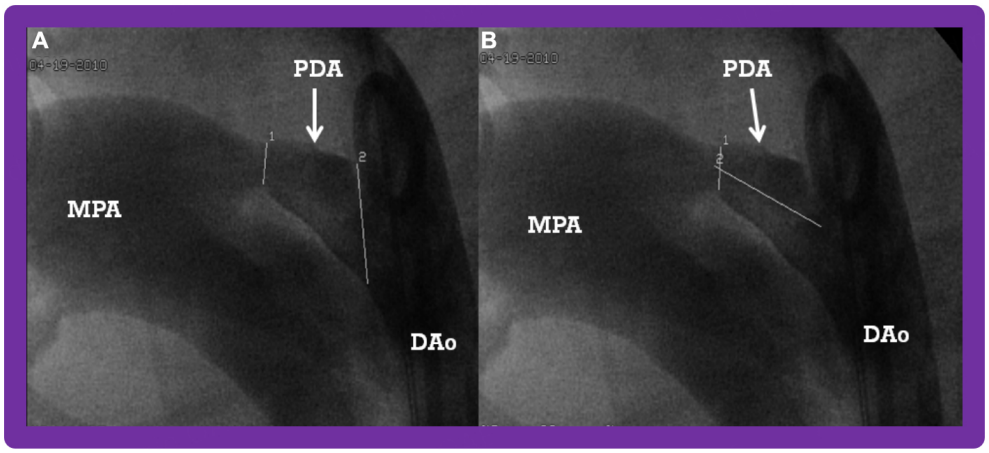

Figure 25. Selected aortic arch cine-angiographic images in lateral projections illustrating different patent ductus arteriosus (PDA) dimensions in a child with a medium to large ducti. Dimensions of smallest ductal diameter in (A and B), ampulla of the ductus in (A), and the length of the PDA in (B) are demonstrated. Descending aorta (DAo) and main pulmonary artery (MPA) are labeled. Reproduced from Ref.[67].

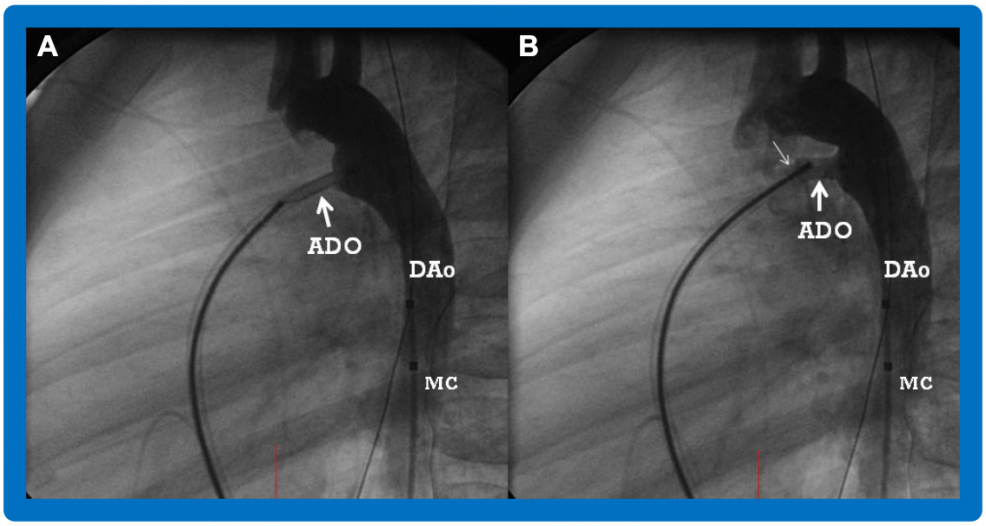

Figure 26. Aortic arch cine images in lateral projections illustrating the sequence of Amplatzer duct occluder (ADO) implantation. (A) shows aortic disc of ADO in the ductal ampulla without impinging on the aortic lumen. The remaining unopened ADO is shown with arrow. (B) shows completely expanded ADO in an acceptable position (thick arrow). Tiny residual shunt (thin arow) through the ADO is seen, but no shunt is detected parallel to the device. MC: Marker pigtail catheter; DAo: descending aorta. Modified from Ref.[67].

After a good device position is ensured, counterclockwise rotation of the delivery wire performed till the ADO is freed resulting in device implantation. Both the delivery sheath and cable are pulled out and the delivery sheath is replaced with a diagnostic sheath. Fifteen minutes after ADO delivery, a cine-angiogram from the aorta is done [Figure 27] views. Measurements of pullback pressures across the descending aorta and oxygen saturations from the right ventricle, the PA and the aorta are secured. The follow-up protocol is like that detailed in the "Gianturco Coil Implantation" segment.

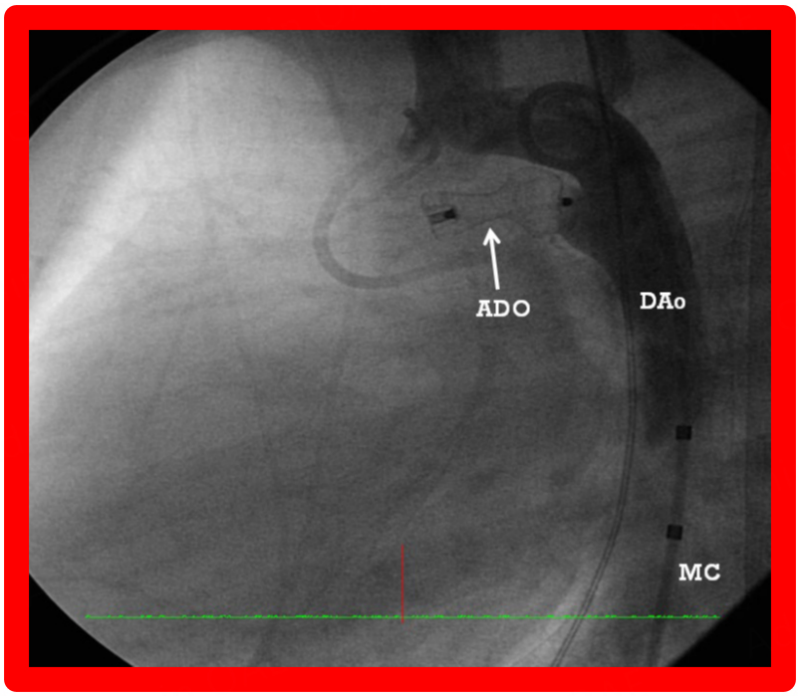

Figure 27. Aortic arch cine image in lateral projection illustrating the result of placement of an Amplatzer duct occluder (ADO) (arrow) across the closed ductus. Note that there is no remaining shunt. Also, there is no protrusion of the ADO into the aortic arch and the ADO is entirely inside the ductus. DAo: Descending aorta; MC: marker pigtail catheter. Reproduced from Ref.[7].

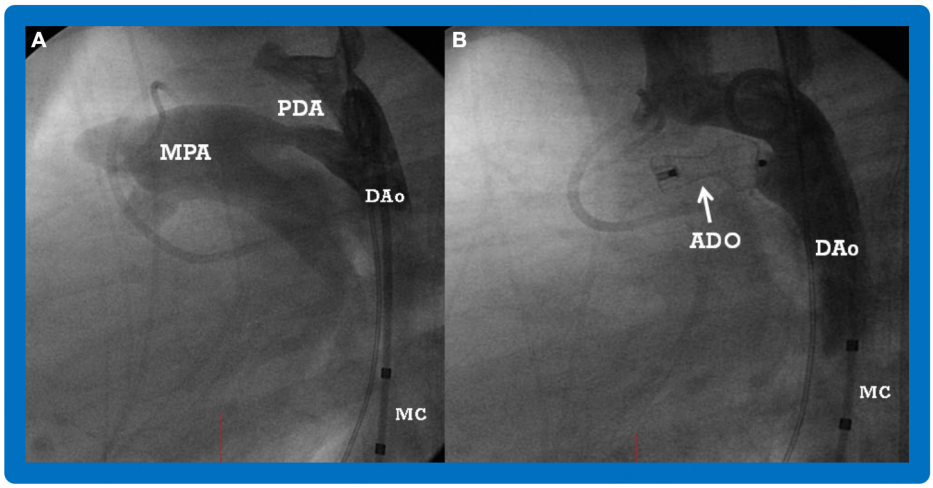

Figure 28. Aortic arch cine images in lateral projections illustrating the result of placement of an Amplatzer duct occluder (ADO) [arrow in (B)] across the patent ductus arteriosus. (A) shows a moderate to large ductus with full visualization of the main (MPA) and branch (not labeled) pulmonary arteries. (B) shows that there is no residual shunt. Also, there is no protrusion of the ADO into the descending aorta (DAo) and the ADO is entirely inside the ductus. MC: Marker pigtail catheter; PDA: patent ductus arteriosus. Reproduced from Ref.[7].

Results of ADO occlusion of PDA from the author's institution

During a nine-and-a-half year period from August 2003 to December 2012, 141 subjects were studied with the intention of closing their PDAs using the ADO[7,78]. Of these, three patients did not have the device implanted secondary to an unstable placement (n = 2) or potential for descending aortic obstruction (n = 1).

The patient's ages ranged between 0.36 to 35.6 years (median of 1.7). The weights differed from 3.5 to 77 kg with a median of 10.8 kg. The smallest PDA diameter measured in lateral projection varied from 0.7 to 6.7 mm (median 2.3 mm). The Qp:Qs was 1.86 ± 0.87 and ranged between 1.0 and 5.4. The PDA types, based on the Krichenko classification[6], were type A1 - 64, type A2 - 22, type E - 13, type C - 11, type B1 - 6, type B2 - 5, type D - 4, and 8 PDAs were of an undetermined type. The most common ADO device used was the 8/6 device, which was used in half (n = 62) of the patients. The other sizes used were the 6/4 device in fifty-two patients, the 10/8 device in sixteen subjects, the 5/4 device in seven patients, and the 12/10 device in one patient. The devices were delivered via #5F to #7F Amplatzer delivery systems (St. Jude Medical Inc. St. Paul, MN) based on the size of the ADO.

The device was inserted effectively in 138 (97.9%) of 141 subjects. The reasons for non-implantation in three patients were mentioned above. All three of these patients had successful surgical ligation of their respective PDAs shortly after attempted device closure. In the other 138 patients, the Qp:Qs was lowered (1.86 ± 0.87 *vs.* 1.0 ± 0.1; $P < 0.01$). The systolic, diastolic, and mean (28 ± 11.9 *vs.* 25 ± 9.8 mm) PA pressures and right ventricular pressures decreased while the aortic pressures increased after device closure. No systolic pressure gradient was noticed across the aortic isthmus after device closure. Aortography following device implantation revealed complete occlusion [Figures 27-29] in 116 (84%) of 138 patients. Echocardiographic examination next day after device placement showed perfect closure in 125 (91%) patients. In the outstanding 13 subjects, the remaining shunts were either small (n = 6) or trivial (n = 7) as defined previously[39]. Successful closure, specified as an absent (N = 125) or trivial (N = 7) left over shunt on echocardiographic examination, was seen in 132 (96%) of 138 patients. No complications were encountered.

Data was available at follow-up from 34 to 87 months (median of 48). Two patients required re-intervention to address left pulmonary artery stenosis. Thrombus formation was not seen in follow-up nor were any thrombo-embolic events. No bacterial endocarditis was observed.

The residual shunts seen shortly after device closure had spontaneously resolved in all but one of the children by one month after the device placement. In the remaining single patient, the residual shunt spontaneously resolved by six months. During the follow-up period, twenty (14.5%) patients showed turbulent flow across the left PA with a peak Doppler velocity ≥ 2 m/s. Of these, two patients underwent stent implantation (three years after the procedure in one patient and seven years after device implantation in the other patient). Of the remaining eighteen patients at the time of data analysis, stent implantation is being contemplated soon in one child. In the outstanding children, the degree of obstruction is not considered significant, and these patients are being followed. Eleven (8%) patients had aortic isthmus flow Doppler velocities greater than 2 m/s by Doppler, but seven of these had Doppler velocities of ≥ 2 m/s prior to device closure. No blood pressure gradients were recorded, and none were considered to have aortic coarctation.

In conclusion, our sizable number of ADO closures of PDA which includes lengthy follow-up (more than 7 years) suggests that the technique is feasible, safe, and successful. Most PDAs, regardless of Krichenko's type, ductal shape, ductal length, and minimal ductal diameter, can be successfully occluded with no significant difficulties. We recommend further follow-up in patients with a left PA Doppler velocities ≥ 2.0 m/s as well as those with an aortic isthmus Doppler velocity ≥ 2 m/s after device implantation[7,79].

Amplatzer duct occluder II

The Amplatzer duct occluder II (ADOII) (St. Jude Medical, Inc., St. Paul, MN) is also made up of Nitinol wire material and contains of two identical-sized retention discs linked by a cylindrical central waist

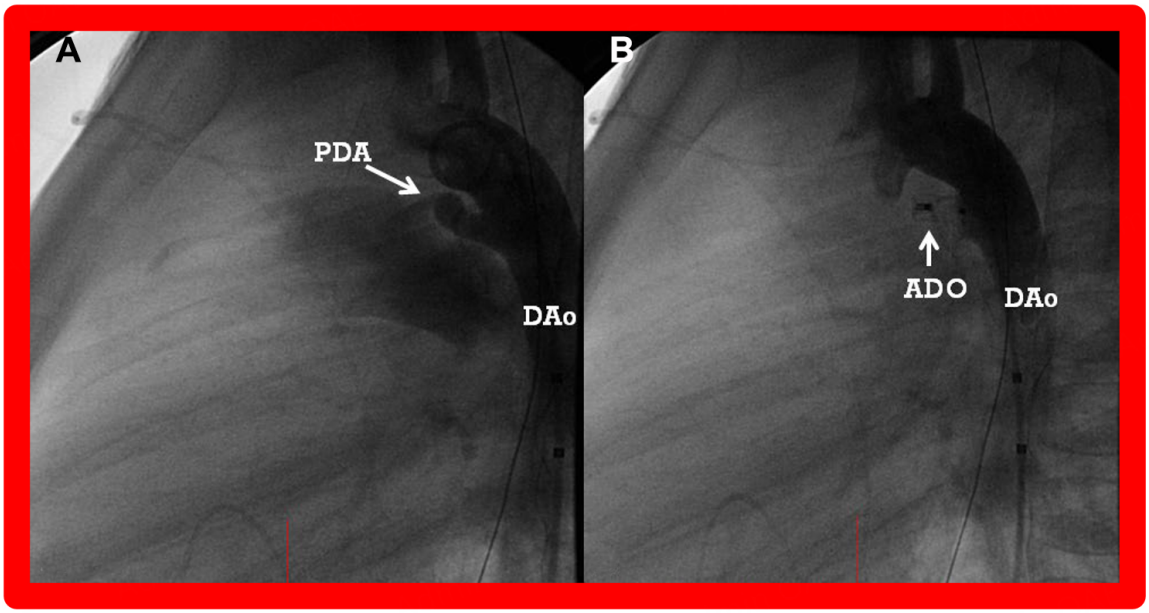

Figure 29. Aortic arch cine images in lateral projections illustrating the result of placement of an Amplatzer duct occluder (ADO) [arrow in (B)] across the patent ductus arteriosus (PDA). (A) shows a moderate-sized PDA [arrow in (A)] with faint opacification of the main pulmonary artery (not labeled). (B) shows that there is no residual shunt. Also, there is no protrusion of the ADO into the descending aorta (DAo). Reproduced from Ref.[67].

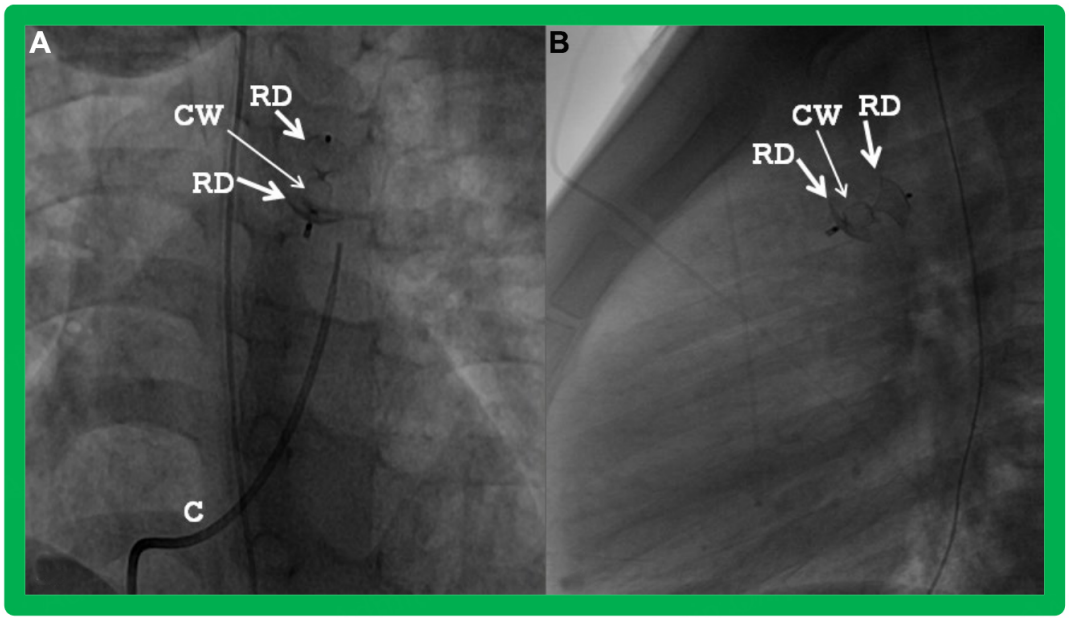

Figure 30. Cineradiographic images in sitting-up (A) and lateral (B) views, demonstrating various components of the Amplatzer duct occluder II. The retaining discs (RD) (thick arrows) are on either side of the ductus while the central waist (CW) (thin arrow) is within the ductus. C: Catheter. Reproduced from Ref.[7].

[Figure 30][8]. Different retention disc sizes (9, 10, 11, and 12 mm) with different-sized central waists (3 through 6 mm) and lengths (4 and 6 mm) are manufactured. No fabric is incorporated into the device. The delivery catheters/sheaths are also provided by the manufacturer. In a comparable way to the ADO, the device is easily recaptured and redeployed as needed.

The author performed PDA occlusion with the Amplatzer duct occluder II [Figure 30] in a few patients. In the five patients in whom the procedure was performed, there was no remaining shunt on angiography shortly after device implantation [Figure 31A] nor was there any DAo [Figure 31B] or PA [Figure 31C] obstruction. An echocardiographic evaluation on the morning after device insertion and at one, six and twelve months after PDA occlusion did not reveal residual shunts. No narrowing of the DAo or the left PA was seen.

Amplatzer vascular plug

The Amplatzer vascular plug (AVP) is constructed with self-expanding Nitinol cable material like that utilized in ADO and ADOII and consists of a single disc [Figure 5D]. Multiple diameters varying from 4 to 16 mm, in 2 mm increases, are manufactured. Two lengths (7 and 8 mm) are available. Each AVP is provided with a 135 cm delivery wire and can be implanted via #5F to #8F delivery sheaths, as per the diameter of the device. An AVP [Figure 5D] may be used in tubular PDAs; an appropriately sized AVP is chosen depending on the measurements (diameter and length) of the ductus [Figure 32].

Although the AVP is designed to embolize blood vessels, we and others have used these AVPs to occlude tubular PDAs [Figure 33][78]. Additional modifications of the device, namely the Amplatzer Vascular Plug II and Amplatzer vascular plug 4, are also available to facilitate better occlusion.

OTHER CLINICAL SCENARIOS ASSOCIATED WITH TRANSCATHETER OCCLUSION OF PDA

Management of the ductus in the preterm infants including closure of ducti in the preterm babies is now feasible and effective and was reviewed elsewhere[5] and will not be reviewed in this this paper. Other interesting clinical scenarios associated with transcatheter occlusion of PDA, namely, reactive ductus arteriosus[80], onset of aortic coarctation after device closure of ductus[81], and simultaneous percutaneous management of aortic valve stenosis and PDA[82] were reviewed elsewhere[80-82] for the interested reader.

SUMMARY AND CONCLUSIONS

PDA accounts for 8% to 10% of all CHDs. Surgical closure, as described by Gross in 1930s was initially used to manage PDAs. After advocacy by Porstmann, Rashkind and their associates in the late 1960s for transcatheter occlusion of PDA, it became a standard treatment of choice to address PDAs. Indications for transcatheter occlusion of small PDAs are their presence except for cyanotic CHD, largely to prevent bacterial endocarditis. In moderate to large PDAs, closure is indicated to address left heart volume overload in addition to prevention of endocarditis. In this review, closure of PDA with buttoned device, *Giantuco coil*, and Amplatzer device was discussed with particular focus on author's contributions to these techniques. While PDA occlusion with buttoned device is feasible and effective, it is no longer available for clinical use. PDA closure with *Giantuco coil* is successful in most patients, its use now is limited to occluding very small PDAs. Our advocacy to use five-loop coils is likely to prevent residual shunts. PDA occlusion with ADO is useful in addressing moderate to large ducts. Most PDAs, regardless of Kriechenko's type, ductal shape, length of the PDA, and minimal ductal diameter can be successfully occluded with no important complications during long-term follow-up.

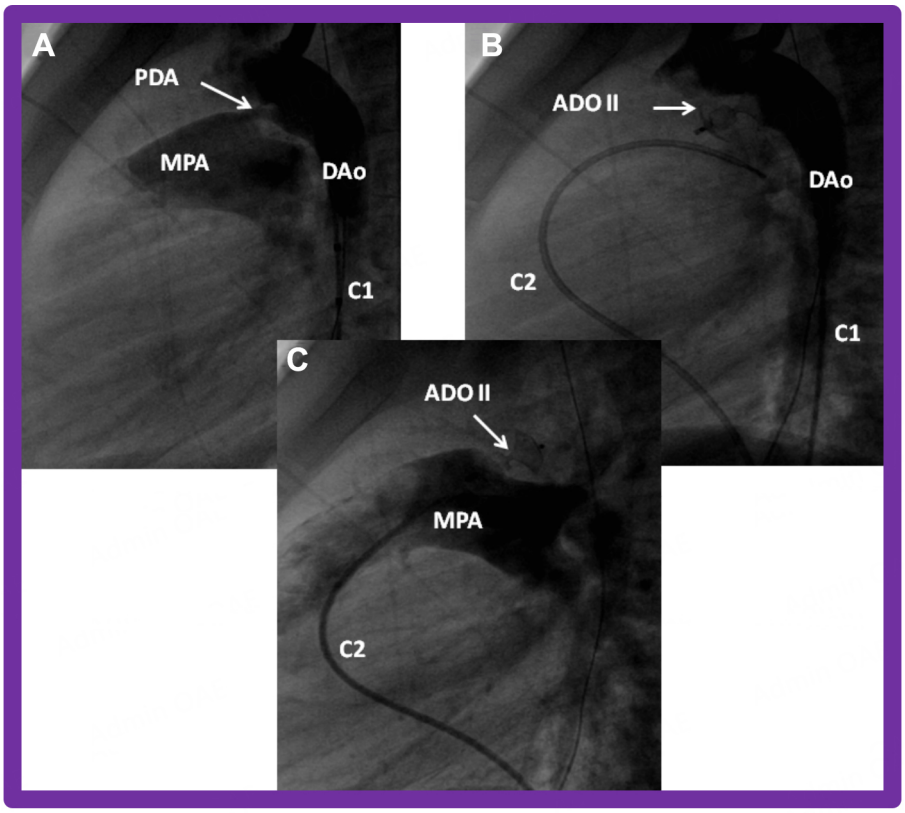

Figure 31. Aortic arch and main pulmonary artery (MPA) cine images in lateral projections illustrating the result of placement of an Amplatzer duct occluder II (ADOII) [arrows in (B and C)] across the ductus. (A) shows a moderate patent ductus arteriosus (PDA) [arrow in (A)] with opacification of the MPA. (B) shows that there is no residual shunt. Also, there is no protrusion of the ADOII into the aorta. (C) illustrates appropriate location of the device without blockage of the pulmonary arteries. C1: Catheter in the descending aorta (DAo); C2: catheter in the MPA. Reproduced from Ref.[7].

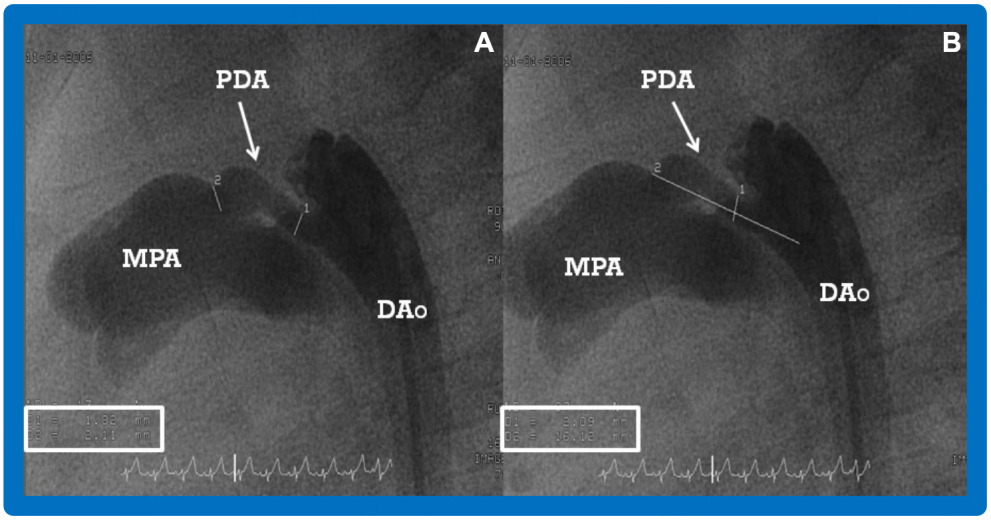

Figure 32. Aortic arch cine-angiographic images in lateral projections illustrating different patent ductus arteriosus (PDA) dimensions in a child with a large tubular PDA. Dimensions of smallest PDA diameter (marked 1 and 2) in both (A and B) and the length of the PDA in (B) are demonstrated. DAo: Descending aorta; MPA: main pulmonary artery. Reproduced from Ref.[7].

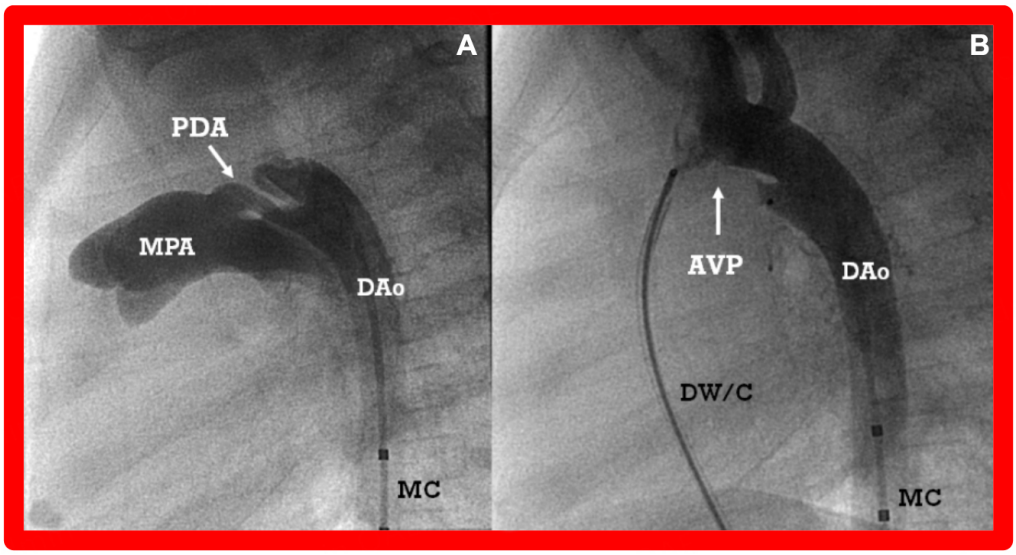

Figure 33. Aortic arch cine images in lateral projections illustrating the result of placement of an Amplatzer vascular plug (AVP) [arrow in (B)] across the ductus. (A) shows a moderate to large ductus with full visualization of the main pulmonary artery (MPA). (B) shows that there is no residual shunt. Also, there is no protrusion of the AVP into the Descending aorta (DAo) and the AVP is entirely inside the ductus. marker pigtail catheter (MC), and patent ductus arteriosus (PDA) are labeled. Reproduced from Ref.[7].

DECLARATIONS

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Many echo-Doppler images utilized as illustrations in this review; a substantial number of these studies were secured at the Children's Memorial Hermann Hospital, Houston, Texas. I take this occasion to convey my thanks to the echo technologists for their thoroughness in acquiring excellent quality echo studies.

Authors' contributions

The author is the sole contributor of this paper.

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Conflicts of interest

The author declared that there are no conflicts of interest.

Ethical approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

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