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Transcatheter Closure of Patent Ductus Arteriosus in an Extremely Low Birth Weight Neonate Using the Newly Approved Abbott Piccolo™ Device

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Introduction

In term or late preterm infants, closure of the ductus arteriosus often occurs spontaneously in the first few days of life.[1] However, this process of ductal constriction is generally delayed in premature infants, especially those with Extremely Low Birth Weight (ELBW). 50-70% of infants born at < 28 weeks gestational age (GA) have a moderate-to-large Patent Ductus Arteriosus (PDA) that persists weeks after birth.[2] Incidence tends to correlate inversely with birth-weight and gestational age.[3] A hemodynamically-significant PDA results in a large left-to-right shunt and aortic diastolic runoff, contributing to pulmonary congestion, Respiratory Distress Syndrome, prolonged assisted ventilation, increased risk of necrotizing enterocolitis, renal insufficiency, intraventricular hemorrhage, and an overall increased risk for morbidity and mortality particularly in ELBW patients.[4-7]

Management of a clinically-significant PDA in ELBW neonates includes: fluid restriction, pharmacotherapy, surgical ligation and, more recently, transcatheter device closure. Up to half of all ELBW babies born prior to 28 weeks gestation require medical or surgical treatment for their PDA.[8]

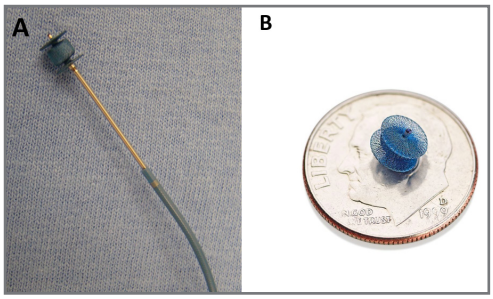

Figure 1. Abbott Piccolo™ Device (formerly ADO II-AS). A self-expending wire mesh device that is shorter and softer compared to its predecessors. Its smaller central waist and slightly-larger retention disks facilitate complete intraductal deployment, which is desirable in the premature Patent Ductus Arteriosus, so as to minimize protrusion into surrounding structures such as the left pulmonary artery and descending aorta. Photograph: Abbott Laboratories.

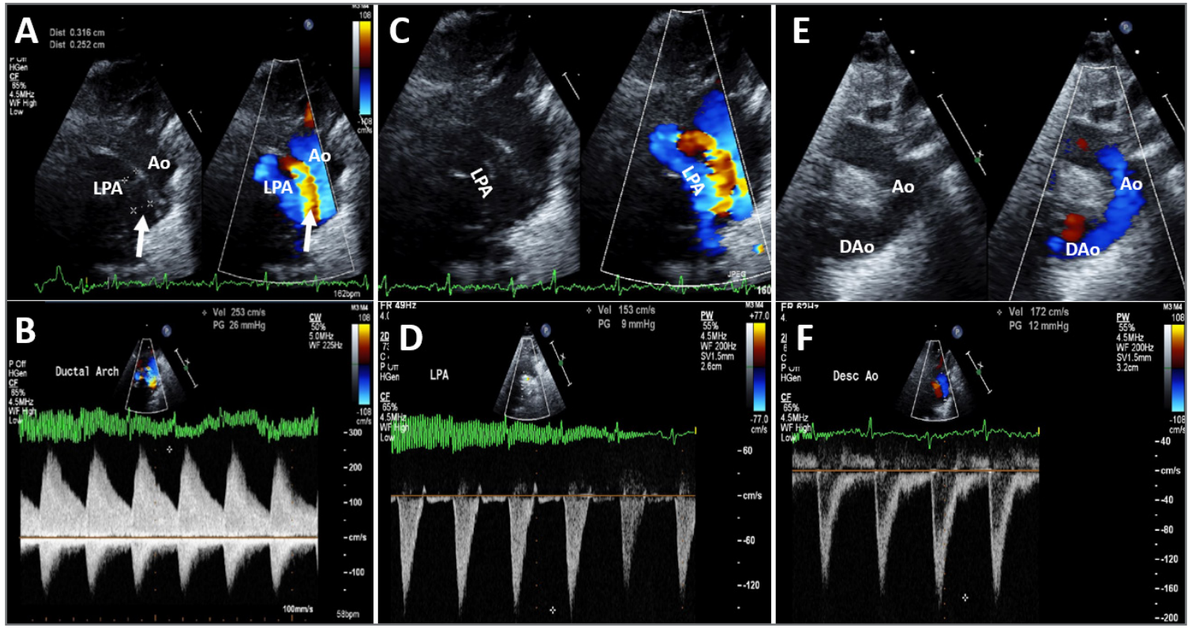

Figure 2. Intraprocedural transthoracic echocardiogram used to obtain baseline data of the Patent Ductus Arteriosus (PDA), Left Pulmonary Artery (LPA), and Descending Aorta (DAo). Images from a high parasternal or suprasternal view demonstrate a large PDA (white arrow, A&B) and an unobstructed LPA (C&D) and DAo (E&F), as evidenced by laminar color Doppler flow and an unobstructed spectral Doppler pattern. The color scale/Nyquist limit is adjusted accordingly to remove unnecessary aliasing. Continuous wave Doppler of the PDA (B) shows only mildly restricted continuous left-to-right shunting across the PDA, typical for this population.

Medical management with non-selective cyclooxygenase inhibitors such as Indomethacin or Ibuprofen in low birthweight infants has an estimated success rate of only 50-60% and may result in complications such as impaired renal function and intestinal perforation.[9,10] When medical therapy is unsuccessful, patients may be referred for surgical ligation, or a continued conservative approach of observation and medical management is undertaken. Surgical ligation, while technically successful, is invasive in nature and typically performed through a limited left thoracotomy. Ligation has also been associated with significant perioperative complications, including pneumothorax, bleeding, wound infection, phrenic nerve palsy, vocal cord paralysis,[11-13] and possible neurodevelopmental impairment.[14] Thus, in the current era, surgical ligation is often avoided in ELBW neonates.

Transcatheter PDA closure has emerged as a viable option for these neonates over the last several years. Previously, a catheter-based option for PDA closure was not widely available for these small infants secondary to concerns related to vascular access, patient fragility, contrast administration, and lack of devices specifically suited for this unique and fragile population. In recent years, a number of groups have reported successful transcatheter PDA closure in ELBW neonates using various devices – including coils,[15] Amplatzer Vascular Plug II,[16] Medtronic Micro-Vascular Plug,[17] Amplatzer Ductal Occluder II,[18] and, most recently, the Amplatzer Ductal Occluder II Additional Sizes (ADO II-AS) device.[19]

While these reports represented remarkable achievements in a high-risk group of patients in great need of a better therapeutic option, there remained no approved device (either in the United States or Europe) for treatment of PDA in infants weighing < 5kg. The ADO II-AS (now renamed the Abbott Piccolo™ device) was designed with this population in mind and included significant improvements in its design and delivery apparatus, making it a more ideal device for transcatheter PDA closure in ELBW infants. Some of the key design features include (Figure 1):

1. Retention disks only slightly larger than the central waist (allowing for complete intraductal deployment, and thereby reducing the risk of left pulmonary artery (LPA) and descending aortic obstruction).
2. Short device lengths more suitable for the PDA in these small premature neonates.
3. A uniquely soft and flexible delivery cable tip, limiting anatomic distortion during deployment and device release.

After recent completion of a multicenter study in the US demonstrating the safety and efficacy of this device,[20] it has been rebranded as the Amplatzer Piccolo™ Occluder (Abbott, Santa Clara, CA), and is the first FDA-approved device for transcatheter PDA closure in infants as small as 700 grams (g). We report a case of a critically-ill ELBW infant with a complicated perinatal course due to extreme prematurity, who showed significant clinical improvement after successful transcatheter PDA closure with the Amplatzer Piccolo™ Occluder.

Case

An ELBW female infant was born at 23 weeks six days gestation, with a birth weight of 740 g and APGARs of 7 and 8 at one and five minutes, respectively. She required intubation in the delivery room secondary to extreme prematurity and was transferred to the Neonatal Intensive Care Unit for further care. Surfactant was given shortly after delivery. The patient developed pulmonary hemorrhage

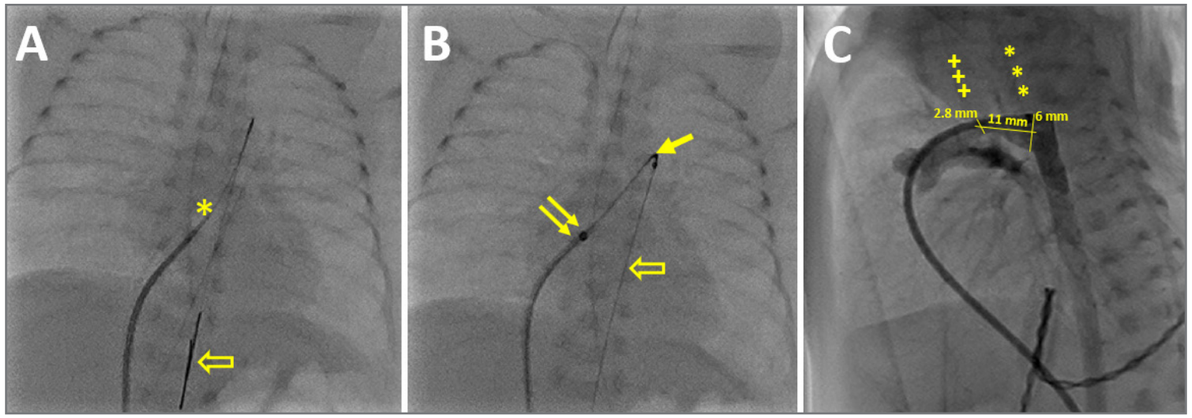

Figure 3. Stored digital fluoroscopic images during the procedure. (A) A balloon-tipped catheter (*) has crossed the Tricuspid Valve and a soft tipped 0.014" ALL STAR coronary guide wire tip (open arrow) has been advanced through the right heart, across the PDA into the descending aorta. (B) A coaxial system consisting of a microcatheter (single closed arrow) within the TorqVue delivery catheter (double closed arrow) is being advanced over the previously-placed coronary guide wire. (C) Lateral angiogram of the ductus arteriosus by hand injection with small volume of diluted contrast to delineate ductus anatomy and obtain quantitative measurements to be used for device selection. Note the esophageal temperature probe (***) and peripherally- inserted central catheter (PICC) line (+++), which serve as fairly consistent landmarks denoting the posterior and anterior margins of the ductus.

on Day of Life (DOL) 2 and had an acute decompensation the following day with marked hypotension requiring initiation of cardiac pressor support. Laboratory values showed lactic acidosis, worsening hepatic and renal dysfunction, and a clinical picture concerning for bowel ischemia. These factors prompted an emergency bedside exploratory laparotomy. While no resection of ischemic bowel was required, the patient was found to have diffuse bowel and liver inflammation.

The patient remained critically ill requiring significant cardiorespiratory support with vasoactive medications and mechanical ventilation, including the use of a high-frequency oscillator due to the severity of her premature lung disease. Over the ensuing days, her hospital course was complicated by worsening chronic lung disease, bilateral intraventricular hemorrhage with hydrocephalus, renal insufficiency, anasarca, and coagulopathy. On DOL 12 there was clinical suspicion of a hemodynamically significant PDA based on a characteristic murmur, bounding pulses on exam, and low diastolic blood pressures, which raised continued concerns about systemic hypoperfusion due to diastolic runoff from the descending aorta across the ductus arteriosus.

Transthoracic echocardiography demonstrated a large PDA with unrestricted left-to-right shunting and severely elevated pulmonary artery pressures. The patient was initially treated conservatively with volume restriction and positive pressure ventilation, without clinical improvement. A course of acetaminophen was administered on DOL 26 for an attempt at pharmacological closure. Indomethacin was felt to be contraindicated in this patient due to renal compromise. Repeat echocardiograms after acetaminophen continued to show a large PDA with significant left heart dilatation, and her physical exam and chest X-rays were consistent with significant pulmonary over-circulation. Due to these clinical and imaging findings, on DOL 33, weighing 1020 g, the patient was sent for PDA device closure.

The baby was transported to the cardiac catheterization suite in a neonatal transport isolette and positioned for catheterization in the usual fashion with arms positioned above the head. A transthoracic echocardiogram (TTE) was performed to obtain baseline 2D images, and color and spectral Doppler profiles of the PDA, left pulmonary artery (LPA) and descending aorta (Figure 2). Both groins were sterilely prepared and draped and the lateral gantry brought into position. A 21g butterfly needle and a 0.018" Micropuncture nitinol guide wire (Cook Medical, Bloomington, IN) were used to gain vascular access to the right femoral vein where a standard 4F vascular sheath (Abbott, St Paul, MN) was placed. A 4F balloon-tipped end-hole catheter was advanced to the mid-right atrium where the balloon was gently inflated. The stiff end of a 0.018" guide wire, upon which a "C-shaped" curve had been placed, was advanced to the tip of the catheter thereby directing it toward the tricuspid valve. With the wire fixed in place, the balloon-tipped catheter was advanced into the right ventricle. This wire was replaced with a 0.014" soft-tipped ALL STAR coronary guide wire (Abbott, Santa Clara, CA) with a hockey stick curve that was advanced across the right ventricular outflow track, across the PDA and down into the descending aorta (Figure 3A). The balloon-tipped catheter was then removed and a coaxial system consisting of a 2.5F microcatheter (Cantata, Cook Medical, Bloomington, IN) within a 4F TorqVue LP catheter (Abbott Medical, MN) was advanced over the 0.014" wire into the descending aorta (Figure 3B). The microcatheter and guide wire were removed and a 1 cc hand contrast injection performed in the proximal descending aorta to delineate the ductal anatomy (Figure 3C). The ductal length was 11 mm, and the narrowest ductal diameter was 2.8 mm measured at the pulmonary arterial end. As the goal in these cases is to have the entire device sit within the body of the ductus so as to minimize the risk of aortic or LPA obstruction, a Piccolo 4/2 (central body = 4 mm, outer disks 5.25 mm, length 2 mm) device was chosen and delivered through the TorqVue catheter. With the device in place, but still attached to the delivery cable, further TTE imaging was performed to examine for the possibility of LPA or descending aortic obstruction (Figure 4A-D). To confirm LPA patency a small hand angiogram was performed through the TorqVue sheath (Figure 4E). When we were assured that the ductus was closed and there was no LPA or aortic obstruction, the device was released from the delivery cable uneventfully. Final echocardiographic images were performed to ensure good device positioning, no significant residual shunting, absence of pericardial effusion, and lack of LPA or aortic stenosis (Figure 5). Thereafter, the venous sheath was removed and

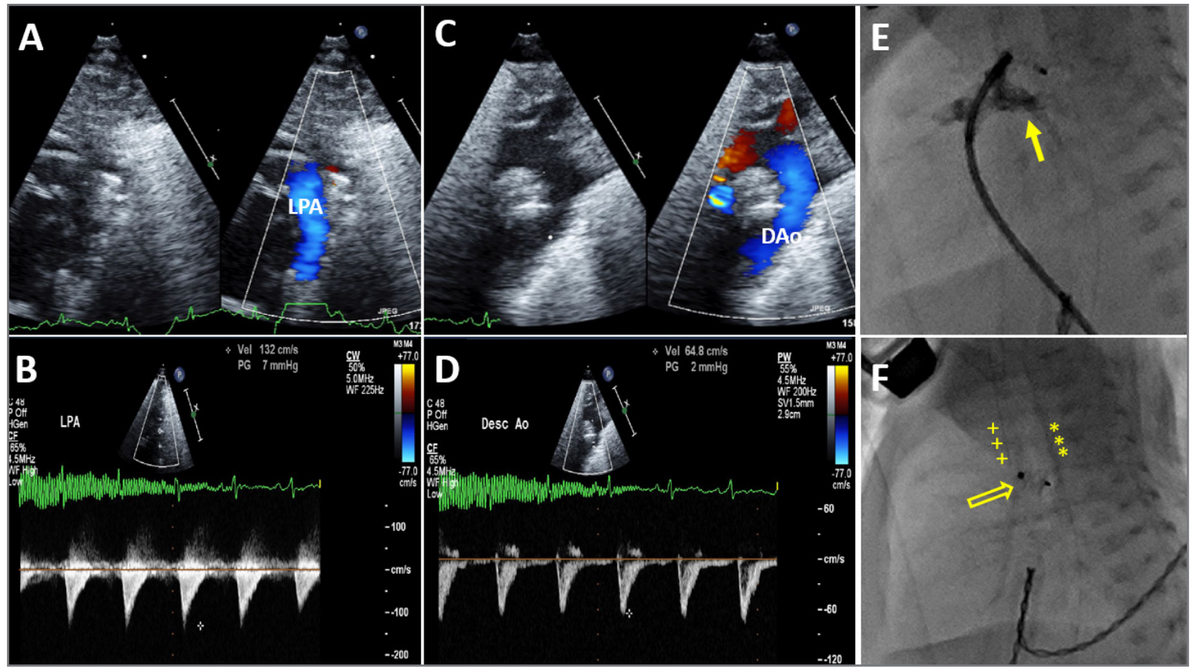

Figure 4. Echocardiographic and angiographic assessment of device position prior to release. Left pulmonary artery appearance and flow are carefully evaluated using a combination of TTE (A-D) and angiography (closed arrow in E) prior to device release. If there is a suspicion of LPA stenosis secondary to device size or position, the device is recaptured and repositioned or replaced with a different size. The descending aorta (C&D) is carefully evaluated by 2D imaging, color and spectral Doppler, and the flow pattern and velocities compared to the baseline measurements. This is a critical evaluation as in preterm PDA closure there is no aortic catheter placed to perform angiograms or measure pressures. Should aortic obstruction be caused by the device it should be repositioned or removed. (F) Fluoroscopy following device release shows a well-positioned device (open arrow) located between the previously noted temperature probe (***) and PICC line (+++) landmarks.

the patient was transferred back to the NICU. It should be noted that prophylactic antibiotics were administered and special attention was paid to maintaining normothermia throughout the procedure.

Within days following the procedure, follow-up chest X-rays showed decreased pulmonary vascular congestion (Figure 6). Dopamine was weaned off 48 hours post-procedure after a 20-day course. Three days post intervention and after a total of 36 days on mechanical ventilation, the patient was successfully extubated to non-invasive respiratory support, with continued weaning amounts of flow throughout the rest of her hospitalization before going home on 1/8 L of oxygen via nasal cannula. Following PDA closure the patient was able to tolerate enteral feeds with no signs of gut hypoperfusion, and ultimately transitioned to oral feeds before leaving the hospital. She was discharged at 4 months of life, at a corrected gestational age of 41 weeks and 3 days. Her discharge echocardiogram demonstrated good device position with no residual shunting, no LPA or aortic arch obstruction, resolution of left ventricular dilation, and near-normalization of the estimated pulmonary artery pressures (in the context of prematurity and chronic lung disease).

Discussion

This case highlights some of the commonly encountered complications seen in ELBW neonates associated with PDA, and the potential benefit transcatheter PDA closure may offer this vulnerable patient population. This case provides a not uncommon example of an ELBW infant who experienced significant early multi-organ morbidity in the setting of a large hemodynamically-significant PDA and failed attempts at medical closure and conservative medical management. The patient showed significant clinical improvement following catheter directed PDA closure, evidenced by objective imaging findings of decreased pulmonary edema and decreased left-heart volume overload, as well as a strong temporal association with significant clinical improvement, weaning of respiratory and vasoactive support, and advancement of enteral feeding shortly after device closure.

Initially established as the procedure of choice for PDA closure in infants >5 kg, the safety and efficacy of transcatheter PDA closure has more recently been demonstrated to be safe and effective in premature neonates as small as 700 g.[21-26] Preterm infants, and especially ELBW neonates, have historically been precluded from transcatheter PDA closure due to the technical limitations of the procedure and the lack of an appropriate device. However, in the last decade there has been increasing interest in bringing this time-tested therapy (in larger patients) to this in-need premature population.[15,18,27,28] Early studies reported using steel coils in a similar technique to that used in older children.[15] While the success rate was high, the nature of the available devices limited use to patients with fairly specific ductal anatomy, which was present in only a small subset of patients. Subsequent reports included use of a newer

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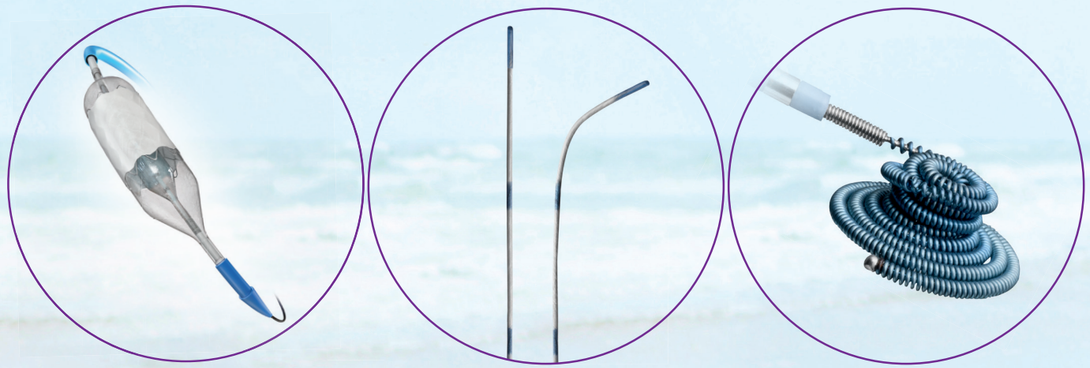

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Nit-Occlud® PDA
Coil System For PDA Closure

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The NuDEL is indicated for use in the treatment of native and/or recurrent coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta where there is adequate size and patency of at least one femoral artery associated with one or more of the following: acute or chronic wall injury; nearly atretic descending aorta of 3 mm or less in diameter; a non-compliant stenotic aortic segment found on pre-stent balloon dilation; a genetic or congenital syndrome associated with aortic wall weakening or ascending aortic aneurysm.

The NuDEL is indicated for use in the treatment of right ventricle to pulmonary artery (right ventricular outflow tract) conduit disruptions that are identified during conduit pre-dilatation procedures performed in preparation for transcatheter pulmonary valve replacement.

Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician. **Contraindications:** Clinical or biological signs of infection. Active endocarditis. Pregnancy. **Contraindications (CoA only):** Patients too small to allow safe delivery of the stent without compromise to the systemic artery used for delivery. Unfavorable aortic anatomy that does not dilate with high pressure balloon angioplasty. Curved vasculature. Occlusion or obstruction of systemic artery precluding delivery or the stent. Known allergy to aspirin, other antiplatelet agents, or heparin. **Contraindications (RVOT only):** Patients too small to allow safe delivery of the stent without injury to a systemic vein or to the right side of the heart. **Warnings / Precautions:** Administer appropriate anticoagulation therapy to reduce potential thrombosis. If the patient is not appropriately anticoagulated, thrombus formation may occur. The sheath must be flushed with heparinized saline via the proximal side port prior to introducing the delivery system into the body. The inflated diameter of the stent should at least equal the diameter of the intended implant site. Excessive handling and manipulation of the covering while crimping the stent may cause the covering to tear off of the stent. Retracting the covered stent back into the sheath may cause the covering to catch and tear off of the stent. Do not exceed the RBP. An inflation device with pressure gauge is recommended to monitor pressure. Pressure in excess of the RBP can cause balloon rupture and potential inability to withdraw the catheter into the sheath. Confirm that the distal end of the introducer sheath is at least 2.5cm back from the most proximal image band before inflating the outer balloon. Failure to do so may stretch the outer tubing and severely hinder balloon deflation. Exercise caution when handling the stent to prevent breakage. The NuDEL system, especially at the stent, is rigid and may make negotiation through vessels difficult. The inflation diameter of the balloon used during stent delivery should approximate the diameter of the obstructive vessel and the intended implant site. If resistance is encountered upon removal, the whole system (balloon, guidewire and sheath) should be removed as a single unit, particularly if balloon rupture or leakage is known or suspected. **Warnings / Precautions (CoA only):** Coarctation of the aorta involving the aortic isthmus or first segment of the descending aorta should be confirmed by diagnostic imaging. The NuMED CP Stent has not been evaluated in patients weighing less than 20kg. The platinum/iridium stent may migrate from the site of the implant. As with any type of implant, infection secondary to contamination of the stent may lead to aortitis, or abscess. Over-stretching of the artery may result in rupture or aneurysm formation. **Warnings / Precautions (RVOT only):** During the Premarket Approval study the Medtronic Melody valve was used for valve restoration. The safety and effectiveness of the Covered CP Stent for pre-stenting of the right ventricular outflow tract (RVOT) landing zone (i.e. prophylaxis or prevention of either RVOT conduit rupture or TPVR fracture; use as a primary RVOT conduit) in preparation of a transcatheter pulmonary valve replacement (TPVR) has not been evaluated. As with any type of implant, infection secondary to contamination of the stent might lead to endocarditis, or abscess formation. The Covered Stent can migrate from the site of implant potentially causing obstruction to pulmonary artery flow. Over-stretching of the RVOT may result in rupture or aneurysm of the RV-PA conduit or the native pulmonary artery.

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The Nit-Occlud® PDA coil is a permanently implanted prosthesis indicated for percutaneous, transcatheter closure of small to moderate size patent ductus arteriosus with a minimum angiographic diameter less than 4mm.

Nit-Occlud® Brief Statement:
Do not implant the Nit-Occlud PDA into patients who have endocarditis, endarteritis, active infection, pulmonary hypertension (calculated PVR greater than 5 Wood Units), thrombus in a blood vessel through which access to the PDA must be obtained, thrombus in the vicinity of the implantation site at the time of the implantation or patients with a body weight < 11 lbs. (5kg). An angiogram must be performed prior to implantation for measuring length and diameter of the PDA. Only the pfm medical implantation delivery catheter should be used to implant the device. Administration of 50 units of heparin per kg bodyweight should be injected after femoral sheaths are placed. Antibiotics should be given before (1 dose) and after implantation (2 doses) to prevent infection during the implant procedure. Do not implant the Nit-Occlud PDA in an MR environment. Do not pull the Nit-Occlud coil through heart valves or ventricular chambers. Contrast media should not be injected through the implantation catheter. The catheter must not be connected to high pressure injectors. Patients may have an allergic response to this device due to small amounts of nickel that has been shown to be released from the device in very small amounts. If the patient experiences allergic symptoms, such as difficulty in breathing or swelling of the face or throat, he/she should be instructed to seek medical assistance immediately. Antibiotic prophylaxis should be performed to prevent infective endocarditis during first 6 months after coil implantation. Potential Adverse Events: Air embolism, Allergic reaction to drug/contrast, Apnea, Arrhythmia requiring medical treatment or pacing, Arteriovenous fistula, Bacterial endocarditis, Blood loss requiring transfusion, Chest pain, Damage to the tricuspid or pulmonary valves, Death, Embolization of the occluder, requiring percutaneous or surgical intervention, Endarteritis, False aneurysm of the femoral artery, Fever, Headache/ Migraine, Heart failure, Hemolysis after implantation of the occluder, Hypertension, Hypotension or shock, Infection, Myocardial infarction, Occluder fracture or damage, Perforation of the heart or blood vessels, Stenosis of the left pulmonary artery or descending thoracic aorta, Stroke/TIA, Thromboembolism (cerebral or pulmonary), Valvular Regurgitation, Vessel damage at the site of groin puncture (loss of pulse, hematoma etc.)

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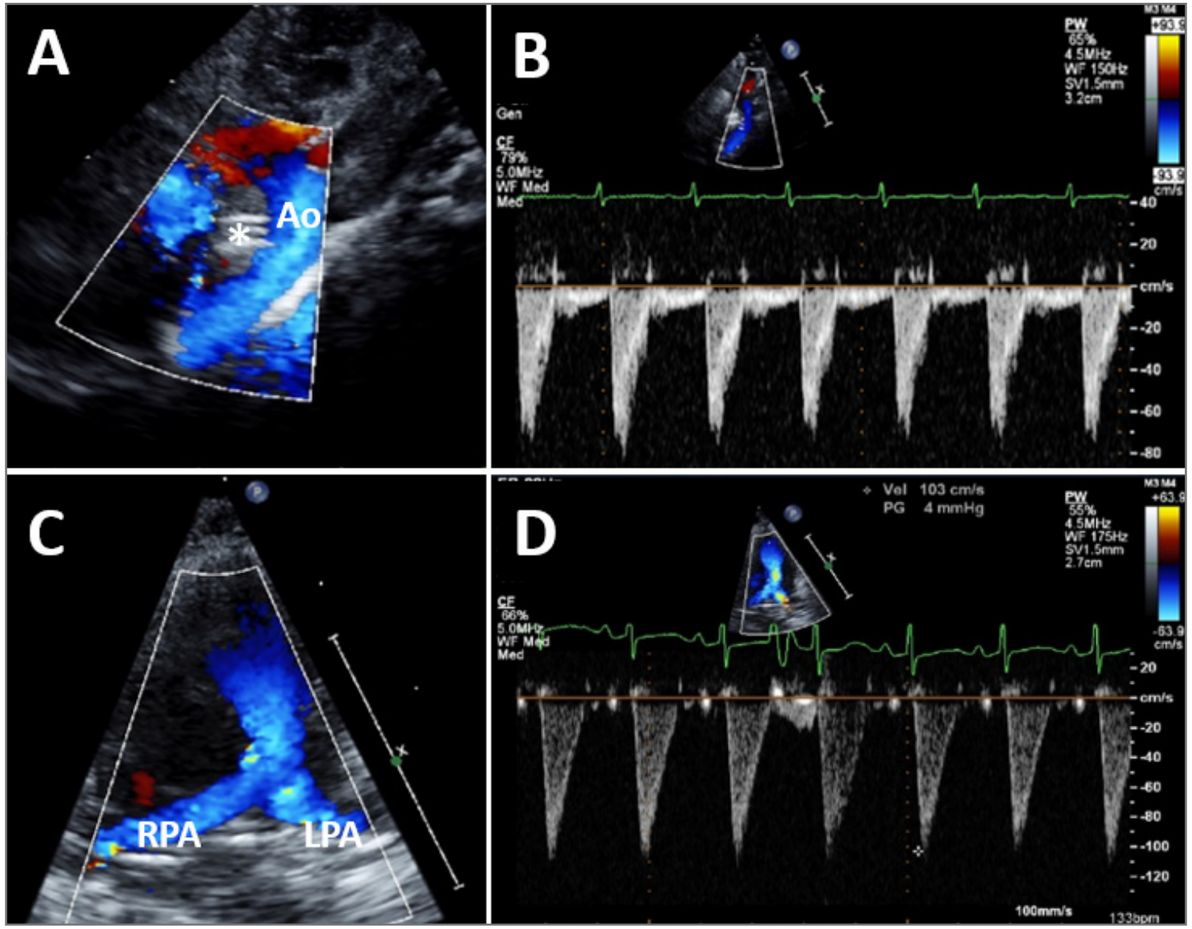

Figure 5. Echocardiography following deployment. The device (*) remains well-positioned with no malrotation or protrusion into the Ao or LPA. Echocardiographic images using color (A,C) and spectral (B,D) Doppler show no residual ductal shunting, no obstruction to LPA or Ao flow, and normal Doppler flow profiles in these vessels.

generation Amplatzer Ductal Occluder (ADO II), which supported a lower profile delivery due to absence of a central fabric and the ability to undertake an arterial or venous delivery approach because of its symmetrical design.[18] Our group described a novel transvenous technique, utilizing echocardiography with limited fluoroscopic guidance using the Amplatzer Vascular Plug II (AVP II) device in ELBW infants.[16,28] Although these reports represented innovative improvements that demonstrated that, in fact, transcatheter PDA closure was feasible in very small neonates, the relatively large outer discs compared to central waist (ADO II) and available lengths of the devices (AVP II), were not optimal for treatment of this unique population. Additionally, while several important technical challenges were overcome in these earlier works (avoidance of arterial access, reliance on echocardiography, etc.), it was recognized that additional modifications, namely a specifically-designed device and delivery system, would be necessary to make this a widely disseminated technique while minimizing risk for aortic and left pulmonary artery obstruction.[28-30]

The Amplatzer Piccolo™ Occluder, designed specifically with the unique characteristics of this population in mind, possesses many of these important traits. This device comes in lengths and diameters well-suited for intraductal deployment within the premature neonatal tubular PDA. The Piccolo is softer with a more malleable delivery cable than previous nitinol mesh devices, also quite desirable characteristics for PDA closer in these tiny infants.

Several authors have reported encouraging early results using the Amplatzer Piccolo™ Occluder device in small infants,[31] and premature neonates.[19,24] Most recently, a US investigational device exemption and subsequent continued access protocol trial studying the Amplatzer Piccolo™ Occluder was completed.[20] This was a single-arm, prospective, US multicenter, nonrandomized, open-label study which demonstrated the safety and efficacy of this device. The study initially included 50 and subsequently 150 pediatric patients, of which 18 and 82, respectively, were premature neonates weighing < 2 kg at the time of device implantation. The complete results of these studies are still in press, but based on these results the Piccolo became the first FDA approved device for transcatheter PDA closure in small infants

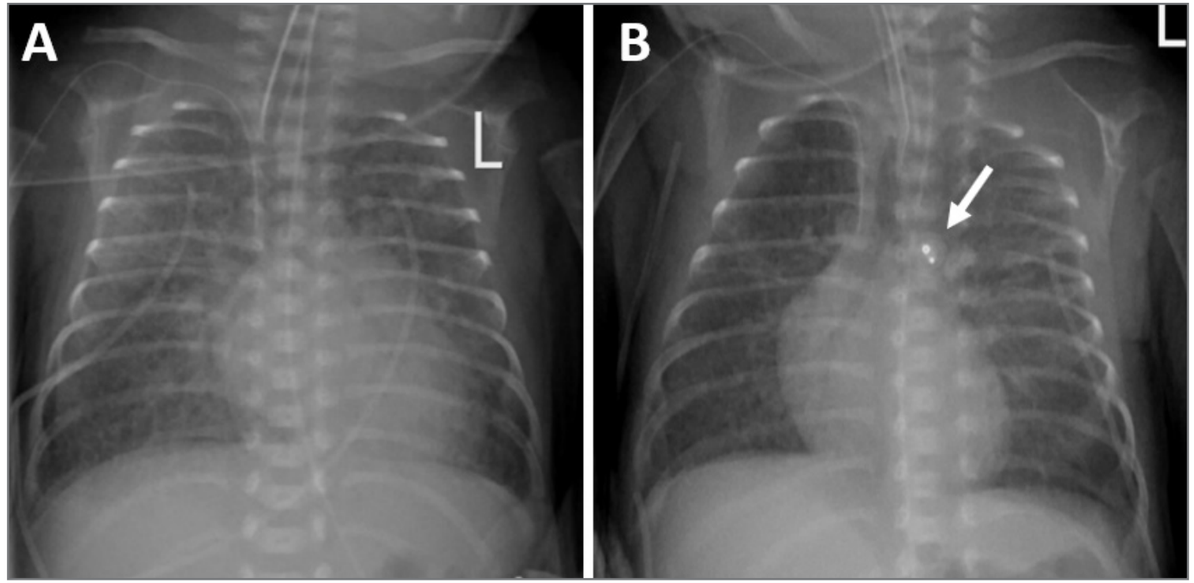

Figure 6. AP chest X-ray images. (A) Prior to the procedure there is diffuse lung granularity with coarse parenchymal infiltrates and mild cardiomegaly, changes consistent with significant premature lung disease and pulmonary overcirculation. (B) Within days following the procedure, there is stable diffuse granularity with improved pulmonary edema. The cardiac silhouette is no longer enlarged. The ductal device is seen in its expected position (arrow).

and premature neonates, recommended for use in neonates greater than three days of age weighing at least 700 g at the time of the procedure.[20]

There is little debate that the presence of a hemodynamically-significant PDA in premature infants is associated with (if not causative of) a variety of adverse effects in this group of vulnerable patients. Traditionally, only medical and surgical therapies were available. But as both have been associated with their respective complications, in recent years there has been somewhat of a change in practice to delay definitive treatment in this population and opt for a more conservative and permissive management approach. However, this carries its own risks, especially in the setting of a patient already predisposed to the vulnerabilities of prematurity, which are likely only exacerbated by the cardiorespiratory pathophysiology of a significant PDA.[5,7,32-34] Recent advances in transcatheter technology and the pioneering work of a number of groups have demonstrated that a minimally-invasive catheter approach is a viable option in small infants, and even in the significantly premature ELBW population. The advantages of the transcatheter route versus the pharmacological or surgical option includes: potential avoidance of sometimes ineffective medications and their side effects, an immediate result as opposed to several days of delayed medical response, a less invasive approach than surgery with avoidance of a thoracotomy, and faster postoperative recovery and decreased risk for Post-Ligation Syndrome.[28]

While potential risks from transcatheter therapy are not insignificant – including the possibility of vascular injury, device embolization, and aortic or left pulmonary artery stenosis – these are uncommon, especially in experienced hands, as has been previously published.[15,17,24,28] Nevertheless, given that the optimal treatment strategy for this lesion in this population still remains uncertain, there is a great need for prospective multicenter randomized trials to compare the short- and long-term outcomes of PDA device closure with other treatment strategies in these premature patients. This notwithstanding, it is clear that transcatheter PDA closure represents an exciting additional therapeutic option warranting further work and attention in this important population.

Conclusion

This case demonstrates that transcatheter PDA closure can be performed safely and effectively in an extremely premature critically-ill neonate, with good clinical success. Recent availability of the Abbott Piccolo™ Device – the first of its kind designed and approved specifically for this unique population – further highlights the promising nature of catheter-based PDA closure in premature neonates. Future large multicenter studies are needed to evaluate the associated short- and long-term risks and benefits of this procedure versus other forms of PDA management in these infants.

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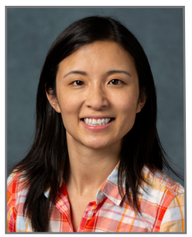

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3DI3 International Symposium on 3D Imaging for Interventional Catheterization in CHD

By Aimee K. Armstrong, MD

3D Rotational Angiography (3DRA) represents the most innovative and sophisticated technique available in heart catheterization imaging for adult and pediatric patients. With its astonishing image quality, it offers significant benefit during diagnostic and interventional catheterizations. It provides a thorough anatomic evaluation with 2D CT-like images and 3D reconstruction of complex structures and interactions, including of the airway and esophagus, with views from an almost infinite number of angles. This allows for a quick and easy understanding of anatomy on which to base optimal therapeutic decisions and gantry angles. It also provides image-guided therapy with overlay of the 3D reconstruction on live fluoroscopy and can decrease radiation exposure by limiting the number of required 2D angiograms. The combined diagnostic and therapeutic advantages are all available in a one-stop shop environment in the catheterization laboratory. The *3DI3* conference will give you and your team the necessary knowledge and hands-on post-processing skills to apply this in your laboratory quickly and simply. Furthermore, the *3DI3* faculty will show additional state-of-the-art 3D imaging capabilities, including 3D TEE, CT, and MRI, as they are used to complement and assist interventional catheterization for Congenital Heart Disease.

Despite the available 3DRA hardware and software from multiple vendors in the early part of this decade, a significant lack of user experience prevailed. Dr. Gregor Krings in Utrecht, The Netherlands, was an early adopter of 3DRA technology, and he started working on x-ray system settings, ventilation and pacing protocols, and injection timing, location, and volumes to optimize image quality and lower radiation dose. In order to share his experience and learn from others around the world with experience in 3DRA, Dr. Krings created the International 3DRA Conference in Utrecht in 2013. This platform for learning and collaboration turned into an annual meeting that was integral in spreading 3DRA technique and its many advantages for interventional therapies around the globe. The hallmarks of these conferences were hands-on rooms for learning 3DRA post-processing from different vendors, live cases, and a “cookbook” lecture on basic 3DRA techniques. After three years of success, it was time to expand both the content and the audience by moving the conference to the US.

Dr. Krings and Dr. Aimee Armstrong at Nationwide Children’s Hospital created 3DI3, an international conference to share knowledge and skills on all 3D imaging, as it pertains to interventional catheterization for congenital heart disease. The first *3DI3* conference was held in October 2016 in Columbus, OH. Since then, *3DI3* has had

3DI3 at PICS 2018 Live Case from Nationwide Children’s Hospital with Drs. Darren Berman, Brian Boe, and Arash Salavitabar and moderators Drs. Evan Zahn, Bryan Goldstein, Lee Benson, and Shak Qureshi.

Dr. Aimee Armstrong teaches basic 3DRA techniques during 3DI3 at PICS 2018.

the privilege of joining the *IPC* workshop in Milan twice (September 2017 and March 2019), and *PICS-AICS* for the entire first day in 2018.

In 2019, *3DI3* will be combining with the prestigious *15th Society for Pediatric Radiology Advanced Symposium on Pediatric Cardiovascular Imaging*. Both conferences will be held at Nationwide Children's Hospital in Columbus, OH with the following schedule:

- *SPR Advanced Symposium*: October 18-20, 2019
- *3DI3*: October 19-21, 2019

Drs. Gregor Krings and Aimee Armstrong direct the first 3DI3 conference in Columbus, OH in October 2016.

These 2 conferences are combining to cover: everything you need to know about iCMR (including an iCMR taped case from Dallas), 3D imaging and management decisions for single ventricles and TOF (Can we predict coronary compression in TPVR with non-invasive imaging? When does the pulmonary valve need replacement? How do we predict successful TPVR in the native RVOT?), and collaboration between radiology and cardiology. Don't miss *3DI3* classics, such as 3DRA boot-camp, 3DRA hands-on post-processing rooms, 3DRA hands-on spin demonstrations, and live and taped cases using 3DRA, as well as new sessions on lymphatic imaging and intervention, 3D printing vs. virtual reality, and practical applications of 3DRA.

Esteemed faculty include: Mario Carminati, Yoav Dori, Damien Kenny, Petru Liuba, Vivek Muthurangu, Fancesca Pluchinotta, Lourdes Prieto, Shakeel Qureshi, Kanishka Ratnayaka, Jennifer Romano, and Silvia Schievano.

See the agenda and register at www.3DI3.org.

Come with colleagues from your institution, and receive a group discount. *PICES* members receive discounts as well!

Prior to the big Columbus conference, come and experience a taste of *3DI3* at *PICS-AICS* in the main session from 2-5:30 pm, Thursday, September 5, 2019, where you will learn about the use of 3DRA for branch PA stenting and TPVR.

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International Medical Graduates—Vital to Cardiovascular Care Here and Abroad

By William W. Pinsky, MD, FAAP, FACC

It's been 40 years since I completed my fellowship in Pediatric Cardiology. In the course of my career, I have been privileged to view cardiovascular care, and health care more generally, from a variety of roles—clinical, academic, regulatory, and administrative. I have had the opportunity to serve in hospitals and health systems around the country that vary widely in size and resources. My experience also includes roles with organizations like the Educational Commission for Foreign Medical Graduates (ECFMG®), which are concerned with the education, training, and assessment of physicians, nationally and internationally.

While much has changed during my career, the important role played by international medical graduates (IMGs) in the cardiovascular disciplines has been a constant. They are leaders in our field, our teachers and mentors, and our colleagues and students. In each of these roles, they are sources of knowledge, inspiration, and support. They also are our healthcare providers.

As providers, IMGs are vital to US health care. Twenty-five percent of our nation's physicians received their medical education outside of the United States and Canada, according to data from the American Medical Association. Even more significant, about one-third of active physicians in the cardiovascular specialties, and 22% of Congenital Cardiac surgeons, are IMGs.

Some IMGs in cardiovascular care in the United States are US citizens who earned their medical credentials abroad. The vast majority, about 85%, come from more than 130 other countries. They are drawn to the United States as one of the world's premiere locations for advanced training in cardiovascular care. In the United States, they have access not only to training in traditional aspects of our specialties, but also to a host of advanced programs, which represent the emerging knowledge, research, and techniques that are shaping the future of the cardiovascular disciplines.

ECFMG is the sole sponsor of foreign national physicians for the J-1 visa to participate in US clinical training programs. Since the J-1 is the most common visa classification employed for this purpose, ECFMG's data provide a representative snapshot of the pipeline of foreign national IMGs who pursue US training to enter cardiovascular care.

In 2018, ECFMG sponsored 651 foreign national IMGs to train in nearly 40 cardiovascular specializations within Anesthesiology, Surgery, Internal Medicine, Pediatrics, Radiology, and Thoracic Surgery. These individuals were engaged in training programs located in 43 US states. The number of foreign national IMGs training in these cardiovascular specializations in J-1 visa status has grown by 23% over the past five years.

The purpose of the J-1 visa is to expose individuals from around the world to the culture and institutions of the United States and to foster a better understanding between nations through educational and cultural exchange. ECFMG-sponsored J-1 physicians are required to return home for at least two years after completing their training. Although there are legal options that allow some of these physicians to remain in the United States, many return to their home countries, where they apply the knowledge and skills acquired in their US training programs. It is common for IMGs who return home to become leaders in clinical and academic settings, influencing the practice and education of new generations of physicians. Additionally, the physicians who return to countries where technological resources are lacking are well-positioned to advocate for the adoption of such resources.

The IMGs who remain here to practice provide healthcare throughout the nation. IMGs are a significant percentage of the physician workforce, and our access to care depends upon their continued contributions. This is especially true in underserved areas, both rural and urban, where IMGs practice in large numbers and become integral to our communities. In addition to providing highly-skilled care, these physicians from around the world bring much-needed diversity to our health care system and enrich our learning and practice environments with their international perspectives.

For those of us who work with them, international physicians elevate our knowledge and practice. For the sake of our field and the patients we serve, we are fortunate that the United States continues to attract the best and brightest from around the world.

William W. Pinsky, MD, FAAP, FACC, is President and CEO of the Educational Commission for Foreign Medical Graduates (ECFMG), Board Chair of the Foundation for Advancement of International Medical Education and Research (FAIMER®), and an Honorary Professor of the University of Queensland, Australia. He is a pediatric cardiologist who graduated from Saint Louis University School of Medicine and trained at Baylor College of Medicine and at Texas Children's Hospital in Houston. Dr. Pinsky has served on the Boards of the Accreditation Council for Graduate Medical Education, the Accreditation Council for Continuing Medical Education, and the Alliance of Independent Academic Medical Centers where he also served as President.

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Medical News, Products & Information

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Driscoll Children's Hospital Expands to Digisonics Enterprise CVIS License

Driscoll Children's Hospital, a leading pediatric tertiary care center in South Texas has upgraded their Digisonics system to Enterprise level licensing.

The Enterprise licensing will deploy access to the Digisonics cardiovascular information system across Driscoll's network of hospitals throughout South Texas, providing clinicians with a system designed specifically for congenital cardiology with z-scores, trend plots and Mullins diagrams. Combined with seamless integration to their imaging modalities and Epic EMR, the Digisonics CVIS enables Driscoll to operate with an automated, efficient workflow, ensuring fast turnaround times and the best quality of patient care.

About Digisonics, Inc.

Digisonics provides top-rated clinical image management and structured reporting systems for cardiovascular (CVIS), radiology, and obstetrics & gynecology. Digisonics structured reporting solutions combine high performance image review workstations, a powerful PACS image archive, an integrated clinical database, comprehensive analysis capabilities and highly configurable reporting for multiple modalities. Key applications are complemented with interfaces to information systems and 3rd party vendors, providing facilities with a seamless, efficient clinical workflow. Find out more at www.digisonics.com

Reusing Patient's Own Blood During Heart Surgery May Improve Outcomes

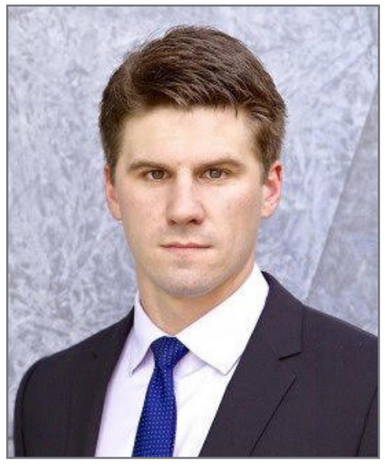
Newswise — Patients whose own red blood cells are recycled and given back to them during heart surgery may experience shorter hospital stays and fewer complications than patients who receive donated blood, according to a scientific presentation at the *55th Annual Meeting of The Society of Thoracic Surgeons*.

"Intraoperative autologous blood donation—when a patient has blood removed at the beginning of surgery and preserved for his/her own use—is a feasible strategy that can be implemented in many different environments," said Eric Zimmermann, MD, formerly of New York-Presbyterian Queens (NYPQ) Hospital in New York, now with Oregon Health & Science University in Portland. "Our study shows that heart surgery teams who use this approach can produce better outcomes for their patients." Dr. Zimmermann and colleagues examined data from 689 patients who received heart surgery at NYPQ Hospital between January 2009 and December 2017. Because the institution launched a "more aggressive" intraoperative autologous donation (IAD) protocol in January 2013, the data were separated into two groups: Group 1 included 268 patients who received heart surgery "before" the IAD protocol, and Group 2 included 420 patients who had heart surgery "after," meaning that their own blood was salvaged and given back to them during their surgeries. Emergency surgeries were excluded from the analysis.

The research showed that with the more stringent IAD protocol, the need for blood transfusion decreased from 70% to 40% and the chest tube output was lower, reducing from 1,295 ml to 1207 ml. The chest tube is a drain that is placed at the time of surgery to help remove extra fluids from the patient. A reduced output is notable because it means patients may be able to get moving quicker and leave the hospital sooner. In addition, patients

experienced a shorter length of hospital stay, 7.8 days versus 6.8 days.

"The effect of IAD translates to roughly one day shorter length of stay," said Dr. Zimmermann. "This may seem modest but it could have a real effect. I believe that blood conservation may offer significant savings in terms of morbidity and mortality. Importantly, these savings have implications for quality of life after heart surgery and also may translate to cost efficiencies for hospitals and care providers."



Eric Zimmermann, MD, formerly of New York-Presbyterian Queens (NYPQ) Hospital in New York, now with Oregon Health & Science University in Portland.

IAD involves a patient's blood being removed at the beginning of surgery and then stored as "whole blood" during the operation. Other than an anticoagulant added to prevent clotting, the blood is physically unmodified. At the end of the surgery, the blood is returned to the patient, with the cells behaving as if they had never been outside of the body. Risks associated with IAD include reduction in circulating red blood cells (causing reduced oxygen carrying capacity) and contamination of blood during storage (bacterial or viral).

According to Dr. Zimmermann, intraoperative blood conservation is not only safe and effective, but it also can be a cost-saving alternative. Blood donated by conventional practices (e.g., patients donating blood weeks prior to surgery and/or the use of donated banked blood) requires extra testing, staffing, and storage fees. As a result, this method carries additional risks and much higher costs than intraoperatively donated blood. "We believe that intraoperative autologous blood donation strikes a reasonable balance between cost and benefit," he said.

Gabriel S. Aldea, MD, of the University of Washington in Seattle, explained that while transfusions following heart surgery remain common, research such as this "conclusively" demonstrates that decreasing transfusions will improve clinical outcomes. "STS, along with surgeon- and physician-led initiatives, continues to highlight and communicate results like these, in addition to offering a broad menu of different options on how to achieve lower transfusion rates, with the goal being a more universal, standard of care acceptance," said Dr. Aldea, who was not directly involved with this research.

It also is important to note that intraoperative autologous blood donation requires buy-in and agreement from many stakeholders, including perfusionists, anesthesia staff, and heart surgeons. "But once all parties are in agreement, the tangible benefits seem to outweigh the upfront effort," said Dr. Zimmermann. "Perfusionists are an especially important part of the team, with their careful accounting of the fluid and blood in and out of the patients who are undergoing heart surgery. Research like this would not be possible without their support."

The American Red Cross reports that more than 36,000 units of red blood cells are needed daily in the United States. In addition, recent data show that up to 50% of heart procedures require blood transfusion, with these operations consuming as much as 15% of the nation's blood supply, according to the most recent clinical practice guidelines from *STS* and the *Society of Cardiovascular Anesthesiologists*. Because of this demand, intraoperative autologous blood donation may become a key surgical blood conservation strategy.

"Heart surgery is a field that has remained essentially unchanged since its modernization in the mid-20th century," said Dr. Zimmermann. "If we continue to use similar techniques, we can expect similar results. While autologous blood donation is not a panacea, it may be a cost-effective adjunct that may provide benefit in addition to other quality improvement measures. In our partnership with New York-Presbyterian/ Weill Cornell Medical Center, we aspire to be one of the first hospitals in the world to consistently use this method in every open heart operation."

The other authors of the study were DV Avgerinos, R Zhu, and T Ogami.

Find comprehensive medical information presented for patients by leading experts in cardiothoracic surgery on the *STS* Patient Website, www.ctsurgerypatients.org. For more information, contact Media Relations Manager Jennifer Bagley at 312.202.5865 or jbagley@sts.org.

Founded in 1964, *The Society of Thoracic Surgeons* is a not-for-profit organization representing more than 7,400 cardiothoracic surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lung, and esophagus, as well as other surgical procedures within the chest. The Society's mission is to enhance the ability of cardiothoracic surgeons to provide the highest quality patient care through education, research, and advocacy.

ASE Celebrates the Impact of Cardiovascular Doppler in Improving Patient Care

The December issue of the *Journal of the American Society of Echocardiography (JASE)*, the research journal of the *American Society of Echocardiography (ASE)*, includes a compendium of five review articles focusing on the introduction and initial integration of different aspects of cardiovascular Doppler into clinical practice over the past 50+ years. In the introduction to the articles, "Celebrating (More Than) 50 Years of Doppler Echocardiography," the *JASE* Editor-in-Chief Emeritus, Alan S. Pearlman, MD, FASE, said, "These five authors helped to introduce Doppler methods into the field of echocardiography. The ability to measure blood flow velocity, and to image flow patterns in health and disease, allows us to examine cardiovascular hemodynamics in a routine, practical, and non-invasive manner. Careful attention to technical details was of high importance in developing and perfecting Doppler methods, and remains relevant today."

Current *JASE* Editor-in-Chief, Michael H. Picard, MD, FASE, said, "We are fortunate to have these contributions from these authors. Each, in their own unique style, provides fascinating insights into various aspects of the history of Echocardiography. I think readers at all phases of their careers, from novice to expert, will find these papers of great interest." Here is a list of the internationally renowned Doppler pioneers and their papers:

- "Directional Doppler in Cardiology: A 50-Year Journey," by Colette Veyrat, MD
- "Clinical Implementation of Continuous-Wave Doppler: It Made All the Difference," by Randolph P. Martin, MD, FASE, FACC, FESE
- "Pulsed Doppler Echocardiography: An Historical Perspective," by Julius M. Gardin, MD, MBA, FASE
- "The Development of Color Doppler Echocardiography: Innovation and Collaboration," by J. Geoffrey Stevenson, MD, FASE, FACC

- "The Integration of Doppler Ultrasound With Two-Dimensional Echocardiography and the Noninvasive Cardiac Hemodynamic Revolution of the 1980s," by Fletcher A. Miller, Jr., MD, FASE

About ASE

As the largest global organization for cardiovascular ultrasound imaging, the *American Society of Echocardiography (ASE)* is the leader and advocate, setting practice standards and guidelines. Comprised of over 17,000 physicians, sonographers, nurses, and scientists, *ASE* is a strong voice providing guidance, expertise, and education to its members with a commitment to improving the practice of ultrasound and imaging of the heart and cardiovascular system for better patient outcomes. *ASE's* International Alliance Partners program includes over 27 nonprofit organizations and was developed to create a pathway for collaborations and shared resources among participating membership-based echocardiography/cardiology societies.

For more information about *ASE*, visit www.ASEcho.org or *ASE's* public information site, www.SeeMyHeart.org.

FDA Approves World's First Device for Treatment of Premature Babies and Newborns with an Opening in Their Hearts (a Common Congenital Defect)

- First and only minimally invasive, transcatheter treatment specifically approved for premature babies with a patent ductus, a life-threatening opening in their heart
- Nearly 12,000 very low birth weight babies are born in the US each year with a persistent opening in their heart that requires medical intervention[1,2,3]
- Life-saving technology provides new and optimally-sized treatment option to address critical need for the tiniest newborns, including premature infants weighing as little as two pounds

Abbott announced the US Food and Drug Administration (FDA) approved the Amplatzer Piccolo™ Occluder, the world's first medical device that can be implanted in the tiniest babies (weighing as little as two pounds) using a minimally invasive procedure to treat patent ductus arteriosus, or PDA. The Amplatzer Piccolo, a device even smaller than a small pea, now offers hope to premature infants and newborns who need corrective treatment, and who may be non-responsive to medical management and high risk to undergo corrective surgery.

One of the most common congenital heart defects occurring in premature babies, PDA is a potentially life-threatening opening between two blood vessels leading from the heart. This channel, which is present in normally developing fetuses, is important prior to birth to allow oxygen-rich blood from the mother to circulate throughout the fetus' body. For most infants, the pathway, or duct, seals itself shortly after birth. In some cases, primarily in babies born prematurely, the PDA fails to spontaneously close, which can make it difficult for babies to breathe normally due to increased blood flow to the lungs. PDA accounts for up to 10 percent of all congenital heart disease.[4]

Approximately 60,000 premature babies in the US are born each year with a very low birth weight[5], and nearly 12,000 (one out of five) of these have a hemodynamically significant PDA –a PDA that is large and causes symptoms – which will require urgent treatment for the baby to survive.[6,7]

"This approval is a potentially life-saving advance for the very smallest premature infants that will help us treat these delicate babies who might otherwise not be able to survive," said Evan Zahn, MD, director of the Congenital Heart Program at Cedars-Sinai's Smidt Heart Institute, and principal investigator for the study that led to FDA approval.

The Amplatzer Piccolo Occluder is a self-expanding, wire mesh device that is inserted through a small incision in the leg and guided through vessels to the heart, where it is placed to seal the opening in the heart. It is designed to allow the physician to insert it through the aortic or pulmonary artery, as well as to retrieve and redeploy the device for optimal placement. Because the device is deployed in a minimally invasive procedure, many of the premature babies who are critically ill in the neonatal intensive care unit are able to be weaned from artificial respirator support soon after the procedure.

Born at 27 weeks, twin babies Irie and Judah Felkner of Columbus, Ohio, were both fighting for their lives in the neonatal intensive care unit when an echocardiogram revealed Irie had a PDA that required immediate treatment.

"The doctor thought Abbott's Amplatzer Piccolo device was the best solution for Irie, and after learning more about the procedure we decided to move forward," said Crissa Felkner, Irie's mother. "You have to live it to fully appreciate what that device did for our daughter. Three days after the procedure, she was making great progress and is now a normal toddler with no limitations. The Abbott device was truly lifesaving for our daughter."

The Felkner twins were treated as part of the US pivotal trial, ADO II AS, which helped to support the FDA approval of the device. The trial evaluated the Amplatzer Piccolo Occluder and enrolled 50 patients with a PDA who were older than three days at eight centers across the US. The safety and efficacy of the device is further supported by additional experience with the device under a continued access protocol involving 150 more patients.

"Piccolo is a critical advancement in the standard of care for the most vulnerable of premature babies who may not be able to undergo surgery to repair their hearts," said Michael Dale, vice president for Abbott's structural heart business. "Our mission is to develop life-changing technology to help people live better lives through improved health. This approval is another important step toward achieving our mission for the patients and physicians we serve."

The Amplatzer Piccolo device builds on more than 20 years of clinical success for Abbott's family of Amplatzer Occluder therapies, including the Amplatzer™ Duct Occluder II product, already approved for use in the US, Europe and countries around the world to treat PDA in larger size pediatric patients.

Abbott is committed to developing minimally invasive life-saving pediatric devices that have an immediate impact with long-term benefits, reduce the risks of life-threatening complications and allow physicians to confidently treat the youngest and tiniest patients. The FDA approval of the Amplatzer Piccolo device follows last year's approval of the world's smallest rotatable mechanical heart valve. The Masters HP 15mm pediatric mechanical heart valve provided surgeons with a much-needed option for treating vulnerable, high-risk pediatric patients with congenital heart defects and no other approved options.

For US Important Safety Information about the Amplatzer Piccolo Occluder, visit www.structuralheartsolutions.com/us/piccolo-ISI.

About Abbott

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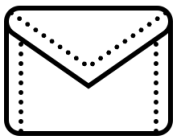

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