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## Table of Contents



# Transcatheter Patent Ductus Arteriosus Closure in Extremely Low Birth Weight Infants: From Catheterization Lab to Bedside

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## Introduction

Many different clinical approaches exist to the management of a Patent Ductus Arteriosus (PDA) in a premature neonate: observation, medical therapy, surgical ligation, and transcatheter PDA closure (TCPC).[1] TCPC in Extremely Low Birth Weight (ELBW) neonates has quickly become a common practice in many centers with expertise with several studies showing safe and successful PDA closure with this technique.[2,3] TCPC in ELBW infants commonly occurs in the catheterization lab requiring the patient to transfer from the neonatal intensive care unit (NICU), and likely adds to the hesitancy of neonatologists to fully support TCPC.[4-6] Therefore, it is imperative to bring TCPC safely and successfully "to the bedside" to provide the best possible outcomes for patients. This article will highlight our programmatic practice regarding PDA evaluation, and the evolution of the TCPC program in ELBW infants from the catheterization lab to the NICU bedside (**Figure 1**).

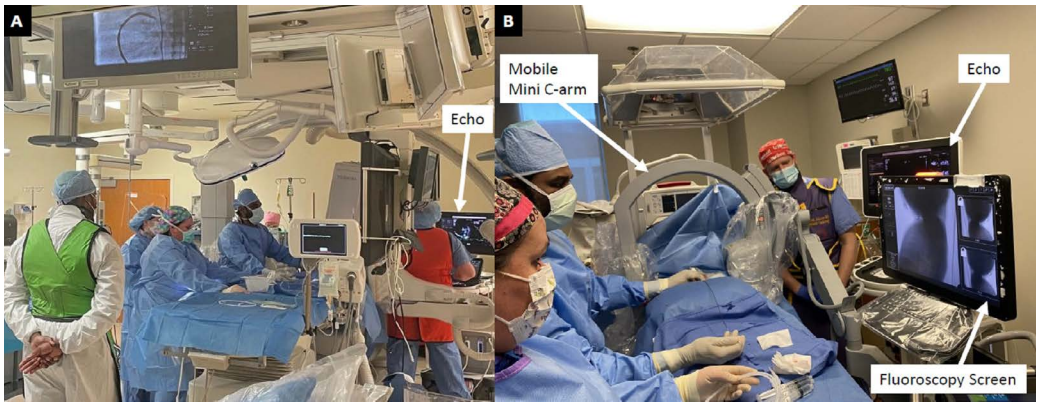


FIGURE 1 *Catheterization lab and neonatal bedside transcatheter patent ductus arteriosus closure set up.* ***A).*** *Catheterization lab. The implanter and assistant stand on the right side of the patient and the sonographer stands of the left side with left-handed scanning.* ***B).*** *Neonatal bedside. The implanter and assistant stand on the right side of the patient while the mobile digital Mini C-Arm and the echocardiographer are on the left side of the patient with right-handed scanning.*

## Hemodynamically Significant PDA

A consensus definition of a hemodynamically significant PDA (hsPDA) does not exist. A combination of clinical history and echocardiographic characteristics is the best way to define PDA significance.[7-10] Clinical factors suggesting a hsPDA are: ventilator support due to pulmonary edema, requirement

# APRIL 2022

International Edition Vol. 20 - Issue 4

## TABLE OF CONTENTS

of inotropes, feeding intolerance, and renal insufficiency in the context of a vulnerable patient.[11] Neonates born <26 weeks' gestation are a vulnerable population because they do not have spontaneous PDA closure until a median of 71 days, sustaining significant complications of a hsPDA.[12]

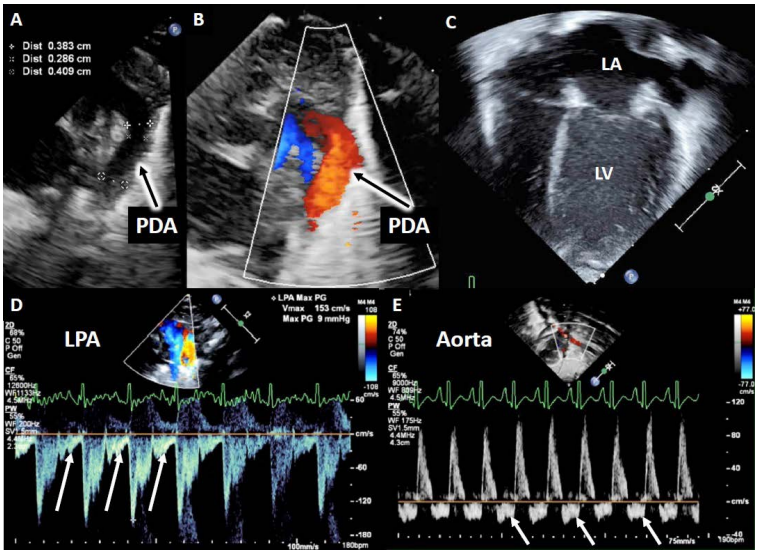


**FIGURE 2** *Echocardiographic assessment of a hemodynamically significant PDA.* ***A).*** *Two dimensional measurements of a large PDA.* ***B).*** *Color Doppler of a large PDA with low velocity left to right shunting.* ***C).*** *Four chamber with moderate left atrial and ventricular dilation.* ***D).*** *Left pulmonary artery spectral Doppler with diastolic continuation of flow (arrows).* ***E).*** *Abdominal aorta spectral Doppler with diastolic reversal of flow (arrows). LA=left atrium. LPA=left pulmonary artery. LV=left ventricle. PDA=patent ductus arteriosus.*

There are numerous protocols to report echocardiographic parameters of a hsPDA, but none have been concurrently confirmed with cardiac catheterization hemodynamics.[1,13,14] Echocardiographic parameters focus on PDA shunt size, extent of volume overload, and evidence of systemic hypoperfusion.[11] A minimal PDA diameter >1.5 mm and low velocity left to right flow pattern suggest a large PDA shunt volume **(Figure 2).** However, PDA diameter alone may not correlate with a large shunt, and there can be interobserver variability in the measurement.[15] Left atrial and ventricular chamber dilation and diastolic continuation of flow in the branch pulmonary arteries suggest a large volume overload from a hsPDA **(Figure 2)**. Diastolic flow reversal in the abdominal aorta suggests systemic hypoperfusion **(Figure 2)**.

Accurate communication of echocardiographic findings of a hsPDA to the neonatology team is essential. Simply stating the PDA is small, moderate, or large is not sufficient information for the neonatologist to determine hemodynamic significance. At our institution a quality improvement initiative improved the echocardiographic communication of the different factors potentially defining a hsPDA. Our echocardiographic summary reports include minimal PDA diameter, PDA shunt direction with peak velocity, left atrial (LA) and ventricular chamber size, and abdominal aorta flow pattern at the minimum. Also, there is no consensus definition of a hsPDA at our institution agreed upon by all cardiologists and neonatologists. The goals of the echocardiogram report are to be consistent and provide easily understandable and reproducible data in a timely manner for the neonatologist. At some institutions, the neonatology team performs and reports the PDA echocardiograms and are experts in echocardiographic evaluation of hsPDA.[16]

## Timing of PDA Closure

An extensive discussion on prophylactic PDA closure, medication attempts at PDA closure, and surgical ligation are outside the scope of this review.[1] However, a brief review of the clinical conundrum the presence and treatment of a hsPDA poses to clinicians caring for ELBW neonates follows. Despite multiple studies outlining the morbidity caused by a hsPDA, there is a lack of decrease in morbidity and mortality in prophylactic medical or surgical PDA closure.[17-19] The PDA-TOLERATE trial found medical treatment after one week of life was not associated with reduced PDA ligations or PDAs present at discharge in infants born before 28 weeks gestation, and infants born between 26 and 28 weeks gestation had increased rates of late-onset sepsis and death when exposed to early medical PDA treatment.[20] Surgical ligation has frequently been linked to increased morbidities such as Bronchopulmonary Dysplasis (BPD), Retinopathy of Prematurity (ROP), and poor neurodevelopmental outcomes.[21-23] Due to no convincing studies showing clear benefit of medical and surgical PDA ligation, many neonatologists have adopted a conservative approach to PDA management.[24] However, spontaneous closure of PDAs and the need for rescue treatment for those in the conservative treatment group make it difficult to accurately evaluate the morbidities associated with conservative treatment alone.[25]

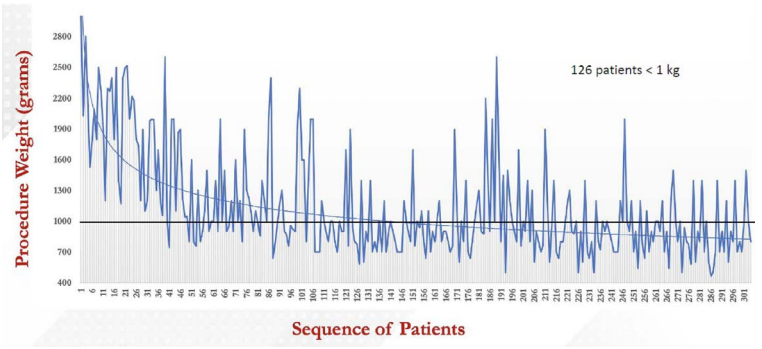


**FIGURE 3** *Sequence of 1-301 patients with the procedure weight at the time of transcatheter patent ductus arteriosus closure at Le Bonheur Children's Hospital.*

Initial results of TCPC in infancy showed mixed results and added to the clinical conundrum of PDA management especially in ELBW neonates.[3] However, a recent meta-analysis of TCPC in infants ≤1.5 kg showed a technical success of 96% with a major adverse event rate of 8%.[2] This increased procedural success of TCPC occurred in an era of decreasing patient weight at time of procedure.[2] Our institutional TCPC experience shows excellent success rate with low adverse events (AE) and suggests that earlier closure (<4 weeks) is associated with improved outcomes including quicker weaning of ventilatory support and improved growth.[26,27] Also, ELBW infants referred for TCPC >8 weeks may have elevated pulmonary vascular resistance suggesting a likely loss of benefit of PDA closure in patients referred late.[27] Over time this has led to our patient referral for TCPC to be younger and weigh less at time of procedure (**Figure 3**). There is no minimum patient weight threshold yet identified, with reports including patients as small as 490 grams, and the Amplatzer Piccolo Occluder (Abbott Medical, New Plymouth, MN, USA, APO) device is approved in infants weighing >700 grams.[28-30] While TCPC is technically feasible at very early ages and small weights, timing is often dictated by medical management in the absence of clear PDA treatment guidelines.[31] Earlier in our experience with TCPC, a core group of neonatologists and cardiologists would discuss the indications and eligibility for TCPC for every neonate <1.5 kg referred for the procedure.

## Transcatheter PDA Closure Expertise

We have created a comprehensive program in the care of preterm neonates and infants with PDA before and after TCPC.[32] This involves developing expertise with PDA management amongst neonatology, cardiology, anesthesiology, pulmonology, neurodevelopmental specialists, nutrition, speech therapy, social work, medical transport, and research collaborators. Our comprehensive neonatal intensive care unit provides multi-disciplinary care to all ELBW neonates and infants regardless of the presence of a PDA. Our program is unique in creating specific outpatient follow-up after patients are discharged following TCPC. This provides an opportunity for long-term follow-up of specific cardiovascular and neurodevelopmental outcomes that are currently ongoing.

TCPC is standard of care for PDA management in children and adults with PDA.[33] However, the technique of TCPC in ELBW neonates is vastly different than TCPC in children and adults. Therefore, creating procedural expertise amongst all individuals assisting in TCPC is essential to programmatic success.[34] This translates to one catheterization implanter, a core group of cardiology imagers and sonographers, a core group of pediatric anesthesiologists and certified registered nurse anesthetists (CRNA) perform and assist in a vast majority of the TCPC procedures in ELBW infants. Repeated TCPC procedural techniques, echocardiographic evaluation, and anesthetic support creates expertise among these individuals when performing TCPC in ELBW infants.[4,30,35]

## TCPC Program Evolution

The TCPC program at our institution has evolved as newer devices, technology, and expertise progressed over time. Initially TCPC was performed with devices, Amplatzer Vascular Plug II (Abbott, Chicago, AVPII) and Microvascular Plug (Medtronic, MVP), that were not necessarily designed for PDA closure in ELBW neonates.[35-38] Our experience with the AVPII led to AEs before we began using the MVP with mostly successful results and fewer AEs.[26] Once the APO received FDA approval for TCPC in neonates >700 grams, we utilized the APO on a vast majority of TCPC cases with excellent results.[26,28] As the devices available improved, the TCPC procedure in the catheterization lab became refined. Performing TCPC in the cardiac catheterization lab allows the device implanter to become comfortable with the subtle aspects of the procedure with biplane fluoroscopy and echocardiographic imaging available. Also, the device implanter has a full assortment of inventory and devices to deal with potential complications that may arise. Developing procedural expertise with multiple TCPC cases in ELBW neonates is recommended before consideration to performing the procedure outside the catheterization lab.

Despite the many benefits of performing TCPC in the catheterization lab, the best place for the procedure for the patient may be the NICU. Transfer of ELBW neonates outside the NICU is associated with increased morbidity and mortality.[39,40] NICU bedside TCPC (bedside-TCPC) has been previously described at other institutions but has not been performed routinely at centers performing TCPC in neonatal patients.[41-44] There are differences between the techniques of TCPC depending upon the location of the procedure.[31] Bedside-TCPC requires greater utilization of echocardiographic evaluation as there is limited fluoroscopy. With anticipation of this difference, we performed several TCPC in neonates with an attempted echocardiographic only approach. This approach was mostly successful, but there were some cases where fluoroscopy was utilized to complete the procedure. Therefore, a hybrid fluoroscopy and echocardiographic approach was adopted at the bedside. Below are the key procedural approaches to both techniques depending upon location.

## Catheterization Lab

When transporting an ELBW to the catheterization laboratory, several important modifications need to be considered and have been well described by our group.[5] A team including the anesthesiologist, CRNA, and two to three Cath lab staff are involved in the transport process. The goal of the transport is to minimize the risk of unplanned extubation during transport, maintain adequate temperature, and reduce the time out of the NICU. Use of a transport ventilator such as a Neopuff (NeoPuff infant resuscitator, Fisher and Paykel, Auckland, New Zealand) or a PneuPAC® BabyPAC (Smiths Medical, Minneapolis, MN) is common in patients on conventional ventilation. For patients on high frequency ventilators (high frequency jet ventilators or high frequency oscillatory ventilators), we use a Bronchotron Transport (TXP®-2D, Percussionaire Corporation, Sandpoint, ID, USA) for transport. Early in our experience, we would give a trial of conventional ventilator for two hours in patients on high frequency ventilators, and if the PCO2 did not increase by more than 10mmHg from baseline, the procedure was performed on a regular ventilator. However, more recently we have found the patients are more stable when we perform the procedure on the high frequency ventilator in the catheterization lab with the assistance of the NICU respiratory therapist.

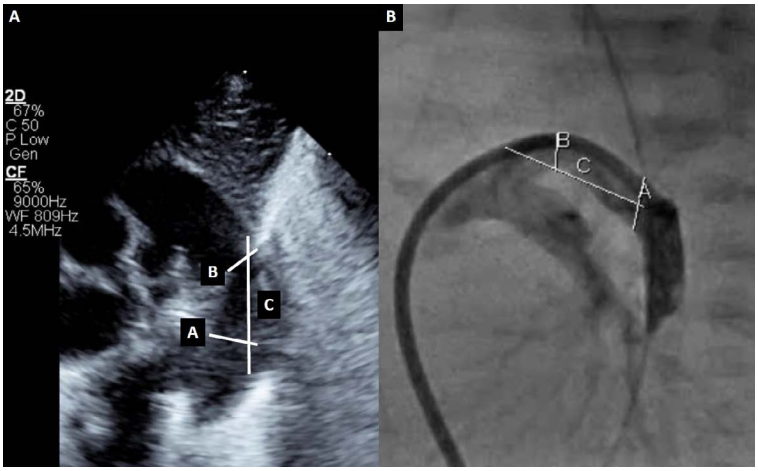


**FIGURE 4** *Pre-procedure transthoracic echocardiogram and lateral angiogram of the patent ductus arteriosus.* ***A).*** *Pre-procedure transthoracic echocardiogram.* ***B).*** *Lateral angiogram. A= PDA diameter at the aortic end; B = PDA diameter at the pulmonary end; C = PDA length.*

Once in the catheterization lab, the infant is positioned on the Bair Hugger (3M Maplewood, MN, USA) by the physician with a folded towel beneath the sacrum to straighten the groins and allow for easier vascular access. A temperature probe (SourceMark, Brentwood, TN, USA) is placed in the esophagus and will later serve as a landmark of the descending aorta for device deployment. Any wires or monitors that are radiopaque are moved out of the view of the frontal and lateral cameras and taped down so as not to obscure the field. During table set-up, a transthoracic echocardiogram (TTE) is performed with a sonographer at the head of the table between the frontal and lateral cameras. It is encouraged to perform the pre-procedure TTE with the lateral camera in place so the sonographer can become accustomed to the arm angle and patient windows during the procedure.[45] The pre-procedure TTE focuses on the details of the PDA as well as the potential structures (aortic arch, left pulmonary artery (LPA), and tricuspid valve) affected by device placement and prograde approach.[31,45] A TTE pre-procedure check list (**Table 1**) and is performed on every patient prior to the procedure.

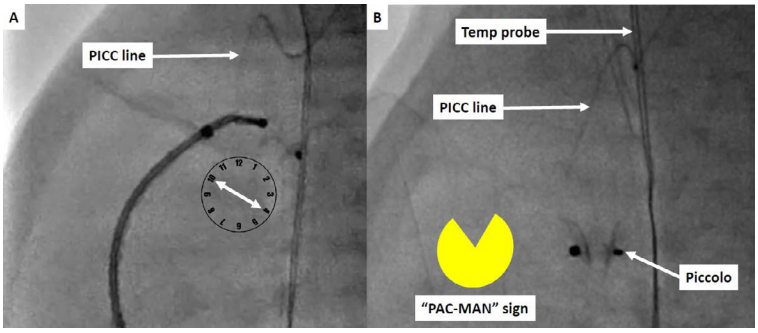


**FIGURE 5** *Lateral fluoroscopy angiogram after Amplatzer Piccolo Occluder (Piccolo) deployment and release. **A)**. The device is between the esophageal temperature probe and upper extremity PICC line in a 10 o'clock to 4 o'clock position. **B)**. The "PAC-MAN" is created by the touching of the proximal and distal discs along the lesser (inferior) curvature of the PDA and the splaying of the discs along the greater (superior) curvature of the PDA. An upper extremity PICC line can highlight the pulmonary end of the ductus. PICC = peripherally inserted central catheter; Temp = temperature.*

A purely transvenous prograde approach was adopted for TCPC to avoid accessing the femoral arteries in neonates.[41,43] A femoral artery diameter <3 mm has been associated with loss of arterial pulse, and ELBW neonates are at high risk of arterial damage.[46,47] Ultrasound guided vascular access of the femoral vein is obtained, and heparinized saline flushes are utilized throughout the case instead of heparin bolus. All fluoroscopy is performed at three frames per second to limit radiation exposure to the patient. There are two methods for catheter access to the PDA from a prograde approach.[4,35,36,48] A balloon tip catheter can be used to access the PDA, but the preferred method at our institution is the method using a 4 Fr/65cm Terumo Glide Catheter and Wholey wire.[4,31,35,43] Once the catheter is in place, a biplane angiogram with 1 ml of contrast is hand-injected with the frontal plane 15° LAO and 15° Caudal and the lateral plane kept at 90°LAO. Measurements are made from the lateral angiogram and compared to the TTE measurements to choose the appropriate APO device size **(Figure 4)**.[49] Most PDA in patients <1000 grams are the F-type described as a long tubular PDA with a bend at the pulmonary artery end much like a hockey stick.[50] The location of the descending aorta in relationship to the esophageal temperature probe should be clearly evaluated on the lateral angiogram as the exact location of the probe in relationship to the descending aorta is slightly different in each patient.[31]

Once the appropriate size device is chosen, the patient should be placed briefly on higher FiO2 until the device is implanted.[51] Through the side-arm of the sheath, Calcium Chloride (CaCl2) 10mg/kg is administered.[51] These maneuvers: brief period of hyperoxygenation and CaCl2 administration at our institution, have been shown to not only keep the infant stable during the device implantation process, but also to decrease the already low incidence of post-ligation syndrome after TCPC.[51,52] The TorqVue LP catheter (Abbott, New Plymouth, MN, USA) is then advanced over the wire to the descending aorta and a Tuohy-Borst Side arm adapter (Nordson Medical, Westlake, OH, USA) is attached. The device is then advanced through the catheter to the tip, which is 3mm beyond the radiopaque marker. For proper implantation, a single operator, two-hand technique, with the left hand on the delivery catheter and the introducer sheath, facing the ground, and the right hand on the delivery catheter and the delivery cable, but facing the ceiling, working in unison with a gentle "push-pull" method to deploy the device intra-ductal. Keeping the tip of the catheter steady with the left hand, the right hand pushes the cable to expose the distal disc of the device within the aortic end of the PDA. After this maneuver, the device can be pushed into place with the right-hand always maintaining catheter position within the PDA.

Once the device is deployed, a lateral angiogram is performed with 1 ml of contrast for verification of device position on the PA end. As stated previously, the esophageal temperature probe acts as a landmark of the descending aorta in this case. If the patient has an upper extremity PICC, this well defines the pulmonary end of the PDA. The device should sit between these two landmarks on the straight lateral position oriented in a 10-4 position on a clock face **(Figure 5)**. Also, the device should be packed within the PDA to create a "PAC-MAN" sign on lateral fluoroscopy **(Figure 5).** The PAC-MAN is created by the touching of the proximal and distal discs along the lesser (inferior) curvature of the PDA and the splaying of the discs along the greater (superior) curvature of the PDA. This position is highly stable and the device is less likely to migrate or embolize.[53] After the device is positioned, lower extremity pulses are checked and blood pressure is obtained to rule out aortic obstruction.[53]

Although a levophase lateral angiogram could evaluate the aortic arch, a TTE is the preferred method to check for aortic obstruction. The first images obtained by TTE should be of the aortic arch as it is often not evaluated by post-deployment angiography. **Table 1** outlines the post-procedure echocardiogram views and techniques to ensure the device is intraductal with no residual shunting and no aortic arch or LPA stenosis. Utilization of post-procedure spectral Doppler patterns of the aortic arch and LPA compared to the pre-procedure Doppler patterns can aid in determining if device obstruction is present.[31,53] Trivial residual shunting through the center of the device is not uncommon immediately after device deployment, and we call this the "flame sign" due to the small width of the color jet by Doppler **(Figure 6)**. Trivial residual shunting almost always resolves within 5-10 minutes and should not be used as an indication to remove the device.[31,45] Instruct the sonographer to obtain images continuously and be as quick as possible. Some patients will become unstable with the delivery sheath across the tricuspid valve, so timely TTE evaluation is important.[53] Accurate, decisive, and quick communication of the post-deployment TTE to the catheterization team is imperative.[45]

If device position is adequate, the device can be released, and the TorqVue catheter is removed immediately. There is no reason to perform another angiogram as a TTE is sufficient to check for device position, aortic or LPA obstruction, residual shunt, tricuspid regurgitation, left ventricle (LV) function and effusion **(Table 1).** At this point, the FiO2 is weaned back down, and fluoroscopy is done to evaluate for device movement. If device is still in place, the sheath can be removed, and manual pressure is held to obtain hemostasis.

**Table 1** *Transthoracic echocardiogram checklist*

| Structure | Techniques | PRE - PROCEDURE | POST - PROCEDURE |
|---|---|---|---|
| PDA | 2D | PDA Measurements | Device Orientation |
| | Color Doppler | Shunt Direction | Residual Shunting |
| | Spectral Doppler | | |
| Aortic Arch | 2D | Rule Out Coarctation | Device Causing Obstruction |
| | Color Doppler | | |
| | Spectral Doppler | Compare to Post-Procedure | Compare to Pre-Procedure |
| LPA | 2D | Rule Out Stenosis | Device Causing Obstruction |
| | Color Doppler | | |
| | Spectral Doppler | Compare to Post-Procedure | Compare to Pre-Procedure |
| Pulmonary Valve | 2D | Valve Mobility | Valve Mobility |
| | Color Doppler | Evaluate for Insufficiency | Evaluate for Insufficiency Without Sheath |
| Tricuspid Valve | 2D | Valve Mobility | Valve Mobility |
| | Color Doppler | Evaluate for Insufficiency | Evaluate for Insufficiency Without Sheath |
| LV Function | 2D | Systolic Function | Systolic Function |
| Pericardium | 2D | Effusion | Effusion |

*2D = Two dimensional; LPA = left pulmonary artery; LV = left ventricle; PDA = patent ductus arteriosus*

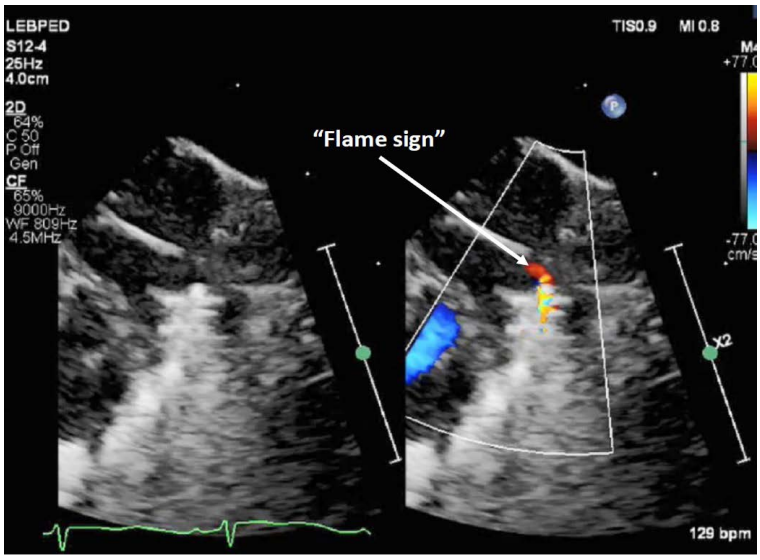


**FIGURE 6** *Color compare transthoracic echocardiogram post Amplatzer Piccolo Occluder deployment. A 4-2 mm Piccolo device is in good position with trivial residual shunting through the center of the device ("flame sign").*

## NICU Bedside Closure

The APO has been FDA approved for TCPC in ELBW neonates for >3 years, and our institution has closed >300 PDA in patients <4 kg. This process took many years of hard work and dedication from multiple members of the TCPC team. The immense experience and expertise in performing TCPC in ELBW neonates in the catheterization lab allowed the TCPC program at Le Bonheur Children's Hospital to begin performing TCPC at the bedside in the NICU. There are similarities between the two procedures, but the main differences are highlighted in this section.

The catheterization team will need to anticipate all the potential needs of the TCPC procedure to bring the appropriate supplies to the NICU. The supplies routinely used for TCPC in the catheterization lab are now kept in a portable cart to mobilize for a bedside-TCPC procedure. We recommend having duplicates of all supplies routinely used available to account for supplies that may be defective or become contaminated. Ensure that the lead aprons of the key personnel to be present in the patient room are available. A discussion about the appropriate size APO device based off the most recent TTE occurs prior to the case so the different potential sizes are available. At least three catheterization lab staff are needed for a successful procedure: one to scrub and assist with the procedure, one to record and operate the mobile digital Mini C-Arm (Orthoscan, Scottsdale, AZ), and one to circulate needed equipment.

Currently, it is our practice that the dedicated pediatric cardiac anesthesiology team performs sedation for the procedure in the NICU. The anesthesiologist and CRNA assess the patient to ensure adequate IV access for sedation is present and help position the patient for the procedure. At our institution our NICU has single patient rooms that are not all designed the same. Therefore, the position of the isolette is unique to each situation. However, the same concepts apply to each case where the isolette is pulled about 1-2 feet away from the wall to allow the anesthesia team access to the head of the bed to manage the patient airway. The isolette is centered in the room to allow for the catheterization team space on the patient right side and the echocardiographic team space to the patient left side. The mobile patient bedside tray is covered with a sterile drape and situated at the foot end of the isolette to allow for room for the catheterization team to rest the distal end of the sterile catheters and wires.

Patient positioning, groin preparation, and drapes are consistent with the catheterization lab techniques. Once the patient is draped, the mobile digital Mini C-Arm is brought into the expected correct lateral position. At this time, a pre-procedural TTE is performed evaluating the same key structures described above **(Table 1).** However, there are key differences to the TTE evaluation in the bedside NICU compared to the catheterization lab **(Figure 6)**. First, the echocardiogram machine is turned 180 degrees compared to the catheterization lab. Second, the cardiologist has been performing the echocardiogram as there is minimal space at the bedside for both a sonographer and a cardiologist. Third, the cardiologist is situated as to scan with the right hand during the procedure where the sonographer is situated to scan with the left hand in the catheterization lab. Finally, the pre-procedural PDA measurements can only be made by TTE, as the mobile digital Mini C-Arm does not allow for angiographic measurements.

Ultrasound-guided vascular access of the femoral vein is obtained, and the portable ultrasound machine is removed from the patient room. The mobile digital Mini C-Arm or the patient bed is moved to get the appropriate lateral fluoroscopy view. There is no anteroposterior (AP) fluoroscopy available throughout the case and this represents the biggest difference between the bedside technique and the catheterization lab technique. The implanter must feel comfortable directing the catheter from the right atrium across the tricuspid valve into the right ventricle toward the right ventricular outflow tract and ultimately across the PDA without the AP fluoroscopy. TTE guided catheter access into the PDA can supplement lateral fluoroscopy if requested. A lateral angiogram is obtained in the same manner described above, but measurements of the PDA by angiography are not available on the mobile digital Mini C-arm.

The "push-pull" technique of intraductal APO deployment remains the same as the catheterization technique. A lateral angiogram can be performed to evaluate the LPA is optional as the TTE can evaluate any potential complications. TTE is used to assess the aortic arch, LPA, and device for residual shunting as described above **(Table 1).** Once correct device position is confirmed the device is released per the same technique as the catheterization lab. TTE is repeated just after device release and five minutes after release to confirm no device migration or other complications. Should complications arise due to device migration or embolization the options for patient care should be discussed at that time. If biplane fluoroscopy is required to complete the necessary intervention, the patient will need to be transferred to the catheterization lab in a timely manner.

## Future Directions

Le Bonheur Children's Hospital now performs a majority of TCPC in ELBW neonates at the bedside in the NICU. This marks a stark program shift and takes years of collaboration and expertise to ensure a smooth transition. We anticipate bedside-TCPC to be the predominate location of TCPC in ELBW infants at our institution. We are actively collecting data on procedure specifics and anticipate similar procedure times, lower radiation exposure, and similar success and complications rates with the catheterization technique.

One of the criticisms of TCPC in ELBW neonates is the technique requires transfer to a catheterization lab. Now that we show bedside-TCPC is feasible and safe, we anticipate a potential increase in device closure of PDAs in ELBW neonates. However, our institution is an all-referral children's hospital without a delivery ward. Therefore, every patient at our institution was transferred from another hospital, and their bedside at our institution is their second bed. If we can continue to show acceptable safety and efficacy of bedside-TCPC, we plan to perform bedside-TCPC in outlying NICUs that do not have access to pediatric catheterization labs. This will

truly allow TCPC to be a one-bedside procedure and prevent transfer of patients to our institution for procedural expertise. If the procedural team can travel to all referring NICUs instead of the babies being transferred, one could then truly consider TCPC performed very early on in life. Our long-term goal of the TCPC program is to become portable to provide true one-bedside-TCPC.


**FIGURE 7** *The 4th PDA Symposium is scheduled for August 5th-6 th, 2022, at the Disneyland Hotel, Anaheim, CA, in collaboration with NeoHeart.*

Collaboration with neonatology and cardiology will continue to improve the care of ELBW neonates with a hsPDA. If you are interested in learning more about building a TCPC program, curious about outcomes following the procedure, and want to connect with the leading neonatologists and cardiologists in PDA management and TCPC, the 4th PDA symposium will help you accomplish these goals. The 4th PDA Symposium is scheduled for August 5th-6th, 2022, at the Disneyland Hotel, Anaheim, CA, in collaboration with NeoHeart. Please join us for an excellent discussion of PDA management, TCPC challenging cases, update on multicenter randomized trials, and ways to move forward with TCPC. Also, a consensus statement on the management of PDA in extremely premature infants will be formalized at the 4th PDA Symposium **(Figure 7)**. To learn more please visit, https://pdasymposium.com/.

## Conclusion

While strategies for PDA management in ELBW neonates evolve, TCPC is a safe and effective method to close PDAs in this vulnerable population. TCPC performed before four weeks is associated with improved respiratory outcomes and better weight gain. Catheterization lab TCPC has an excellent success rate with low adverse event rate across multiple institutions. Centers beginning a TCPC program should start in the catheterization lab with patients between 2-3 kg before transitioning to 1-2 kg and, ultimately, patients <1kg, and only transition to the bedside once the technique is mastered. Based on our early experience, bedside-TCPC appears to be just as safe and effective as catheterization lab TCPC.

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# Nicklaus Children's Hospital Proudly Welcomes Pediatric Cardiologist Dr. Nancy Dobrolet

Nancy Dobrolet, MD
Pediatric Cardiologist

Nicklaus Children's Hospital is honored to welcome board-certified pediatric cardiologist Nancy Dobrolet, MD. Her career includes advanced training in cardiac intensive care and interventional cardiology right here at Nicklaus Children's Hospital. Her residency and fellowship training took her from New York to Boston to Pittsburgh and now she has returned to South Florida to provide compassionate care to infants, children and young adults with congenital heart disease in Plantation and Weston.

For over 70 years Nicklaus Children's Hospital has served as the region's pediatric care leader, providing a full range of services for every stage of your child's life. Through Nicklaus Children's Pediatric Specialists, the organization's medical group practice, we offer expertise in nearly every pediatric subspecialty, including our nationally ranked services for cardiology and cardiovascular surgery.

To learn more about her background or training, please visit **nicklauschildrens.org/DrDobrolet**

*To schedule a consultation with Dr. Dobrolet, please call* **305-662-8301**.

BEST CHILDREN'S HOSPITALS U.S.News & WORLD REPORT CARDIOLOGY & HEART SURGERY 2021-22

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# Report From the Field – Early Career Colleagues

*Kamel Shibbani, MD*

This is the first of a series of articles from the PICS Society that focuses on early career members who have been picked at random. Keep an eye out for other "Report from the Field" articles in the future that highlight our early career members! These articles will serve as an opportunity for our colleagues to share their thoughts on their own experience and on the avenues with which PICS Society can support early career development.

Today we met up with Dr. Bassel Mohammad Nijres (BMN) from the University of Iowa and Dr. Dan McLennan (DM) from the Children's Hospital of Wisconsin.

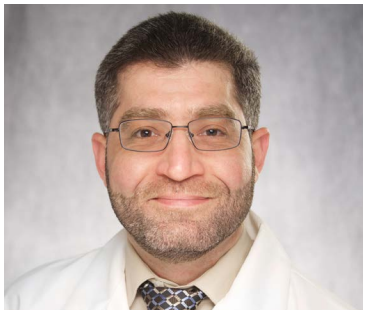
Dr. Nijres completed his pediatric cardiology fellowship at Rush University in Chicago and went on to do pediatric interventional cardiology training at Texas Children's Hospital/ Baylor College of Medicine in Houston. He has been at the University of Iowa two years.

We started out the discussion with Dr. Nijres about the challenges faced by early career interventional cardiologists.

***KS:*** Dr. Nijres, thank you for sitting down with us today! I'm curious, what drew you to the field?
***BMN:*** A lot of things drew me to the field. The field is continuously growing - every year we have new devices and new procedures. And every year we gain the ability to treat diseases that we could not treat in the past. In addition, I feel that it's both fun and challenging at the same time. Interpreting your angiograms with your hemodynamic data, understanding the limitation of this data, and then putting all those pieces together, it's like solving a puzzle!

*Dr. Daniel McLennan*

*Dr. Kamel Shibbani*



*Dr. Bassel Mohammad Nijres*

> *"I think PICS Society can play an important role in promoting and facilitating collaboration."*
> *Dr. Bassel Mohammad Nijres*

***KS:*** I'm curious, what are some challenges you ran into as an early career interventionist?
***BMN:*** I think my start was a good one because I landed in a good program. The University of Iowa has offered a lot of support; we have a collaborative surgical team, and I have a great mentor in Dr. Aldoss. I think one of the main challenges for an early career interventional cardiologist is going to be finding an appropriate first job. Finding the right environment is crucial. At the same time, I think that those jobs nationwide are rather limited.

***KS:*** Given the importance of being in a supportive environment for your first job as an interventionist, what role do you see the PICS Society playing to help facilitate that?
***BMN:*** It would be tremendously helpful if the PICS Society can organize a list of available jobs nationwide. Perhaps even provide details about each job like the number of interventionists, surgical and cath volumes, number of surgeons, etc… I think that would be very helpful.

***KS:*** That's a fantastic idea! Beyond that, what role do wish to see PICS Society playing?
***BMN:*** As an early career interventionist, I think it's important to look for new research projects. Here, I think the PICS Society can play a very important role in promoting and facilitating research collaboration. Certain diseases that need to be studied are rather rare. Take pulmonary vein disease for example - PICS Society can play a vital role in establishing a multicenter study in pulmonary vein disease. Individually, programs don't have enough volume. But engaging many programs can allow us to compare various treatment options, surgical vs cath vs medical management. To this day, we don't know what the best treatment option is.

***KS:*** You raise a great point Dr. Nijres - Recently, the PICS Society and CCISC have partnered to create the PICS/CCISC Docmatter community with this exact thought in mind, to help facilitate peer-to-peer interaction and promote collaboration. Have you had a chance interact with the Docmatter community?
***BMN:*** I did actually yes! I like the platform and find it to be very helpful.

***KS:*** On a more personal note, what sort of projects have you been involved in?
***BMN:*** Our program is one of the busier programs as far as transcatheter PDA device closure in premature infants. As I mentioned earlier, as an early career interventionist you want to try to look for new projects, and PDA device closure in premature infants works nicely. The procedure is a newer procedure that we have been doing for the past few years, and we have enough volume to be able to generate and share our data.

***KS:*** From a clinical standpoint, what role do you see the PICS Society playing in preparing 4th year interventional cardiology fellows for life as an attending?
***BMN:*** I think creating a cath simulation can be very helpful. A place where we can safely practice new techniques and familiarize ourselves with a new device, like the Harmony valve for example. I'm thinking of something like an event, perhaps, where people can meet and listen to dedicated lectures and hear from people who have a done such procedures a lot. This, coupled with cath simulations, would be very helpful.

***KS:*** Dr. Nijres, thank you for taking some time to chat with us!

We also had a chance to catch up with Dr. Daniel McLennan at the Children's Hospital of Wisconsin. Dr. McLennan completed his pediatric cardiology training in Sydney Children's Hospital and Bristol Children's Hospital, before going to Colorado for his interventional training at Children's Hospital Colorado. From there, he joined the University of Iowa for one and half years before transitioning to Children's Hospital of Wisconsin, where he's been for the past year.

***KS:*** Dr. McLennan, thank you for your time today! I would love to hear about your experience as an early interventionist and about challenges you've faced out of fellowship.
***DM:*** People always say that the hardest job you get is always going to be the first one. When you're coming out of fellowship, you have to be sure to choose a good job. You want someone around you who is senior to help you make the right choices. Some people I know are stuck in jobs where they are the only interventionists straight out of fellowship, and that can be a really difficult situation to be in.

*"You'll find that most junior [interventionists] are pretty keen to take on projects... Trying to afford more opportunities for early career people will be a great step."*

*Dr. Daniel McLennan*

***KS:*** What role do you see PICS Society playing in helping early career interventionists?
***DM:*** One of the things that PICS Society can do for every interventional fellow is to create a mentor-mentee relationship outside of fellowship. This is someone who can serve as an external mentor during fellowship and also someone who can help beyond training. For example, if people are not doing a certain type of procedure that they have an interest in, this mentor-mentee relationship gives them the opportunity to go to another center and get hands on experience, or perhaps to bring the mentor to their center to teach them. Variations of this program were offered before COVID. Now that the world is starting to open up a little more, PICS Society can work with other organizations to help create a mentor-mentee program again.

Beyond just early interventionist, I think the PICS Society is starting to do a lot more. For example, the DocMatter platform that they have going on for different discussions is quite good. One thing they can consider adding to that is a "case of the month" presentation where people can talk about cases with great learning points. I hate sitting through webinars at 7pm at night but having a pre-recorded "case of the month" that you can watch anytime would be great way of doing it!

Also, it would be nice to have more opportunities for people to be involved in the conferences, especially early career people. The PICS conference might want to separate out, a little bit more, the senior from the junior interventionists. This might create conversations with the junior interventionists that focus on where they are at in their career, which is going to be different from where the senior folks are in theirs.

***KS:*** Those are great ideas Dr. McLennan! How about the flip side of that question? What are ways that early career interventionists can contribute to PICS Society?
***DM:*** I think you'll find that most of the junior guys coming out of fellowship are usually pretty keen to take on projects. Often they're up-to-date with the latest information since they just came through fellowship. They also might have good tips and tricks that they learned during training. I think trying to afford more opportunities for the early career people will be a great step.

***KS:*** On a more personal note, can you tell us more about some of the projects you've been working on?
***DM:*** Some of the stuff I'm interested in is trying to bring in devices from international companies that are not in the US yet. Having worked in Europe and Australia, and having had access to some of the devices that we don't have in the US, I've been working with the FDA on trying to get approval for some of these devices. I also have an interest in neonatal physiology and hemodynamics, for example promoting the understanding of the impact of PDA and ASD closure in neonates. I've been trying to improve that in our hospital.

***KS:*** Dr. McLennan, you mentioned your involvement in getting approval for new devices. I'm wondering what advice you have for folks that are interested in getting involved in this?
***DM:*** If there's a device that you know of that is not in the US, it starts with simply reaching out to the company that makes it. Sometimes that company is not aware that there is a market for their device in the US, so I can help to push that device into the market. Sometimes the company might know that the market exists and are in the process of obtaining FDA approval. Then you can put your name in the hat to be one of the centers that trials their device. It comes down to seeing where there is an opportunity and seeking it out.
***KS:*** Dr. McLennan, thank you very much for your time!

# CTA and ACC Create First-Ever Industry Framework for Cardiovascular Technology

The Consumer Technology Association (CTA)® and the American College of Cardiology (ACC) announced the first-ever industry framework to evaluate and give guidance for consumer devices or applications designed to improve cardiovascular health. CTA and ACC have convened health and technology industry leaders to advance guidance and best practices for cardiovascular health technology developers and companies. The goal of the project is to reduce the burden of cardiovascular disease on patients and health care systems – allowing more people to access better cardiovascular care while freeing valuable public health resources.

Cardiovascular disease is the leading cause of death globally, taking an estimated 17.9 million lives every year according to the CDC. U.S. spending on cardiovascular disease has steadily increased over the last 20 years to over $100 billion per year, mostly from costs related to Ischemic Heart Disease, heart failure, stroke and hypertension.

## Best Practices for Consumer Cardiovascular Technology Solutions

"Health tech companies will be in a better position than ever to improve cardiovascular technology with a roadmap to integration for clinicians and their practices," said Gary Shapiro, president and CEO, CTA. "We have seen enormous breakthroughs in medical technology in the last decade alone, better cardiovascular devices are essential in improving global health and saving lives through stronger preventative care."

The framework targets the use of consumer cardiovascular technology solutions for prevention, screening, diagnosis and health management or treatment. This guidance gives health tech companies a framework to manufacture products that allow clinicians to confidently integrate cardio technology into their practices. Consumer Cardiovascular Technology Solutions facilitate ongoing cardiovascular health promotion, disease detection and care management, instead of patients solely relying on intermittent and costly clinical visits.

"Use of digital technologies, including consumer wearables and apps for monitoring heart health, is widespread and has the capability to transform how clinicians work with their patients to treat and prevent heart disease," said Ritu Thamman, MD, FACC, ACC Innovation Work Group member. "By working with our colleagues on all sides of technology to ensure we are implementing these technologies safely and effectively, we're helping clinicians use the latest technologies in a way that ensures their patients receive the highest quality care and live better, healthier lives."

Practical uses for Consumer Cardiovascular Technology Solutions include:

**Prevention:** Consumer devices can monitor physical activity and heart rate to help promote healthy behaviors and give clinicians insights into the cardiovascular health of their patients. Consumer cardiovascular technology also allows clinicians to potentially identify areas of risk sooner.

**Screening/Diagnosis:** Atrial Fibrillation (AFib) is the most common abnormal heart rhythm. It affects about six million Americans and is a major cause of stroke. Cardiovascular Technology Solutions can be used to detect the presence of an irregular rhythm that is potentially AFib and prompt the user to confirm the diagnosis with a clinician.

**Health Management/Treatment:** For people undergoing cardiac rehabilitation (rehab), the first 6-8 months is especially critical to ensure the timely recovery. Wearables that can monitor physical activity and heart rate accurately and remotely are useful tools for home-based cardiac rehab. Leveraging these technologies can help overcome some of the barriers patients face with on-site rehab programs while expanding the breadth and depth of monitoring.

The framework also accounts for the need to protect consumer data rights and privacy. Health technology solutions need to capture comprehensive and privacy sensitive information about their users. But this data can sometimes be aggregated, analyzed, shared or sold in ways that are poorly disclosed or understood. By adhering to industry privacy guidelines, mobile technology developers can ensure that their solutions optimally protect consumers' privacy, promote trust and mitigate perceived risks about the use and sharing of data.

The project is the first collaboration between the ACC and CTA to create best practices for evaluating Consumer Cardiovascular Technology Solutions. CTA is collaborating with the American College of Cardiology (ACC) through participation in the ACC's Applied Health Innovation Consortium for the purpose of building a roadmap for Artificial Intelligence and digital technology in cardiology. The Consortium brings together academic, clinical, industry and technology partners and patient advocates to collaborate in the digital transformation of healthcare.

## About Consumer Technology Association

As North America's largest technology trade association, CTA® is the tech sector. Our members are the world's leading innovators – from startups to global brands – helping support more than 18 million American jobs. CTA owns and produces CES® – the most influential tech event in the world. Find us at CTA.tech. Follow us @CTAtech.

## About the American College of Cardiology

The American College of Cardiology envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular care team, the mission of the College and its 54,000 members is to transform cardiovascular care and to improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions. For more, visit https://www.acc.org/.

## MAY

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### 19-22

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### 10-13

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Bloomington, Minnesota, USA
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# Structured Reporting Systems are Expected to Dramatically Improve Patient Care and Data Management

Cardiology is an inherently data-dependent and data-driven practice. Patient medical history records, images, test results, and more go into every diagnosis and treatment decision. However, most organizations don't take advantage of structured reporting; most cardiovascular information systems (CVIS) cannot effectively mine the wealth of data from a facility's cardiology department. There is no debate on how crucial structured reporting is. It is considered the first step to improving patient care and enhanced data accuracy—important points raised by a coalition of 14 professional societies led by the American College of Cardiology and by the Society for Cardiovascular Angiography and Interventions.[1] It's estimated that only 10% of United States cardiac Cath labs use structured reporting to improve efficiency and bolster patient outcomes.[1]

Dr. Serge Makowski, CEO and Co-founder of leading healthcare software development firm MediReport, says, "The goal of structured reporting is to make sure there is consistency in the documentation reporting of every cardiac procedure, regardless of the physician's training, background, or style of work and that 100% of procedural data is recorded abiding by the latest clinical guidelines. The system intelligently guides the clinician on the required and important procedural data and generates near real-time reports which are automatically incorporated into the facility's existing electronic health record. Subsequently, this can be accessed by any healthcare provider, which informs evidence-based treatment decisions, improves billing, and betters the patient care experience."

Structured reporting systems fully incorporate data, workflow, analytics, inventory management, billing, and process improvement in one central documentation system.[1] The same data may be repurposed repeatedly for clinical research or registry participation, without the need for any manual data re-entry.

**Basic Features of Structured Reporting**

A growing number of healthcare organizations are exploring structured reporting. But not all structured reporting systems are created equal. Clinicians should look for several key features to ensure maximum efficiency, such as:

- The centralization of all information (dosimetry, pressures, measurements, dynamic drawing, key PACS images…) from the cardiac procedure. This means the system must seamlessly interface and operate with the facility's software packages (EMR, modalities, HIS...).
- The effortless recording and tracking of all materials and devices before, during and after the procedure using techniques like barcode scanning.
- The generation of reports complete with full sentences, which may be easily understood by the patient, or any other clinicians involved in follow-up care.
- The ability to select multiple languages for report generation, offering both convenience for patients and flexibility to providers.
- Continuous connectivity to cloud-based platforms which allows remote access to data at any time.

**A Unified System[2]**

Two interventional cardiologists developed such a software suite, called CardioReport 360™ to help improve workflows, reduce errors, and save hospitals time and money. This platform offers several advantages compared to other CVIS; one being calculating automatic SYNTAX scoring, which saves time during procedures and reduces error rates to improve diagnostic accuracy. Additionally, the system integrates in real-time the latest clinical guidelines and classification systems continuously available to generate reports. Another important asset are its templates, which are customizable to the physician and the practice's specific workflows and procedures, which improves clinical adoption and satisfaction during use.

However, one of the most important features of a unified reporting system is the intelligent report conclusions. The auto-generated report conclusions are based off selected key words from procedural data which provides a quick, but thorough, understanding of the lesion's description and the procedure results. Dr. Makowski says: "The algorithm behind the conclusion synthesis is based on 25-plus years of medical expertise that applies globally and is paramount in the patient's care journey and treatment. A bifurcation of a lesion can complicate an angioplasty as the physicians will make a decision between angioplasty and surgery, hence the bifurcation criteria will be selected as an important item in the conclusion. Or, if thrombosis appears in the description of the procedure, it will be selected as a determinant item in the conclusion, as it might complicate the angioplasty and will carry a tremendous impact on the patient's treatment. However, if, let's say, the lesion is concentric, or eccentric is not deemed determinant thus will not be retained in the conclusion."

Lastly, reports are finalized before the patient even leaves the Cath Lab which vastly improves timely reporting as well as valuable Cath Lab throughput time. Referring doctors, as well as those participating in follow-up care, have near instant access to all vital information about the patient and procedure. Patients benefit from no lapse in care, while hospitals and ambulatory surgical centers can boost the bottom line through quicker turnover.

Dr. Makowski says, "We, the physicians, rely on intelligent insights to be gathered from the reports, data that otherwise would be ignored.

I no longer need to rely on multiple applications to get the complete picture of my patient. Having access to an extensive number of reporting parameters in a single unified CVIS and being able to generate a high quality and accurate report almost instantly, maximizes efficiency and accuracy."

**About MediReport**

MediReport, a global supplier of cloud-based software for medical applications, was founded in 1995 by cardiologists Dr. Serge Makowski and Dr. Fabrice Beverelli. Through its comprehensive CVIS, CardioReport™ Suite, MediReport provides vastly improved clinical workflows that save time, improve quality, and generate high revenue for client organizations. The company is committed to delivering quality products that address the evolving needs of cardiology and IT technologies, based on its foundational principles: clinical excellence, customer satisfaction, continuous improvement of its products and innovations, and commitment and responsiveness. The system is already used by healthcare providers in more than 40 countries. For more information, visit medireport.net.

**References**


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