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Standards and Guidelines

SCAI Position Statement on Transcatheter Occlusion of Patent Ductus Arteriosus in Premature Infants

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ABSTRACT

Historically, pharmacotherapy and surgical ligation have been the primary treatments for occlusion of patent ductus arteriosus (PDA), but recent advancements have led to the US Food and Drug Administration approval of the first transcatheter PDA occlusion device for low birth weight infants in 2019. Although short-term outcomes have been encouraging, successful outcomes are highly dependent on proper patient selection, awareness of key procedural considerations, appropriately trained operators, and institutions meeting a standard of required infrastructural requirements. A multidisciplinary approach involving neonatologists and cardiologists is beneficial, as well as shared decision-making with the patient's family. This position statement from the Society for Cardiovascular Angiography & Interventions provides comprehensive suggestions to optimize the safety and efficacy of transcatheter PDA occlusion in premature infants, aiming to improve long-term outcomes in this vulnerable population.

Introduction

The ductus arteriosus is an essential component of fetal circulation, allowing oxygenated placental blood to bypass the fetal lungs and supply the systemic circulation. When a patent ductus arteriosus (PDA) persists beyond the immediate postnatal period, the resulting left-to-right shunt can have numerous cardiac and extracardiac sequelae. Extremely premature infants suffer a higher incidence of PDA[1] and are uniquely vulnerable to its potential consequences, which may include worsening of chronic lung disease, pulmonary vascular disease, higher respiratory support requirements, necrotizing enterocolitis (NEC), and mortality.[2]

Closure of a hemodynamically significant PDA (hsPDA) may benefit certain preterm infants.[3] Historically, pharmacotherapy treatment has been the first-line intervention for premature infants selected to undergo PDA closure. Ibuprofen, indomethacin, and acetaminophen have all been shown to be efficacious, without clear evidence for superiority of any individual agent.[4-11] A meta-analysis demonstrated a 67% rate of PDA closure in response to medical therapy vs 38% for those who did not receive treatment.[12] Definitive closure for a hsPDA is typically indicated after conservative and/or pharmacological failure, if there is a contraindication to pharmacotherapy, or if there is a severe decline in clinical status with end-organ dysfunction. Surgical ligation was historically the definitive therapy in premature infants weighing less than 5 kg who failed medical closure. Although generally successful in eliminating the shunt, the traditional thoracotomy approach may be associated with multiple adverse issues, including prolonged postprocedural mechanical ventilation, injury to adjacent anatomic structures (eg, vasculature, airway, and nerves) resulting in complications such as

Abbreviations: FDA, US Food and Drug Administration; hsPDA, hemodynamically significant patent ductus arteriosus; LPA, left pulmonary artery; NICU, neonatal intensive care unit; PDA, patent ductus arteriosus; tcPDA, transcatheter patent ductus arteriosus.

Keywords: congenital interventional cardiology; premature patent ductus arteriosus occlusion.

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vocal cord paralysis, and a low cardiac output state referred to as "postligation cardiac syndrome."[13,14]

Although transcatheter PDA (tcPDA) occlusion has been a mainstay of congenital interventional cardiology practice for decades, very low birth weight infants were historically excluded from consideration due to vascular access limitations and lack of appropriately sized devices. Recent technological advances culminated in the US Food and Drug Administration (FDA) approval of the first PDA occlusion device for low birth weight infants in 2019.[15,16] The subsequent 5 years have seen rapid uptake of tcPDA occlusion in this population, such that catheter-based procedures have overtaken surgical ligation at an increasing number of centers.[17] Short-term outcomes have been favorable, but enduring success requires knowledge and implementation of procedure-specific best practices.[18] This Society for Cardiovascular Angiography & Interventions (SCAI) position statement addresses patient selection considerations, optimal procedural and technical considerations, operator training and competency, and institutional factors for programmatic success.

Methodology

This document has been developed according to SCAI Standards and Guidelines Committee policies for writing group composition, disclosure and management of conflicts of interest, internal and external review, and organizational approval.[19]

Following proposal submission and approval by SCAI Standards and Guidelines Committee, final selections for the writing group were made by the chair and co-chairs (S.P.B., B.M.G.), and the writing group was approved by the SCAI Standards and Guidelines Committee. A diverse and experienced multidisciplinary group of content experts was formed, which included interventional cardiologists (S.P.B., D.B., T.D., C.H., R.A.L., A.S., S.S., N.T., J.Z., E. Z., and B.M.G.), neonatologists (P.L., S.M.), and a pediatric anesthesiologist (T.H.).

The writing group has been organized to ensure diversity of perspectives and demographic characteristics, multistakeholder representation, and appropriate balance of conflicts of interest. Relevant author disclosures are included in Supplementary Material 1. Members of the writing group were asked to disclose all financial relationships from the 12 months prior to assignment to the writing group. Most of the writing group disclosed no relevant financial relationships. Disclosures were periodically reviewed during document development and updated as needed. The work of the writing group was supported exclusively by SCAI, a nonprofit medical specialty society, without commercial support. Writing group members contributed to this effort on a volunteer basis and did not receive payment from SCAI.

Literature searches were performed by each section leader, who then developed initial drafts in collaboration with other members of the writing group. Members of the writing group participated in a series of conference calls and email conversations between December 2023 and December 2024.

The draft manuscript was posted for public comment for 30 days in February 2025, and the document was revised to address pertinent feedback. The writing group unanimously approved the final version of the document. The SCAI Standards and Guidelines Committee and Executive Committee endorsed the document as official Society guidance in June 2025.

Patient selection considerations

The selection of premature infants for tcPDA occlusion is a complex decision, and considerations include the degree of respiratory support and pulmonary overcirculation as well as clinical signs of systemic hypoperfusion such as feeding intolerance, NEC, renal impairment, or hypotension.[20,21] An interdisciplinary team, including a neonatologist, cardiologist, and the patient's family, is essential in the decision-making process. Once the decision has been made to treat the hsPDA, centers may opt for pharmacotherapy or proceed with primary tcPDA occlusion per their discretion and expertise.[17] The safety and efficacy of this procedure have been demonstrated through multiple recent studies[15-18,22,23] and indications to refer for transcatheter occlusion are typically based on specific patient and institutional factors.[24-29] A recent multicenter manuscript recommended considering tcPDA closure for preterm infants born before a gestational age of 28 weeks.[29] The data suggest this procedure may be appropriate for infants older than 10 postnatal days who require invasive mechanical ventilation.[30] The recommendation applied specifically to centers with high rates of mortality and/or bronchopulmonary dysplasia, provided the institution has sufficient expertise and the patient's characteristics are suitable.

Several scoring systems have been developed to define an hsPDA by echocardiography with a focus on the impact of the shunt volume, as PDA dimensions alone do not correlate with hemodynamic significance. Echocardiographic signs of left heart volume overload and holodiastolic flow reversal in the postductal aorta are some measures included in these scoring systems. Additionally, the presence of a larger atrial level communication can underestimate the shunt volume if utilizing traditional markers such as left heart dilation, potentially masking the true hemodynamic significance of the PDA.[31]

Key anatomic factors to consider for patient selection include the following: ductal size and morphology; preexisting aortic coarctation or left pulmonary artery (LPA) stenosis; hemodynamically significant pulmonary vascular disease[32,33]; and presence of an intracardiac thrombus.[15] Other patient factors include hypotension requiring vasoactive infusions, decreased urine output and acute kidney injury, and requirement for high invasive ventilatory support.[17] Similarly, other comorbidities may counterbalance the indication for catheterization, including active infection, NEC, elevated inflammatory markers, and significant intracerebral hemorrhage.[17,26,34] Additional issues can develop in the months after birth that affect patient selection, including changes in ductal anatomy and pulmonary vascular resistance. Specifically, PDA morphology can change with time and increasing patient weight (ie, >2 kg), potentially increasing procedure time and making device positioning more challenging.[15,35] Similarly, pulmonary vascular resistance may increase in patients with large PDA, increasing the risks and complexity of procedural and postprocedural care.

Procedural considerations vs clinical guidance

Preprocedure planning

A comprehensive, systems-based preprocedural evaluation will help optimize transport, technical aspects of the procedure, and postcatheterization care. Assessments are ideally performed at least 1 day prior to the procedure to allow for thorough preprocedural evaluation.[36] This writing group advises that the following elements be addressed and/or obtained prior to catheterization (Figure 1)[37] (a downloadable checklist of these elements may be found in Supplementary Material 2):

- Relevant laboratory evaluations and chest radiograph
- Preprocedural endotracheal intubation in the neonatal intensive care unit (NICU)
- Appropriate intravenous access
- Medication reconciliation

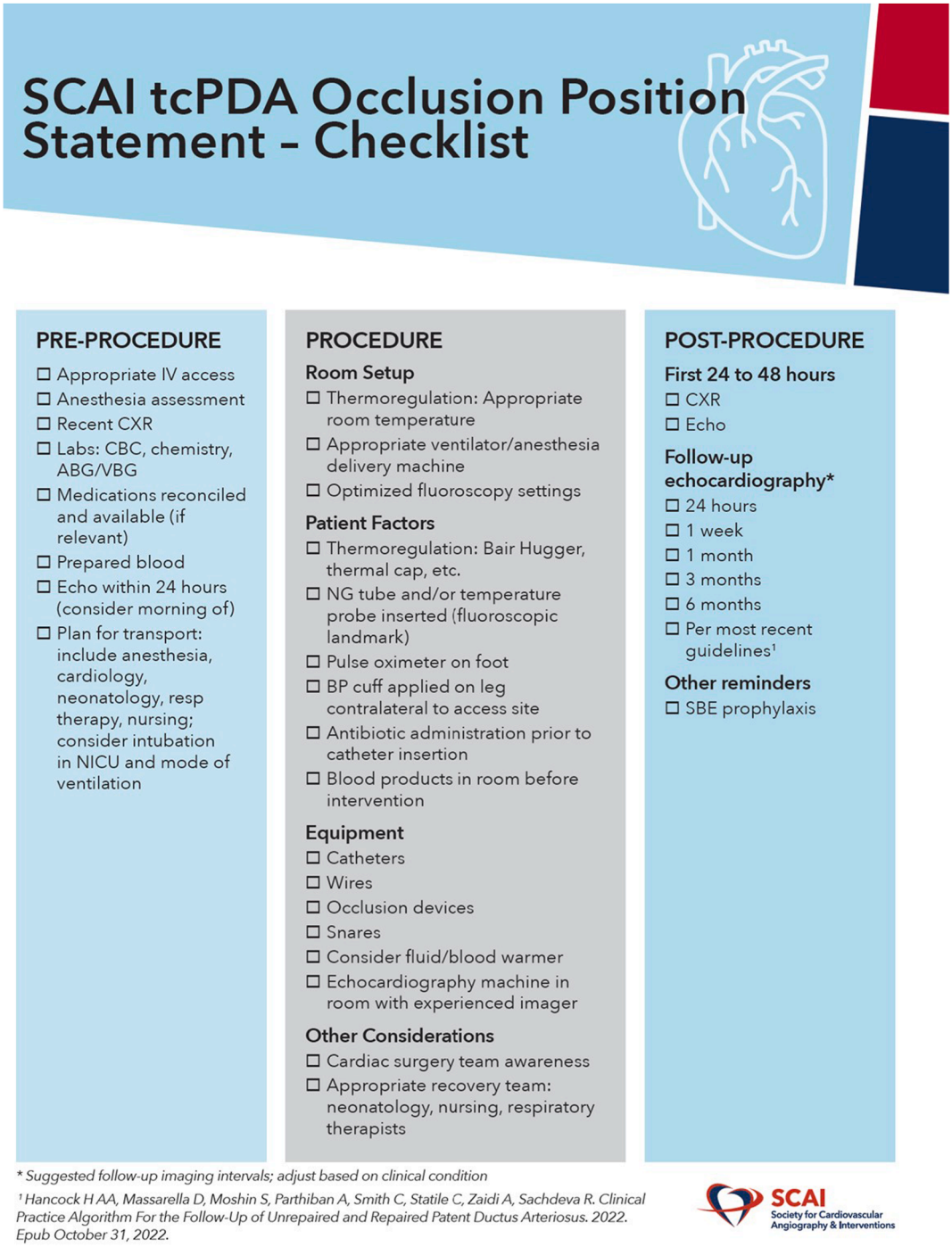

Figure 1.
Transcatheter patent ductus arteriosus occlusion procedure checklist.[37] ABG, arterial blood gas; BP, blood pressure; CBC, complete blood count; CXR, chest x-ray; NG, nasogastric; NICU, neonatal intensive care unit; SCAI, Society for Cardiovascular Angiography & Interventions; SBE, spontaneous bacterial endocarditis; tcPDA, transcatheter patent ductus arteriosus; VBG, venous blood gas.

- Blood products physically available at the start of the case
- A complete echocardiogram within 24 hours of the procedure, focusing on relevant anatomy

Ventilation strategies for premature infants undergoing tcPDA occlusion—most of whom have some degree of lung disease—vary widely and include the use of both conventional and high-frequency ventilation (HFV). Precise CO_2 control while avoiding barotrauma, volutrauma, and atelectasis will allow for optimal ventilation goals while protecting the developing lungs. Standard anesthetic machines may not adequately meet these goals, necessitating neonatal-specific ventilator use for the procedure.[38] Transporting premature infants on HFV presents unique challenges, and anesthesia providers may have limited experience managing these ventilators.[39] Strategies to mitigate this issue include temporary transition to a conventional ventilator for transport or performance of the procedure in the NICU, utilizing either conventional or HFV.[39]

Procedural considerations and technique

Successful tcPDA occlusion in preterm neonates has been performed both under fluoroscopic guidance in the catheterization suite[8,16] and in the NICU using primarily echocardiographic guidance (± portable fluoroscopy to visualize intracardiac catheter manipulation).[40,41] Although each location has advantages and disadvantages, the decision of where to perform tcPDA occlusion is an institutional decision and depends on multiple factors, including operator experience, equipment, procedural space, and personnel. To date, superiority of one location over another has not been demonstrated, but the overriding emphasis should be the ability to perform the procedure safely and with minimal disturbance to the patient's delicate physiologic state.[36]

Anesthesia for tcPDA occlusion is inherently similar to the surgical candidate insofar as size and cardiac pathology are concerned. Typically, intravenous paralytics and analgesics are administered, avoiding or limiting the use of volatile inhalational anesthetics.[42] Premature infants are susceptible to a profound and rapid drop in core temperature due to their immature skin, decreased fat stores, and increased body surface area to volume ratio, necessitating close monitoring of the infant's temperature throughout the procedure. Actions taken to maintain normothermia include careful control of the room temperature (often set to greater than 75 °F), use of convection temperature, thermal-reflecting, and simple plastic/fabric blankets and hats, as well as warmed ultrasound gel and fluids administered to the infant. An esophageal temperature probe advanced to the stomach allows for accurate monitoring of core temperature while also providing an anatomic landmark corresponding to the anterior wall of the aorta on lateral projection. The blood pressure cuff and pulse oximeter should be placed on the leg contralateral to the catheterization access site to monitor for the development of coarctation after device implantation. Blood gases should be obtained as soon as vascular access is secured and throughout the case, as end-tidal readings may be inaccurate.

Because femoral arterial access is typically avoided in these patients, the procedure is guided significantly by echocardiography. As such, an echocardiographer with experience in intraprocedural imaging of premature infants with PDA should perform the study, with strong consideration of having an attending-level cardiac imager present. The procedural echocardiogram focuses on the same anatomic factors outlined previously for preprocedural echocardiography and is initiated before catheters are introduced, as manipulation across the PDA can induce ductal spasm in premature infants.[42] In addition, the imager will identify optimal positioning of the echocardiography machine relative to the catheterization equipment and the echocardiography probe because the patient will be under sterile procedural drapes. A neck roll may facilitate visualization of the aortic arch.

The most commonly utilized devices for tcPDA occlusion include the Amplatzer Piccolo Occluder (Abbott) (Figure 2A), MVP micro vascular plug system (Medtronic) (Figure 2B), and Micro Plug Set (Merit Medical Systems) (Figure 2C), with only the Piccolo currently FDA approved for this indication in infants weighing 700 g to 2 kg.[42-44] The groins are prepared with either a chlorhexidine solution in isopropyl alcohol or betadine, considering the potential effects of topical iodine exposure in premature infants. Periprocedural antibiotics are administered per institutional practice, typically at case start. Using ultrasound guidance, a low-profile, thin-walled, hydrophilic sheath is inserted in the femoral vein under fluoroscopic guidance to avoid vascular injury. Positioning the distal tip of the sheath below the cavoatrial junction allows for optimal catheter manipulation. Either an end-hole directional or balloon-tipped catheter is advanced through the right heart, across the PDA, and into the descending aorta. Care should be taken to prevent tricuspid valve injury when traversing the right heart. For example, size mismatch should be avoided when using coaxial systems (eg, wires and microcatheters). Similarly, an exaggerated curve can be applied to the tip of a wire to minimize the risk of valve and chordal injury as the system traverses the tricuspid apparatus. Importantly, all catheters and wires should be withdrawn, and the tricuspid valve recrossed if any resistance is noted. Finally, given the potential risks and lack of data on its use in this patient population and procedure, the administration of heparin should be considered carefully. Although acute thrombus can develop during the procedure, the decision should balance the risks and benefits, including the relatively short procedural time and increased risk for hemorrhagic complications—intraventricular and elsewhere—in this patient population.

If utilizing fluoroscopy, a small hand injection of contrast is performed with the catheter in the para-ductal thoracic aorta to profile the ductus (Figure 3A). The contrast can be diluted with saline to reduce iodine exposure. Straight lateral fluoroscopic angle generally profiles the PDA optimally, and if biplane angiography is used, 15° left anterior oblique/15° caudal angulation of the frontal camera often provides useful baseline imaging of the branch pulmonary arteries. This angiogram is used to identify ductal length, minimal/maximal diameters, and relationship of the aortic and pulmonary insertions of the PDA to important landmarks such as the temperature probe and upper extremity central lines if present (Figure 3). If the PDA is not well visualized initially, angiography can be repeated with the catheter in a slightly different position or while slowly withdrawing the catheter through the PDA over a coronary wire during the injection. With evolving clinical practice, some experienced operators have performed the procedure at the bedside guided solely by echocardiography, although this is not common practice at the time of this publication.[41]

Once the device has been implanted but remains attached to the cable, a targeted echocardiogram is performed to evaluate for significant LPA or descending aortic obstruction and any residual shunting.[45] Expected Doppler findings immediately after device placement are a slight decrease in aortic flow velocity with a slight increase in LPA velocity,[45] both remaining <2.5 m/s. The device should be repositioned or removed if there is evidence of significant aortic or pulmonary artery obstruction, demonstrated by Doppler velocities exceeding 2.5 m/s, particularly if associated with a "run-off" pattern, or significant change in

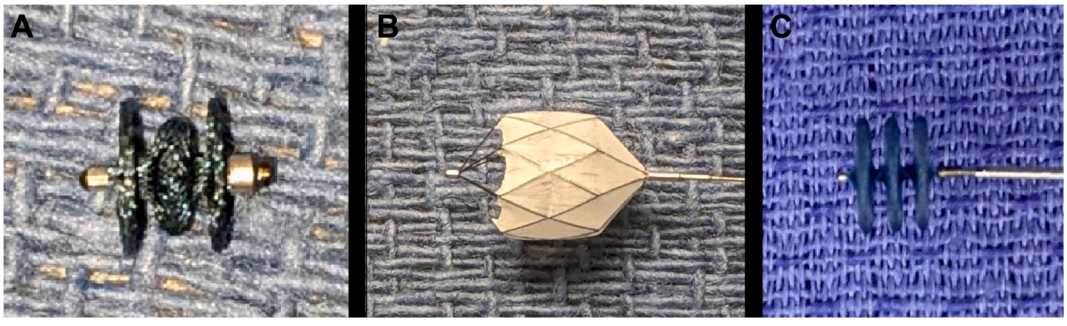

Figure 2.
Profiles of three commonly utilized tcPDA occlusion devices. (**A**) Amplatzer Piccolo Occluder (Abbott), (**B**) MVP micro vascular plug system (Medtronic), and (**C**) Micro Plug Set (Merit Medical Systems).

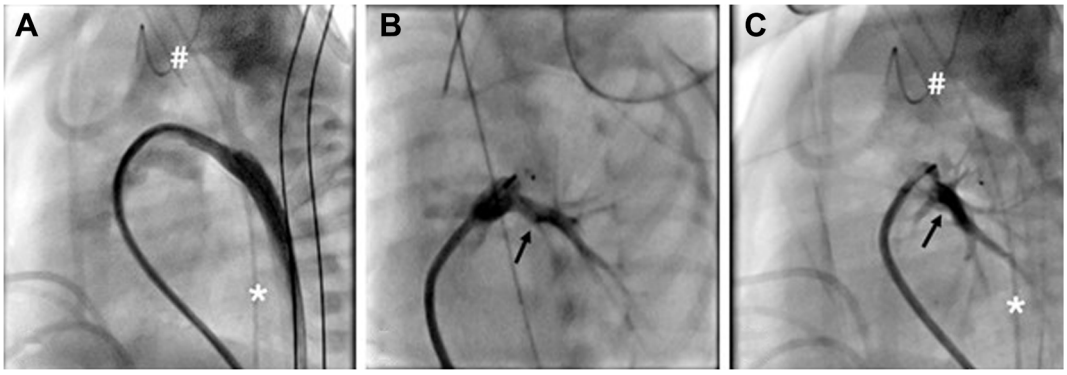

Figure 3.
Key angiographic markers during tcPDA occlusion procedures. (**A**) Angiogram in straight lateral projection of patent ductus arteriosus (PDA). Note the temperature probe (*), which marks the posterior portion of the PDA as it meets the aorta and the upper extremity peripherally inserted central catheter line (#) that demarcates the anterior portion of the PDA. Repeat angiogram after PDA device implantation but before release in (**B**) anterior left anterior oblique projection and (**C**) straight lateral projection. Note that the device sits anterior to the temperature probe (*) and posterior to the peripherally inserted central catheter line with unobstructed flow into the left pulmonary artery (arrow). Importantly, the device is slightly elongated and constrained by the PDA, suggesting that it is stable and well-sized.

2-dimensional or color Doppler appearance compared to baseline. An angiogram can also be performed through the delivery catheter to assess for LPA and aortic obstruction on levophase (Figure 3B, C). Angiographically, the relationship between the distal device and the descending aorta is best imaged from either a straight lateral or right anterior oblique projection during late levophase; however, this writing group strongly advises that aortic obstruction be investigated primarily by echocardiography. The device should be released if all the above conditions are met, and conversely, should be recaptured if in an unsatisfactory position. Based on the mechanism, the operator can attempt another implantation with the same device or replace it with a different size/model.

Additional considerations to be aware of at the time of device implantation include hypotension and hypoxemia. Specifically, the delivery systems may hold open the tricuspid and pulmonary valves, resulting in hypotension. Administration of inotropes before introducing these systems may prevent hemodynamic instability. Additionally, hypoxemia may occur because of increased right-to-left shunting at the atrial level and ventilatory changes. Supplemental oxygen may temporize the infant while the device position is evaluated. Device release or recapture—with removal of all catheters—typically results in rapid improvement of oxygen saturation. After release, straight AP and lateral fluoroscopic images are saved to document device position for comparison with postprocedure radiographs. Echocardiography is repeated to carefully reevaluate all the elements outlined previously, as well as the degree of tricuspid valve insufficiency, ventricular function, and new pericardial effusion.

Procedural complications and management

The most common reported procedural complications, excluding vascular obstruction, are device embolization, tricuspid valve injury, and cardiac perforation. The reported incidence of device embolization ranged between 0% to 8%[46] and was 2% in the US Piccolo clinical trial in infants <2 kg.[15] Embolization typically occurs during or immediately following the procedure, and most often into a branch pulmonary artery, with aortic embolization far less common. The most common causes of device embolization are improper positioning or inaccurate size selection, potentially related to suboptimal ductal imaging.[41,45] Attempts at transcatheter retrieval of an embolized device with a snare have a high success rate but can be challenging and may lead to hemodynamic instability.[46] Although every attempt should be made to snare and extract the device through a long sheath or catheter, the operator must determine the safest method of device extraction for the patient if removal through a catheter/sheath is not technically possible.

Tricuspid valve injury, typically presenting as new or worsened regurgitation, has been reported in 0% to 5% of cases and is hypothesized to result from damage to the septal leaflet chordae.[47] As noted above, a variety of techniques have been developed to minimize the incidence of this complication.[48] Most cases are clinically well tolerated and may improve over time; however, in rare instances, significant cyanosis has been reported secondary to increased right-to-left shunting at the atrial level.[46] Finally, the reported incidence of cardiac perforation ranges between 0% to 8.3% and is often the result of wire manipulation.[46] The right atrial appendage and inferior vena cava are particularly susceptible to injury and rapid recognition, pericardial drainage, and even surgical repair may be needed to prevent procedural mortality.

Extremely premature infants are exposed to significantly higher doses of radiation during their NICU course than infants who are less premature.[49] Although there are reports of this procedure being performed with echocardiographic guidance alone,[50] use of fluoroscopy with either a portable C-arm at the bedside or in the cardiac catheterization laboratory remains common practice. Given the vulnerability of the patient population and the relatively high level of radiation exposure these patients receive throughout their NICU stay, the operator should be diligent in adhering to the as low as reasonably achievable principles.[51] Additionally, echocardiographic guidance should be utilized for as many aspects of the procedure as safely possible to minimize radiation exposure.

The potential impact of intravascular iodinated contrast media (ICM) exposure in premature infants remains unknown. Risk factors for hypothyroidism in term infants and children include younger age at exposure, renal insufficiency, multiple cardiac procedures, trisomy 21, and repeated ICM exposures.[50-57] Although premature infants remain at increased risk of baseline hypothyroidism, several studies failed to demonstrate an increased risk of clinically significant ICM-associated hypothyroidism in preterm vs term infants.[56,58-61] Given these concerns, the FDA recommended that decisions about thyroid monitoring after iodine exposure in children be individualized.[49] Select patients with additional risk factors may benefit from postexposure thyroid function monitoring. Further, limiting the dose of ICM to the lowest level possible is prudent in this vulnerable population.

Postcatheterization care

After successful tcPDA occlusion, postprocedure imaging (eg, echocardiography and/or chest x-ray) should be obtained after returning to the NICU to document device position. Although the incidence of postligation syndrome is significantly lower after

transcatheter occlusion, as compared to surgical ligation,[13] infants should be monitored closely for signs of low cardiac output and treated appropriately if present.[62] Ventilator and oxygen requirements may also transiently increase in the first days after occlusion, especially in older infants.[62] Hemolysis from residual shunt through the device has been reported, but is exceptionally rare and tends to resolve with time and supportive care.[16] Last, endocarditis prophylaxis is indicated per guidelines, currently for at least 6 months.[63]

Device malposition and embolization are most often identified either immediately or within 24 hours after device placement, with fewer instances occurring after 24 hours. Many cases may be amenable to transcatheter device retrieval, with the decision to reattempt device occlusion determined individually. Data from the Piccolo Occluder premarket trial included a 3-year follow-up of 200 preterm infants and reported a low incidence of LPA (n = 2) and aortic (n = 2) obstruction requiring reintervention.[16] A meta-analysis of tcPDA occlusion in 373 infants <1.5 kg described 8 (2.1%) cases of LPA and 5 (1.3%) cases of aortic obstruction that required intervention with an additional 18 (4.8%) and 3 (0.8%) patients with increased LPA and aortic Doppler velocities, respectively, who were monitored without subsequent indication for intervention.[18] Interestingly, clinically significant LPA or aortic obstruction did not manifest until 3 to 6 months after device placement in some cases, even without device migration, presumably related to progressive remodeling of ductal and vascular anatomy after device implantation.[64] This finding further reinforces the importance of close clinical and echocardiographic follow-up after tcPDA occlusion.

Regular echocardiograms should be performed after tcPDA occlusion with a reasonable schedule consisting of 24 hours, 1 week, 1 month, 3 months, and 6 months postprocedure, with additional studies performed if clinical concerns arise. Although a trivial to mild residual shunt can occur in up to 8% of patients, most of these shunts resolve on longitudinal imaging.[65] As alluded to earlier, Doppler flow velocities ≥2.5 m/s through the LPA or aortic arch may signal developing obstruction, prompting more frequent echocardiographic assessment or advanced imaging (ie, nuclear perfusion scan, CT angiography).[25] Further, advanced imaging should be considered if there is a discrepancy between the clinical exam and noninvasive imaging.

Once identified, LPA and aortic arch obstruction should be managed on an individualized basis. Shared decision-making by key stakeholders should take into consideration the patient's age, size, clinical status (particularly ventilatory support and nutritional status), vascular access limitations, and other comorbidities. Transcatheter treatment often involves stent placement, which needs to be carefully planned and executed in these small infants.[66] Close observation may be reasonable in the setting of echocardiographic obstruction without obvious clinical consequences, particularly in smaller patients (<2 kg) for whom catheter or surgical intervention would carry significant risk, as one study demonstrated that echocardiographic gradients may improve over time.[67]

For infants born at an outside institution, transfer back to the referring center is reasonable once clinically stable and with reassuring imaging findings. Ideally, the device should be in a stable position with echocardiography demonstrating no significant residual shunt or important LPA or aortic obstruction. Decisions about the timing of return to the referring center should consider distance, subspecialist availability, and resources available at the referring center. Finally, all patients should be seen by cardiology after hospital discharge, with some guidelines advocating lifelong follow-up.[37,68,69]

Training and competency

The PICS/AEPC/APPCS/CSANZ/SCAI/SOLACI expert consensus statement on cardiac catheterization for pediatric patients and adults with congenital heart disease delineated standards for operator knowledge and technical procedural skills for the performance of catheterizations on patients with congenital heart disease.[70] The document outlines special considerations for premature infants, and this committee recommends that all physicians who perform this procedure thoroughly review that consensus statement. However, this committee notes that the broad consensus manuscript does not specify suggested case volumes for premature PDA occlusion procedures.

Given the evolving clinical landscape for these interventions, this writing committee agreed upon the following based on expert consensus, outlined in Table 1. First, trainees and practicing cardiologists who plan to perform this procedure independently should be involved in the multidisciplinary decision process regarding indications and timing of tcPDA occlusion in this patient population. Second, the committee agreed that pediatric and congenital interventional cardiologists who seek to perform tcPDA occlusion in premature infants should demonstrate proficiency in specific skill sets relevant to the procedure (Table 1). In terms of procedural volumes, for current advanced trainees specializing in pediatric and congenital interventional cardiology, this committee recommends that they directly participate in a minimum of 10 cases of tcPDA occlusion in patients under 2.5 kg during interventional cardiology training. After completion of training, the writing committee further recommends a minimum of 5 proctored cases in initial independent practice. If the trainee is unable to complete the recommended 10 cases during fellowship, those remaining cases should be added to the proctored total in independent practice. For practicing interventional cardiologists who did not perform these procedures during training, the writing committee recommends a minimum of 5 proctored cases. For the purposes of this procedure, this committee considers an experienced proctor as someone who has performed at least 25 of these procedures; this person can be an interventional cardiologist at the same center or a requested external proctor, whichever is applicable or preferred by the implanter. Last, this committee recommends performing or being involved in at least 5 cases/y to maintain operator skill set and clinical proficiency of the multidisciplinary teams (eg, cardiac anesthesia and catheterization laboratory staff) involved with these cases.

Institutional considerations

Infrastructure

Institutions that provide tcPDA occlusion therapies for premature infants should have several key elements in place. First, the institution

Table 1. Recommended skills for physician operators performing transcatheter PDA occlusion in premature infants.

- Knowledge of relevant periprocedural considerations
- Understand complex physiology of extremely premature infants (eg, respiratory, cardiovascular, and thermogenesis)
- Vascular access in infants <2 kg
- Access site complication management
- Radiation and contrast-limiting measures
- Knowledge of aortic, pulmonary artery, and specific PDA morphology in preterm infants
- Know techniques to safely perform cardiac catheterization on infants <2 kg
- Know techniques to utilize available PDA occlusion devices
- Knowledge of the risks and benefits of available PDA occlusion devices
- Recognize and treat potential complications during PDA occlusion (eg, pericardial effusion, device embolization, tricuspid valve injury)
- Recognize and treat potential postprocedural complications (eg, post-PDA ligation syndrome, aortic/LPA obstruction)

LPA, left pulmonary artery; PDA, patent ductus arteriosus.

should possess cardiac catheterization laboratories with appropriate equipment to perform these procedures on premature infants. In addition to equipment in the NICU, the catheterization laboratory must possess the necessary technology for appropriate thermoregulation, delivery of anesthetics, and ventilation strategies for premature infants.[17,36] Institutions performing the procedure in the NICU should possess specialized equipment, including portable fluoroscopy (eg, miniature "C-arm") and the appropriate room configurations and air-control modifications.[40] As many patients are referred to the treatment center, the interhospital transfer process requires a specialized transport team trained in the unique cardiopulmonary physiology of the extremely premature infant.[36,71]

Beyond equipment, the institution must employ appropriate staff to safely perform the procedure as well as treat potential complications and comorbidities common to preterm infants. In terms of the procedure, this includes a catheterization laboratory team comprised of nurses, radiation technologists, anesthesiologists, imagers, and cardiac interventionalists capable of caring for extremely low birth weight premature infants. A cardiothoracic surgeon, ideally on-site, must be available to provide a prompt response to complications that require immediate surgical intervention.[72] Finally, pediatric subspecialists in other major domains, including pulmonology, gastroenterology, surgery, endocrinology, and infectious diseases, among others, should be readily available to help treat common comorbidities often present in these patients.

Regional network

In addition to infrastructure, institutions interested in becoming regional referral centers can consider creating a multidisciplinary team with a defined clinical pathway to support these procedures. This team-based system, conducted by a dedicated service line, can ensure optimal candidacy, timing of intervention, procedure coordination, and follow-up as outlined in Table 2.[43,71-73]

Strong working relationships with referring hospitals are important because patient selection decisions are best made by collaboration between the referring hospital's and treatment center's multidisciplinary team. Once the outside center makes a referral, the treatment hospital's team can help coordinate the requisite administrative work, including insurance approval and interhospital transport.[43] A patient navigator, nurse coordinator, and email distribution list can help synchronize the teams. A well-developed and coordinated interdisciplinary communication process must exist to help guide all phases of care, including transfer back to the referring center.

Tracking outcomes

Tracking outcomes from large multicenter neonatal[20,74,75] and cardiac[18,23] focused registries can provide insights into trends, safety, and clinical outcomes following tcPDA occlusion. However, patient-specific demographic characteristics and clinical data are often incomplete in these larger registries, limiting the ability to analyze long-term impact. As such, each center should strongly consider maintaining local databases to better understand its own center-specific outcomes, delineate regional referral trends, and foster quality improvement projects in this arena.[17,76,77]

Conclusions

An hsPDA occurs more often in extremely premature infants, and its presence can contribute to long-term morbidity and mortality. In the last decade, tcPDA occlusion has replaced surgical ligation as the procedure of choice in premature infants. Device occlusion can be performed safely, with a low incidence of complications, utilizing a variety of occlusion devices. Programmatic and procedural success is intricately related to appropriate patient selection, preprocedural evaluation, periprocedural technique, operator training standards, and infrastructure.

Table 2. Multidisciplinary referral process.

Process	Considerations
Patient selection	• Clinical and echocardiographic determination of PDA's hemodynamic significance by neonatology and cardiology to identify optimal candidacy • Assessment of ductal morphology to ensure appropriate for catheter-based intervention (echocardiography) • Joint assessment by neonatology and cardiology to evaluate risks/benefits and inclusion/exclusion factors (cardiac and noncardiac) • Standardized cardiology or PDA team consult
For external referrals	• Functional image transfer process • Telemedicine consultation with caregivers • Clear, consistent, complete, and regular communication between treatment and referral centers • Regional and local insurance process • Consider echocardiogram within 24 h of transport • Transportation considerations o Team experienced with premature infants and cardiovascular pathology o Discuss the mode of mechanical ventilation o Communication between the referring and treatment center NICU teams, including nursing and respiratory therapists

NICU, neonatal intensive care unit; PDA, patent ductus arteriosus.

Declaration of competing interest

Tacy Downing is a site principal investigator for the COMPASS Trial. Allen Ligon is a proctor for Abbott. Shyam Sathanandam is a consultant, advisor, and speaker for Abbott and is a principal investigator for the US PDA Registry, which is funded by Abbott. He is also a principal investigator for a preclinical trial sponsored by Medtronic. Nathaniel Taggart is a coinvestigator on the Harmony TPV trial sponsored by Medtronic. Jenny Zablah is a consultant for Medtronic and a principal investigator for a clinical trial on OCT in pulmonary vein stenosis sponsored by Abbott. Brent M. Gordon is a proctor and consultant for Abbott and Merit Medical. The other authors reported no financial interests.

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Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2025.103866.

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