

# Stenting of the ductus arteriosus for ductal-dependent pulmonary blood flow—current techniques and procedural considerations

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## Abstract

The use of prostaglandin-E1 immediately after birth and subsequent surgical creation of the modified Blalock-Taussig shunt (BTS) shunt have remarkably improved the prognosis and survival of children with congenital heart disease and ductal-dependent pulmonary blood flow (PBF). Despite the advancement in surgical techniques, bypass strategies, and postoperative management, significant morbidity and mortality after BTS still remain. Patent ductus arteriosus stenting has been shown to be as an acceptable alternative to BTS placement in select infants with ductal-dependent PBF. Newer procedural techniques and equipment, along with operator experience have all contributed to procedural refinement associated with improved outcomes over the recent years. In this article, we review the procedural and periprocedural details, with an emphasis on recent advances of this procedure.

## KEYWORDS

congenital heart disease, ductal-dependent pulmonary blood flow, patent ductus arteriosus, stent

## 1 | INTRODUCTION

Despite being first performed in 1944, and subsequently refined over the ensuing decades, the modified Blalock-Taussig shunt (BTS) procedure remains an operation with significant mortality and morbidity even in the current era. In a large multicenter report from The Society of Thoracic Surgeons Congenital Heart Surgery (STS-CHS) Database, a cohort of neonates who underwent modified BTS placement without concomitant procedures experienced in-hospital mortality at a rate of 7.2%.<sup>1</sup> Using an audit dataset from the United Kingdom to capture a large cohort of patients who had surgery for placement of an isolated BTS, Dorobantu et al reported an overall mortality rate of 13.9% and a 17.8% risk of BTS reintervention.<sup>2</sup> Considering the high mortality and morbidity associated with a BTS,

alternative less invasive approaches to maintaining ductal patency (eg, stenting of the PDA) have been explored.

Stenting of the PDA for ductal-dependent pulmonary blood flow (PBF) can be a technically challenging procedure. The first reports of PDA stenting for ductal-dependent PBF infants were published in 1992 by Gibbs et al.<sup>3</sup> In their initial experience, the operators faced a number of technical barriers. The stents that were initially used for this procedure were hand crimped on balloons, thus necessitating the use of relatively bulky delivery systems and sheaths. Since then, a number of innovations in techniques, equipment, and subsequent experience of operators have all played a vital role in how the procedure has evolved over the recent years.<sup>4-11</sup> In fact, in the current era, PDA stenting for ductal-dependent PBF has been found to be an acceptable alternative to surgical BTS in select patients. In two relatively large multicenter studies, one reported from our group

and one from the United Kingdom, PDA stenting was found to be noninferior or superior to BTS placement with regards to primary outcomes, in addition to having a number of important other advantages over BTS placement.<sup>12,13</sup>

Attention to important procedural and periprocedural details are key to ensuring the success of PDA stenting, which are discussed in this article.

## 2 | PREPROCEDURE PLANNING

Most infants with ductal-dependent PBF rely on PGE-1 infusion to prevent PDA constriction prior to stenting. A detailed transthoracic echocardiogram is performed to delineate the aortic arch anatomy, origin, and insertion of the PDA. In addition, it is important to note the morphology of the PDA in addition to the pulmonary artery (PA) anatomy. If the anatomy cannot be accurately discerned with standard transthoracic echocardiography, a computerized tomography (CT) scan may be obtained to obtain high-resolution definition of the PDA and branch PAs (Figure 1). Computerized tomography scan imaging allows the operator to exclude patients from the procedure in whom a highly tortuous or long PDA is present which may not be amenable to stenting, depending on operator comfort and center experience. In addition, complex PA anatomy (eg, PA isolation necessitating initial surgical PA plasty) may be better defined with CT imaging. Transthoracic echocardiography and CT scan imaging are

both helpful in planning for the intended vascular access route (see below), to ensure the most direct trajectory.

While being maintained on PGE-1, the size of the PDA may be large, precluding implantation of a reasonable size stent. Since each PDA reacts differently to infusions of PGE-1, we prefer to give a trial off PGE-1 a few days prior to the anticipated ductal stenting procedure while monitoring the saturations closely. As the ductus constricts, there is an expected decline in systemic oxygen saturations. At this time, an echocardiogram can roughly estimate the size of the ductus arteriosus. Defining this time to adequate ductal constriction is very helpful in further logistical planning of the ductal stenting as it can give a rough estimate for the amount of time PGE-1 should be turned off prior to the procedure. Subsequent to this determination, PGE-1 is restarted and maintained until the planned procedure. For patients in whom constriction is present despite PGE-1, it may be reasonable to leave the PGE-1 infusion on.

## 3 | INTERVENTIONAL PROCEDURE

The procedure is performed in the cardiac catheterization laboratory with general anesthesia and biplane fluoroscopy. It is imperative to have secure intravenous/central venous access in case the administration of inotropes/vasopressors, emergency medications or blood products is necessary. Heparin is administered to achieve an activated clotting time (ACT) of > 250 seconds.

PGE-1 infusion may be continued during the catheterization, but in the event that the operator elects to hold the infusion, PGE-1 should be kept in the line. If there is a downward trend in saturations, the infusion can then quickly be reinitiated. Similarly, if ductal spasm is encountered during wire or catheter advancement in the PDA, PGE-1 must be reinitiated unless a stent is placed immediately after the ductal spasm occurs. The blood pressure should be optimized (an infusion of vasopressors to counteract the effects of anesthesia may be needed). This also facilitates blood flow through the PDA, thus increasing PBF, which may help should ductal spasm occur.

### 3.1 | Morphology and vascular access

Special attention is given to the morphology of the PDA, as this can influence techniques and help anticipate important outcomes (see below). We have proposed a morphological classification scheme for PDAs in infants with ductal-dependent PBF.<sup>14</sup> In this scheme, PDAs with Tortuosity Index Type I are relatively straight, Type II have a single turn and Type III have multiple turns and are often complex. Further, origin of the PDA on the systemic arterial end presents as a subtype classification; PDAs are classified as originating from the descending aorta, underside of the aortic arch, innominate artery, subclavian artery, or ascending aorta. In our experience, procedure times and need for placing more than one stent did not differ based on Tortuosity Index type, likely related to use of unconventional access sites to facilitate direct access to the PDA (see below).



**FIGURE 1** Computerized tomography (CT) scan in an infant with ductal-dependent pulmonary blood flow in whom the patent ductus arteriosus (PDA) origin and anatomy could not be accurately discerned from transthoracic echocardiography. An unusual origin of a tortuous PDA (arrow on left) from an aberrant left subclavian artery (arrow on right) is seen. Abbreviations: A, anterior; I, inferior; P, posterior; S, superior

Vascular access is a vital part to the success of the procedure. *It is crucial that the straightest trajectory to access the PDA is chosen based on preprocedural imaging.* While PDAs originating from the descending aorta (and some from the head and neck vessels) are accessible with relative ease from a retrograde femoral or umbilical arterial approach (Figure 2), PDAs that originate from the underside of the aortic arch can be challenging to access from a femoral arterial approach. In the case of a ventricular septal defect, an antegrade femoral or umbilical venous approach may be used for PDAs that originate from the underside of the arch, however, negotiating multiple angles and curves in the PDA may still be cumbersome and add to the difficulty of the procedure. In addition, in small infants, there may be a risk of femoral arterial trauma/thrombosis when using four French delivery sheaths.<sup>15</sup> The umbilical vessels may mitigate the risk of vascular access complications if available for use. For PDAs that originate from the underside of the aortic arch (and some from the head/neck vessels), percutaneous axillary artery or common carotid artery access facilitates a direct and straight trajectory which allows for easier maneuverability of guidewires/stent systems. While previously axillary artery or common carotid artery access was performed via surgical cut down techniques, percutaneous axillary and percutaneous carotid artery access for PDA stenting has been shown to be safe and effective.<sup>16-19</sup> We perform percutaneous axillary (Figure 3) and percutaneous carotid artery (Figure 4) access for these procedures with ultrasound guidance to ensure an isolated anterior wall puncture. In our multicenter experience, most PDAs from the underside of the aortic arch were accessed from a common carotid or axillary artery approach, while the femoral artery/femoral vein was the preferred access site for those PDAs originating from the descending aorta.<sup>14</sup> Once access is obtained, a 3.3 Fr or 4 Fr short sheath is advanced with fluoroscopic guidance to avoid inadvertent trauma to important structures, including the PDA. Another technique that has proven helpful for stenting of PDAs from the underside of the aortic arch is the "flip" technique.<sup>20</sup> In this technique, the patient is positioned

such that the feet and head are swapped (feet face the head of the bed). The fluoroscopic equipment is digitally configured such that that the imaging obtained still reflects that of standard imaging acquisition. This technique is used for percutaneous carotid arterial access and allows for equipment to be laid down the length of the table, mimicking typical femoral vascular access, which facilitates wire stability and easier exchange of equipment when compared to traditional positioning. Though not statistically significant, we have noted procedural times to be shorter with this technique.<sup>20</sup>

### 3.2 | Crossing and stenting the PDA

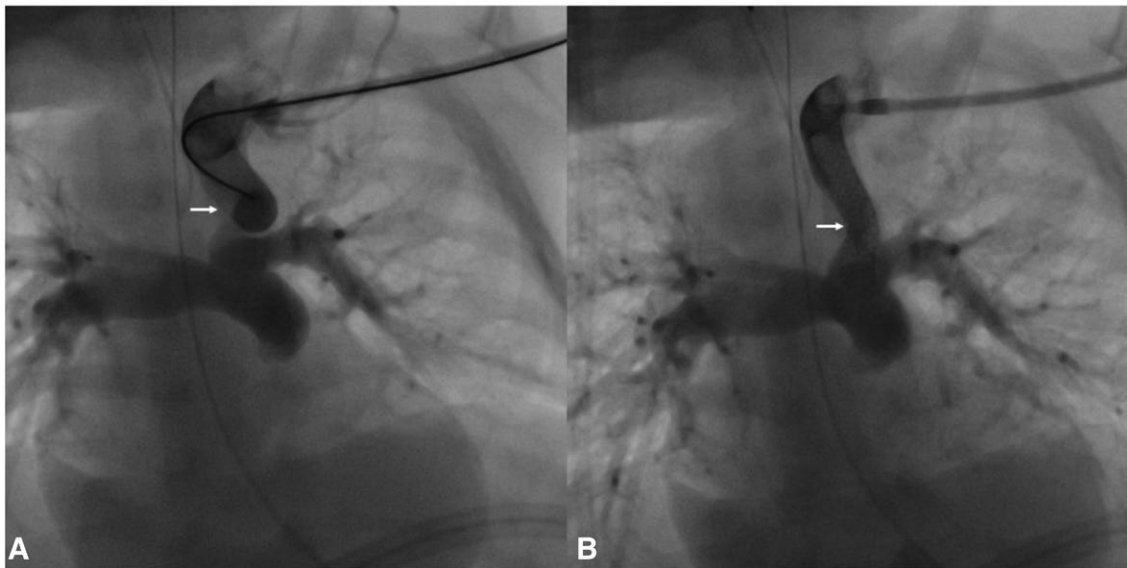
Prior to crossing the PDA, the operator should have equipment readily available based on angiographic assessment obtained prior to ductal manipulation. Angiography in angled projections is obtained to best profile the PDA. In the instance of catheter- or wire-induced ductal spasm (with associated hemodynamic consequence), once the PDA is crossed, availability of preselected equipment facilitates rapid stent deployment.

It is important that there is enough constriction in the PDA (constriction in one focal point will suffice) to allow a stent to be anchored securely. Measurements of the PDA are made to help choose the desired stent (s) length needed (though this can be difficult to predict, particularly in the instance of PDAs with higher grades of Tortuosity Indices). Although a number of factors must be considered with regards to nominal stent diameter (eg, presence or absence of antegrade flow, length of PDA to be stented), in general, for infants weighing > 3.0 kg, a 3.5-4 mm diameter stent is chosen, for those weighing 2.0-3.0 kg, a 3.5 mm diameter and for those < 2 kg, a 3-mm stent is chosen for deployment.

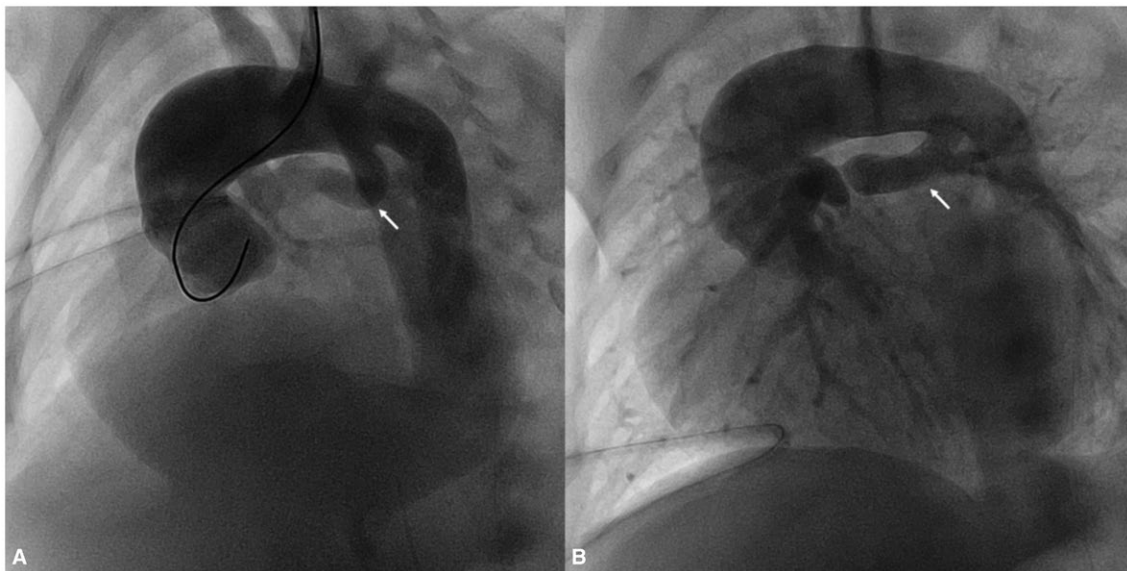
A floppy 0.014" guidewire (eg, Choice PT Floppy Guidewire, Boston Scientific, Marlborough, Massachusetts) is used to cross the PDA. The use of microcatheters (alone or with the help of a 0.014" guidewire) to cross the PDA may be helpful when a 0.014" wire is not



**FIGURE 2** Pre (A)- and post (B)-PDA stent placement images from a percutaneous femoral artery approach in an infant with neonatal Ebstein's anomaly. Arrows point to the PDA and PDA stent in the respective figures



**FIGURE 3** Pre (A)- and post (B)-PDA stent placement images from a percutaneous axillary artery approach (same patient whose CT scan is shown in Figure 1) in an infant with Tetralogy of Fallot and pulmonary atresia. Arrows point to the PDA and PDA stent in the respective figures



**FIGURE 4** Pre (A)- and post (B)-PDA stent placement images from a percutaneous carotid artery approach in an infant with double outlet right ventricle, ventricular septal defect, and pulmonary atresia. Arrows point to the PDA and PDA stent in the respective figures

able to negotiate turns easily, eg, for PDAs with Type III Tortuosity Index. While the choice of 0.014" guidewire used is highly institutional and operator dependent, it is advisable to not use a stiff guidewire for primary ductal crossing, as this may cause trauma to the PDA, which can be catastrophic. If any hemodynamic instability occurs due to ductal spasm, quick decision making is crucial. At times, wire withdrawal should be performed to allow relief of ductal spasm if immediate stent implantation is not feasible. In other situations, quick placement of the ductal stent is necessary to reestablish stable PBF. However, if there is persistent hemodynamic instability,

the procedure may need to be abandoned and the patient should be referred for a surgical shunt. Rapid availability of venoarterial extracorporeal membrane oxygenator support (ECMO) can be life-saving.

The stents typically used for PDA stenting are newer generation, flexible coronary artery stents that are available in over-the-wire or monorail (eg, "Rapid Exchange") systems. Though primarily bare metal stents have been used, recently, drug eluting stents (DES) have been used for their potential benefits when deployed in PDAs. Drug eluting stents have been purported to result in less lumen loss than bare metal stents when deployed in the PDA in an animal model.<sup>21</sup>



Preliminary data on the use and pharmacokinetics in neonates using a single DES to stent the PDA have been reported.<sup>22</sup> These preliminary data suggest significantly lower clearance of sirolimus in neonates and peak sirolimus levels being 20 times higher than in older children and adults. Despite these findings, the authors did not note any adverse clinical outcomes due to the prolonged immunosuppressive sirolimus levels. We have used DES in neonates for ductal stenting and have noted significant benefits with regards to less luminal loss and decreased reintervention rates compared to bare metal stents, in retrospective analysis, without identification of adverse clinical outcomes due to systemic immunosuppression.<sup>23</sup> However, multi-institutional studies need to be performed to verify these benefits in larger cohorts of patients.

Once the stent is deployed, the PDA anatomy is reassessed with the wire still in place to ascertain whether placement of another stent is necessary. Restenting is much easier to accomplish over the same guidewire and can be difficult after guidewire withdrawal. Examination of distal pulses (if femoral or axillary arterial access is used) and ultrasound of the access site can be performed in the cardiac catheterization laboratory prior to patient transfer.

### 3.3 | Complications

In addition to other complications, adverse events specifically related to ductal stenting should be kept in mind. In our experience, the complication most frequently encountered (9%) is vascular-related injury.<sup>12</sup> Ductal dissection, though rare,<sup>13</sup> can occur and this highlights the importance of exercising great care when crossing the ductus with a guidewire. Ductal spasm and its management are described above. Most of the time, the procedure can be safely resumed after a period of stabilization. The procedure may have to be aborted if ductal spasm with hemodynamic compromise is encountered again. Formation of acute stent thrombus is another serious complication encountered rarely in some patients. If this occurs acutely during the procedure and the wire is still traversing the ductus/PDA stent, balloon inflation at the site of the thrombus (multiple inflations may be necessary) can be helpful. If the wire is removed, then a wire can be passed through the thrombus and followed by balloon inflation. Attention to maintenance of adequate ACTs and administration of heparin for a period of time after the procedure may be necessary. Occasionally, acute PDA stent thrombosis may indicate reduced flow owing to luminal narrowing, and restenting of the PDA may be necessary. Heparin's action is dependent on anti-thrombin III, which may be deficient in neonates and involvement of hematology may be necessary. Stent migration or malposition can also occur in a minority of cases. With adequate allowance for ductal constriction by keeping patient off PGE-1, the chances of this complication are reduced. Nevertheless, if the ductus arteriosus is not adequately constricted at the time of stent implant, the stent can potentially migrate forward (or backward during balloon withdrawal). The stent may be repositioned in the catheterization laboratory, or even secured in place with the

addition of a second stent. If the stent cannot be repositioned in the cardiac catheterization laboratory, it can be left in place (jailing of a branch PA or systemic arterial branch is usually not flow limiting) and dealt with at the time of subsequent surgical repair/palliation. Rarely, the stent may need to be acutely retrieved in the operating room with concomitant placement of a BTS.

## 4 | POSTPROCEDURE PRECAUTIONS AND MONITORING

Patients are monitored in the hospital for at least 24 hours after the procedures with follow up chest radiographs and echocardiograms. We start patients on aspirin 3-5 mg/kg/day and heparin is administered if there are any concerns of decreased pulses, occlusion of the access vessel/s or occurrence of stent thrombosis (rare) during the procedure. Dual antiplatelet therapy with the addition of clopidogrel can also be considered but is not universal. A decrease in oxygen saturations in follow-up should prompt a repeat cardiac catheterization for interrogation/dilation/restenting of the PDA or surgical repair/palliation if an appropriate time has been reached.

## 5 | SPECIAL CONSIDERATIONS

According to the 2011 AHA guidelines,<sup>24</sup> PDA stenting in patients with sole supply PBF is a Class II b indication (level of evidence: C). Similarly, the presence of branch pulmonary artery stenosis is currently listed as a Class III indication for PDA stenting (level of evidence: C). However, we<sup>4,12</sup> and others, have stented the PDA in the setting of single source of PBF and also in cases where a significant proximal branch PA stenosis is present (using techniques of intentional jailing of a branch PA and dilation/stenting through stent side cells). Partial or complete jailing of a branch PA (with or without preexisting branch PA stenosis) was noted in 22% of patients in our experience,<sup>14</sup> more often with higher degrees of tortuosity. This was also associated with greater planned/unplanned reintervention rates and PA plasty. However, in the long term, there does not appear to be any significant difference in branch PA size and symmetry whether a branch PA is jailed or not. It is important to note that though these above situations may not be an absolute contraindication to PDA stenting in all patients, *they must be approached with caution and based on each individual center's experience*. As with any other complex interventional procedure in a neonate, ductal stenting requires a high degree of technical skill, expert pediatric cardiac anesthesiology support, and ready access to surgical backup and ECMO support. The learning curve associated with PDA stenting has been demonstrated by Santoro et al.<sup>5</sup> With more expertise being accumulated in the recent years and the increase in the volume of cases, we should expect to see more widespread adoption of initial palliation with PDA stenting, even in highly tortuous PDAs with challenging anatomy.

## 6 | CONCLUSIONS

Techniques of ductal stenting for infants with ductal-dependent PBF have evolved rapidly over the last decade. Attention to anatomic and technical details optimizes the success of the procedure. The morphological classification scheme is helpful in anticipating acute and long-term outcomes of the procedure. It is likely that we will see further refinement of imaging, procedural techniques, and equipment used for PDA stenting in the ensuing years.

## CONFLICT OF INTEREST

None.

## AUTHOR CONTRIBUTIONS

Athar M. Qureshi, Varun Aggarwal, Christopher J. Petit, Andrew C. Glatz and Bryan H. Goldstein were all involved in the concept/Design, data analysis/interpretation, drafting article and critical revision of article. All authors approve the final version of the manuscript.

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