# Stenting the arterial duct: Practical aspects and review of outcomes

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## ABSTRACT

**Cyanotic congenital heart lesions with duct-dependent pulmonary blood flow often require early intervention. Surgical palliation remains the treatment of choice, but is associated with substantial morbidity and mortality. Ductal stent implantation is becoming a recognised alternative to maintain pulmonary blood flow. Results of ductal stenting have improved and outcomes are good. We discuss the outcomes of published data and the practical aspects of ductal stenting.** SAHeart 2013;10:514-519

## INTRODUCTION

Cyanotic congenital heart disease with duct-dependent pulmonary blood flow is a life threatening condition. Typical lesions include pulmonary and tricuspid atresia, critical pulmonary stenosis and tetralogy of Fallot. Establishing adequate pulmonary blood flow is essential for survival in these patients and early intervention is often required.

This may be accomplished by using intravenous prostaglandin therapy to maintain duct patency until surgical intervention is possible (palliation or complete repair). Surgical options may, however, be limited by centre experience and patient factors such as critical illness and very low birth weight. Surgical palliation consists of a systemic-to-pulmonary artery shunt as a first stage procedure. Although this has been used since the mid 1940s, it is still associated with significant morbidity and mortality.[1,2] Complications such as shunt thrombosis, pleural fluid collections and nerve injury with diaphragmatic paralysis have been described.[3,4] Ongoing problems include progressive endovascular growth with obstruction, distortion and differential growth of the branch pulmonary arteries, as well as adhesions which may complicate future surgeries.

Maintaining ductus arteriosus patency by the percutaneous placement of coronary artery stents provides an alternative to surgical systemic-to-pulmonary artery shunts. This maintains pulmonary blood flow and serves as a temporary bridge towards later surgical repair. Since the first report by Gibbs, et al. in 1992, the success and outcome of ductal stenting have improved due to advances in technique and equipment. This is now considered an acceptable option for these patients in many centres.

## OUTCOMES OF DUCTUS ARTERIOSUS STENTING: A REVIEW OF CURRENT LITERATURE

### Immediate outcomes of PDA stenting

A detailed description of the immediate outcomes of PDA stenting can be viewed in Table 1.[3-15] The majority of patients underwent patent ductus arteriosus (PDA) stenting at an early age, usually shortly after birth, with weights ranging between 1.5 - 4.5kg. Procedural success was good and stent placement was successful in 80 to 100% of the cases. The effectiveness of the procedure is highlighted by the fact that all studies have shown a significant improvement in arterial saturations after stent placement. Some cases have required more than 1 stent in an attempt to ensure adequate coverage of the entire ductal length. Reported peri-procedural complication rates were low: major complications included stent migration, acute thrombosis and permanent femoral vessel damage. Very few immediate deaths were directly related to

the procedure and were reported in only 2 studies: acute stent thrombosis (n=1),[14] pulmonary haemorrhage (n=1) and retro-peritoneal haemorrhage secondary to an underlying coagulopathy (n=1).[15] Early re-intervention within the same admission consisted of mostly duct re-stenting. In most cases this was necessary to overcome early significant constriction as a result of unstented ductal segments. Deaths before discharge (not including deaths related to the procedure) were few and unrelated to stent implantation. These were mostly due to nosocomial sepsis and respiratory complications.

## Mid-to-long term outcomes of PDA stenting

The majority of studies followed up on patients at 6 months post-procedure. Follow-up intervals were scheduled to detect stent occlusion. A summary of the mid-to-long term outcomes of PDA stenting can be seen in Table 2.[3-15] Progressive stent stenosis

**TABLE 1: Immediate outcomes of PDA stenting**

| Number of cases attempted (reported success %) | Age at stent | Weight (kg) at stent | Major complications | Early reintervention | Deaths before discharge* | References |
|---|---|---|---|---|---|---|
| 21 (100) | median 13.3d | median 3.06 | 2 (permanent vascular occlusion) | 2 (restent) | 2 | Schneider 1998[6] |
| 10 (100) | median 6d | median 3.3 | | 1 (restent) | 1 | Gewillig 2004[7] |
| 21 (95.2) | median 10.5d | median 3.3 | 3 (stent migration), 2 (stent thrombosis) | 3 (restent) | 2 | Michel-Behnke 2004[8] |
| 56 (91) | median 2.3mo | median 3.9 | 1 (stent migration), 1 (hour-glass stent) | | 2 | Alwi 2004[3] |
| 10 (100) | median 16d | median 2.7 | | | | Mahesh 2005[9] |
| 10 (80) | median 3.5mo | median 5.4 | | | | Celebi 2007[10] |
| 16 (87.5) | mean 24d | mean 2.9 | 2 (stent migration) | 4 (restent) | 1 | Hussain 2008[11] |
| 26 (92.3) | mean 15.2d | mean 3.3 | | | | Santoro 2008[5] |
| 27 (100) | median 6d | median 3.2 | 1 (stent migration) | 2 (dilatation), 1 (restent) | | Schranz 2010[12] |
| 45 (93.3) | mean 66d | mean 4.4 | | | | Erdem 2011[13] |
| 33 (100) | range 3 - 56d | range 2.7 - 4.1 | 1 (stent migration) | 2 (dilatation) | 2 | Matter 2012[4] |
| 18 (83.3) | median 20d | median 3.2 | 1 (stent thrombosis), 1 (duct spasm) | | 2 | Amoozgar 2012[14] |
| 13 (100) | mean 10.5d | mean 3.1 | | | | Odemis 2012[15] |

*See text for details*

**TABLE 2: Mid-to-long term outcomes of PDA stenting**

| Number followed up | Age at follow-up | Cases of stent stenosis | Palliative surgery | Complete surgical repair | Deaths | References |
|---|---|---|---|---|---|---|
| 19 | group 1 median 8.7mo, group 2 median 6mo | 4 (dilated), 7 (to surgery) | | 7 | | Schneider 1998[6] |
| 10 | median 5.7mo | 1 (restent) | 2 | 2 | | Gewillig 2004[7] |
| 21 | mean 975d | 6 (dilated) | 8 | 4 | | Michel-Behnke 2004[8] |
| 49 | mean 9.6mo | 4 (to surgery), 2 (restent), 3 (dilated) | 4 | | 1 | Alwi 2004[3] |
| 10 | median 5.5mo | 1 (dilated) | | | | Mahesh 2005[9] |
| 8 | mean 9.3mo | 1 (restent) | | | | Celebi 2007[10] |
| 13 | mean 13mo | 1 (dilated), 4 (restent) | 6 | 2 | 1 | Hussain 2008[11] |
| 24 | mean 15mo | 2 (to surgery), 4 (dilated/restent) | 2 | 7 | | Santoro 2008[5] |
| 27 | | | 18 | 6 | 2 | Schranz 2010[12] |
| 42 | mean 34.5mo | 12 (dilated) | 20 | 14 | 2 | Erdem 2011[13] |
| 33 | 3 | | 24 | | 4 | Matter 2012[4] |
| 15 | 6mo | | | | 3 | Amoozgar 2012[14] |
| 13 | | 1 (to surgery) | 5 | | 2 | Odemis 2012[15] |

was reported in a few cases. These cases were either re-stented or a balloon angioplasty was performed. Where this was not successful in improving systemic saturations, surgery was carried out. Spontaneous occlusion of the stented duct without a decrease in arterial saturations has been reported at follow-up in lesions with an additional source of pulmonary blood flow. Lesions showing this phenomenon included critical pulmonary stenosis where the right ventricle had adapted and adequately increased in size to support pulmonary blood flow.

A small number of deaths were reported at follow-up and occurred between the time of initial discharge and before the first surgery was performed. These were mainly attributed to sepsis and pneumonia in most cases and unrelated to the PDA stent.

At first surgery (including systemic-to-pulmonary artery shunts, cavopulmonary shunts and complete repair), reported pulmonary artery growth was reasonable in all studies. The effect of PDA stenting on the anatomy of the branch pulmonary arteries is still unclear. Early on a significant number of cases required pulmonary arterioplasty. Lately most studies reporting on complications at first surgery found that most stents were easily removed with very few patients requiring reconstruction for pulmonary artery distortion. As a matter of fact, it seems that pulmonary artery growth is promoted by PDA stenting. It has been postulated that since a stent is implanted in the natural position of a duct, this may result in a better angle between the PDA and the branch pulmonary arteries, allowing for improved growth.[5]

## TECHNICAL ASPECTS

The procedure is usually performed under general anaesthesia or deep conscious sedation. In our practice, all patients are discussed beforehand with the cardiothoracic team and surgical standby is routinely available. In order to facilitate stent placement, it is preferable to have a mildly constricted duct (enough to allow the stent to be secured). It is therefore recommended to stop prostaglandin infusion 6 - 12 hours before the procedure. However, in patients with low oxygen saturations, intravenous prostaglandin administration should be continued, but titrated down to the lowest dose required to maintain ductal patency. Prolonged prostaglandin treatment may give rise to a big, dilated ductus, which usually precludes stent placement due to the lack of a narrowed ductal segment where the stent can find adequate "grip". If there are any concerns regarding PDA size, it is advisable to confirm ductal size in the neonatal unit using echocardiography before transport to the catheterisation laboratory and to delay the procedure if the duct does not show a degree of constriction. It is imperative to have intravenous prostaglandin and Ibuprofen (cyclo-oxygenase inhibitor) available in the catheterisation laboratory. If ductal diameter is large as a result of prostaglandin therapy it may be of benefit to administer a prostaglandin inhibitor (ibuprofen 5 - 10mg/kg intravenously) in theatre and then to continue with stent placement once constriction occurs. We prefer to ensure good guide wire position before administering a prostaglandin inhibitor as a protective measure. Also, all equipment should be ready in case immediate intervention is required.

Retrograde femoral arterial access is most commonly used but carotid and axillary routes have been described. The latter requires cut down by a vascular surgeon. Depending on the underlying pathology, antegrade stenting through a stenotic pulmonary valve may occasionally be possible. Smaller sheath sizes are preferred to avoid vascular complications and we prefer starting with a short 4

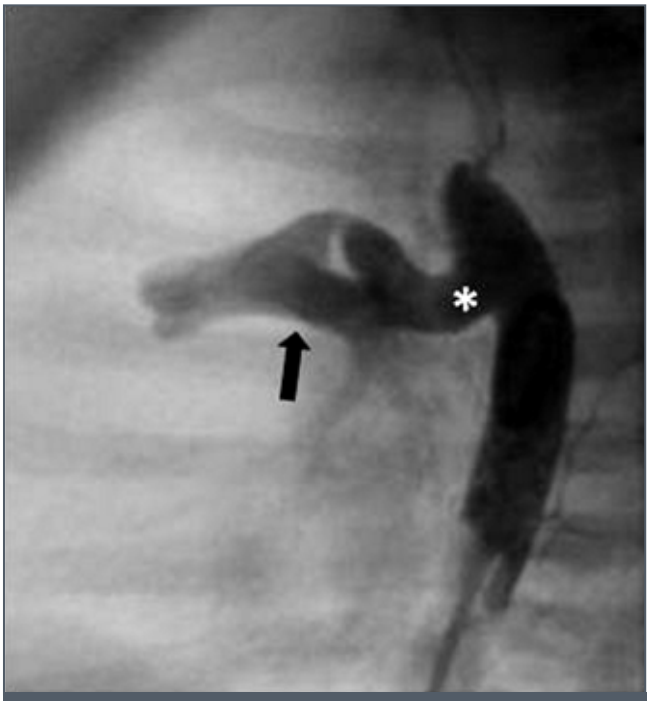

**FIGURE 1: PDA pre stent implantation**
The asterisk indicates a PDA considered for stent placement. This ductus demonstrates mild convolution and is fairly straight with a good anchoring point for a stent at the stenotic pulmonary aspect. Arrow shows origin of the left pulmonary artery.

French (F) sheath. Care should be taken in low birth weight infants, as femoral vessel injury is an ever-present reality. Patients are heparinised (50 - 100U/kg ivi) and routine prophylactic antibiotics are given according to local protocols.

Meticulous investigation to delineate ductal anatomy is essential and initial angiography is usually performed in the antero-posterior and lateral positions. Right anterior oblique projections with some caudal angulation may be of benefit if uncertainty exists regarding underlying PDA morphology and/or branch pulmonary artery anatomy. Some experimentation is typically required to find the best angulation to view the anatomy. The following should be clearly demonstrated: origin from the aortic arch, diameter at pulmonary artery (most often the narrowest), ampulla diameter and ductal length (Figure 1). Ductal length can be misleading due to the fact that ducts are often convoluted or angled and thus difficult to measure accurately. Therefore, it is recommended to measure the length of the PDA only after it has been crossed and with the guide wire in position; this tends to straighten the ductus and allows an improved estimation of ductal length.

Various catheters may be utilised for angiography and stent. Routine angiography is usually performed with a pigtail catheter followed by selective and detailed angiography. We prefer to do angiograms in close approximation to the ductal origin and use an array of catheters for example: right Judkins, Cobra, Multipurpose (Cordis, Roden, Netherlands). In the majority of cases, the configuration of a right coronary artery catheter should enable one to cross the duct safely, but sometimes a cut-off pigtail may be useful to cross the PDA. In difficult cases a coaxial system may be extremely helpful.[16] In our experience, the ductal tissue in some of these PDAs may be quite sensitive and prone to spasm. We therefore routinely use a microcatheter with a very soft guide wire e.g. Progreat™ (Terumo, Somerset, NJ, US) to cross the duct. Once the duct has been crossed, the microcatheter is positioned as distally as possible in one of the pulmonary artery branches. This allows one to safely and easily exchange the soft guide wire with a stiffer 0.014" wire. Care should be taken to obtain stable guide wire position since this will allow one the best opportunity for successful stent placement. In our practice the most common coronary guide wires (0.014") used includes the Galeo (Biotronik, Berlin, Germany) and the ChoICETMPT (Boston Scientific, Miami, USA) which lend various degrees of support depending on required wire stiffness. As a general rule - the more complex and difficult to cross, the stiffer the guide wire that should be used. It is also helpful to have an extendable guide wire available since some microcatheters are quite long and standard length guide wires may thus be too short to enable removal of the microcatheter without losing guide wire position.

Standard bare metal coronary stents commonly available in adult interventional catheterisation laboratories are used e.g. Omega™, (Boston Scientific, Natick, MA, US) or Racer® (Medtronic, Minneapolis, MN, US) (Figure 2). As it happens, one often has to use whatever is available, but stents with the lowest profile are preferred. Open cell designs may be advantageous in a convoluted duct. Drug-eluting stents should be avoided and are not approved for use in children. It should be pointed out that this is an off-label indication for a coronary stent. It is of the utmost importance to stent the entire length of the duct as any unstented segment will soon become constricted and may be extremely difficult to recannulate (Figure 3). Stent foreshortening may be variable and should be taken into account when deciding on the length of stent. Manufacturers supply a chart indicating expected final stent length at different diameters. We usually select a stent 1 - 2mm longer than the ductus after taking these facts into account.

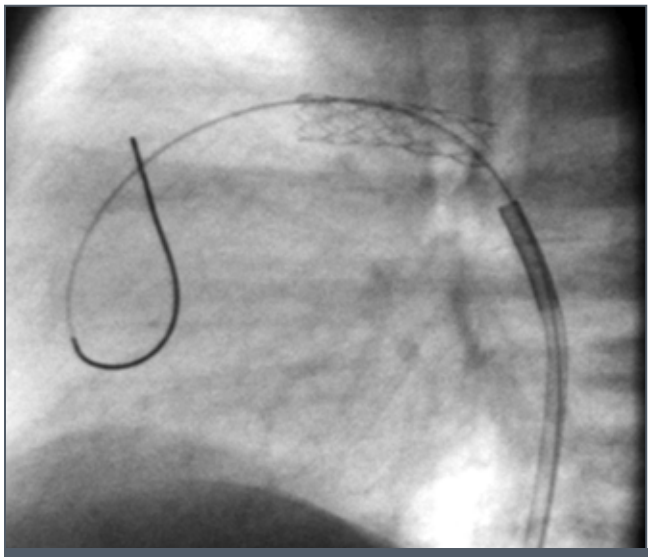

**FIGURE 2: Stented PDA**
Successful stent placement in arterial duct. Note good guide wire position. Stent was delivered by means of 5F Vistabritetip® catheter (for more details see text).

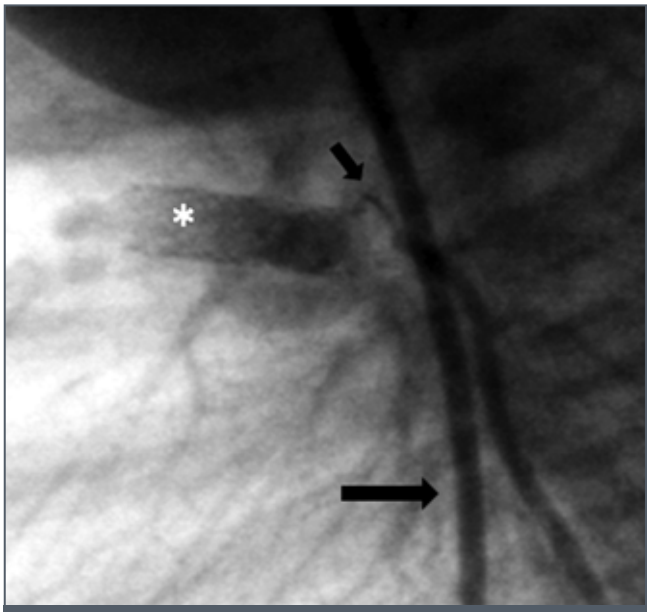

**FIGURE 3: Result of an incomplete ductal stent placement**
The short arrow points towards a stenotic ductal segment resulting from incomplete ductal covering becoming apparent 7 days after initial stent placement. Note the acute angle and extreme stenosis of the remaining ductal tissue at the aortic origin of the PDA. This was eventually crossed using a cut-off pigtail catheter and a co-axial system. Longer arrow demonstrates a contrast filled nasogastric tube used as a marker for stent delivery. Asterisk shows patent original stent in situ.

Some stent protrusion into the aorta and pulmonary artery (1 - 2mm) is acceptable. We keep to the stent sizes as recommended by Alwi[3] : 3.5 mm diameter in those patients weighing <3kg, 4mm in those weighing 3 - 5kg, and 4.5mm stents in those patients weighing 5kg and above.

If patients are ventilated, they should be extubated as early as possible. Heparin infusion is continued at a dose of 25U/kg/hr for 24 - 48 hours. Aspirin is simultaneously initiated at 2 - 3mg/kg/day and patients are discharged on this dose.

## GENERAL COMMENTS

As we gained experience with the technique, we now deliver stents bare without using a guiding catheter/long sheath especially in smaller infants. Control angiography can be performed through the side port of the 4F sheath with a saline chaser. However, in more difficult cases or in a situation where sharp angles need to be traversed, a Vistabritetip® (Cordis, Florida, US) catheter is used to deliver the stent – this lends additional support whilst simultaneously allowing control angiography. Filling a nasogastric tube with a small volume of diluted contrast agent may serve as a good marker (especially aortic origin of the PDA) to facilitate stent placement.

In our catheterisation laboratory, we avoid stenting tortuous and vertical ducts. If ductal spasm occurs, we immediately start with a continuous infusion of intravenous prostaglandin. If the PDA was crossed with a guide wire, it is imperative to leave it in position as it tends to "splint" the duct open and also allows one to do emergency stenting if required.

Although rare, acute stent thrombosis may occur. In order to avoid it, one should aim to limit the time spent by the guide wire across the ductus to less than 10 - 15 minutes. Should thrombosis occur, it is imperative to maintain guide wire position and a local infusion of streptokinase or alteplase may be considered. In cases of overshunting, due to a large internal diameter of a stented ductus, medical treatment with diuretics is preferred. Alternatively, the inner diameter of the stent may be decreased by means of placing an additional stent or stents, or a covered stent inside the original stent. Additional technical details can be found in the bibliography.[3,7,8]

## LIMITATIONS OF PDA STENTING

The most frequently reported limitations include technical problems related to patient size (e.g. prematurity) and duct morphology. Numerous variations of PDA anatomy have been described and may affect the success of stent delivery. Lesions with a higher success rate include pulmonary atresia with ventricular septal defect (VSD) and tricuspid atresia as these are associated with a simpler duct anatomy. Pulmonary atresia with intact ventricular septum is often associated with long, tortuous ducts with multiple areas of stenoses.[4] Therefore, complicated duct anatomy is a contraindication to stent placement.[11] Branch pulmonary artery stenosis is aggravated by PDA stenting and this should therefore also be avoided.[3] Other reported peri-procedural complications include acute stent thrombosis (2 - 3%), pre-stent ductal spasm (<1%), stent dislodgement and migration, vessel or chamber perforation and neointimal proliferation of which the overall incidence is low.[3,8,11,12,14] Long term complications resemble those of surgical shunts and consist of progressive stent stenosis, pulmonary overflow with pulmonary hypertension and branch pulmonary artery distortion.[3]

## ADVANTAGES OF PDA STENTING COMPARED TO SURGERY

A major benefit of PDA stenting is a reduced waiting period before intervention; this may be especially helpful in centres with crowded surgical lists. This also avoids the side-effects of continuous prostaglandin infusion. Recovery time post-procedure is rapid and hospital stay is short. It is a minimally invasive procedure with a low risk profile and can be performed on relatively small and premature newborns that are often critically ill.

## CONCLUSION

Early reparative surgery should be considered the treatment of choice for the majority of cyanotic cardiac conditions. In cases where this is not possible, the modified Blalock Taussig shunt should be considered as the gold standard of treatment and all other therapies should be measured against it.

Stenting of the arterial duct offers an alternative to surgical systemic to pulmonary artery shunts. Current literature provides evidence that ductal stenting is feasible, safe and effective. Results are encouraging and the technique is now well established.

The procedure should, however, be carried out by skilled operators in a unit accustomed to dealing with children. It should be emphasised that the whole length of the duct should be covered by the stent.

PDA stenting is a viable option in selected cases. In developing countries this interventional catheter procedure may assist to reduce the load on overburdened surgical lists.

**Conflict of interest: none declared.**

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