



## Original Article

# Stenting of patent ductus arteriosus in low birth weight newborns less than 2 kg- procedural safety, feasibility and results in a retrospective study

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## ABSTRACT

**Objective:** Retrospective analysis of the feasibility, safety and results of patent ductus arteriosus (PDA) stenting in low birth weight babies weighing < 2 kg. Background: Stenting of patent ductus arteriosus is a well known palliative technique for several years as an alternative to shunt surgery in babies weighing > 2.5–3 kg. Ductal stenting in babies weighing less than 2 kg is not done routinely all around the world due to limited experience and concerns regarding its feasibility and safety in such small subset.

**Methods:** Records of patients who underwent PDA stenting at our institution from June 2014 to December 2016 were reviewed. In this period, we attempted to do PDA stenting using femoral artery approach in babies weighing < 2 kg. Echocardiography and colour Doppler were used for patient selection and assessment of procedural outcome.

**Results:** PDA stenting using femoral artery approach was successful in all 5 patients weighing < 2 kg. In this group, patient age ranged from 2 days to 16 days and weighed 1.8 kg to 1.97 kg. All patients had good post-procedure outcome. One patient had stent malposition from aortic end towards main pulmonary artery which was managed by an additional stent.

**Conclusion:** PDA stenting is feasible and safe with good end results in carefully selected low birth weight babies weighing < 2 kg.

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## 1. Introduction

The trend towards definitive surgery within first year of life in patients with duct dependent pulmonary or systemic circulation is increasing, especially in developed countries. Surgical creation of an aortopulmonary shunt in these patients is still being used as a palliative procedure, especially in smaller babies with unfavorable pulmonary artery anatomy. However, shunt-related complications such as shunt occlusion, shunt stenosis, distortion of the pulmonary arteries, pulmonary hypertension and differential growth of the right and left pulmonary arteries, as well as surgical adhesions, increase the complexity and risks of the final definitive surgery.<sup>1–5</sup> In low birth weight babies, especially less than 2 kg, complications such as morbidity and mortality increases in cardiac surgery.<sup>6</sup> Due to increased risk of complications in surgery, we decided to electively perform patent ductus arteriosus (PDA) stenting in this subset of patients.

## 2. Methods

### 2.1. Study design

The records of all patients who underwent transcatheter PDA stenting between June 2014 and June 2016 at our institution were reviewed. Low birth weight babies <2kg were focus of this study.

### 2.2. Patient selection

All patients with duct-dependent pulmonary circulation in whom PDA stenting was planned underwent detailed echocardiographic evaluation with special focus on ductal anatomy and branch pulmonary arteries. This was performed using broadband 8 MHz and 12 MHz frequency transducers (ie 33, Philips). The ductal anatomy was defined in parasternal short axis, suprasternal short axis and suprasternal long axis views. Careful two dimensional and Doppler imaging of the branch pulmonary arteries was also performed to define confluence, size or any stenosed segment. All 5 patients in our study had tricuspid atresia and normal origin of duct, so femoral artery route was preferred.

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### 2.3. Procedure

After obtaining detailed written informed consent from the parents, patients were taken to cardiac catheterization lab. All cases were done under general anesthesia and endotracheal intubation with surgical back up. Catheterization lab was pre warmed up to 25°C and pre warmed saline was used.

PGE1 infusion was used to keep the duct open. PGE1 was stopped at the beginning of the procedure. An arterial line and a central venous line were secured in all patients for monitoring and administration of drugs during and after the procedure.

### 2.4. Vascular access

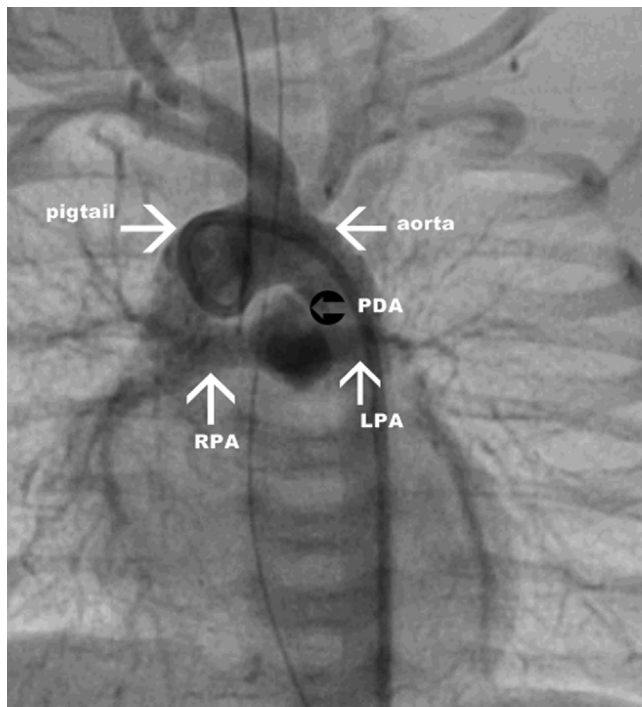
Right femoral arterial/left femoral arterial access was taken with 22 gauge cannula under fluoroscopy/ultrasound guidance and secured with 4 French (4F) short sheath (Cordis corporation, 14201 NW 60th Ave. Miami lakes, FL 33014, USA). 100 units/kg unfractionated intravenous heparin and prophylactic antibiotic was given to every patient.

### 2.5. Angiographic definition

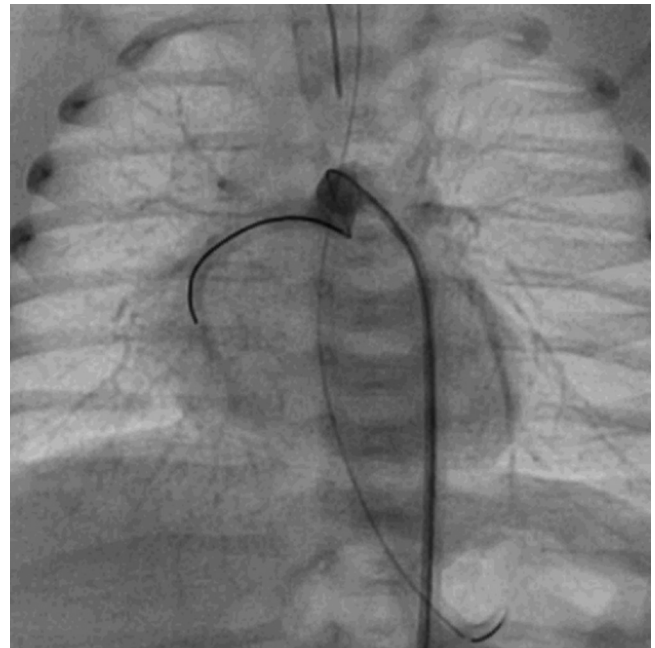
4F right coronary artery (4F RCA)/pigtail catheter was tracked inside 4F short sheath along with 0.035 inch J tip terumo wire. Angiographic study was done through the catheter to delineate the origin of the duct from the aorta, its shape, size, course and the site of constriction (Fig. 1). Branch pulmonary artery anatomy was also delineated. Hand angiograms were done in antero-posterior, lateral and left anterior oblique (LAO) cranial views to delineate the anatomy.

### 2.6. Stent selection

We chose bare metal, non-drug eluting, pre-mounted coronary stents in all the cases. The diameter was chosen with respect to the



**Fig. 1.** Aortogram done through 4F pigtail catheter showing patent ductus arteriosus with normal origin, confluent branch pulmonary arteries with good arborisation and no antegrade flow. PDA – patent ductus arteriosus, RPA–right pulmonary artery, LPA left pulmonary artery.



**Fig. 2.** Patent ductus arteriosus is crossed with wire and wire is placed in right pulmonary artery.

weight of the patient, size of the PDA, its constricted segment and branch pulmonary arteries. Length of stent was chosen to cover the entire length of the duct with proximal end into aorta and distal end into branch PA.

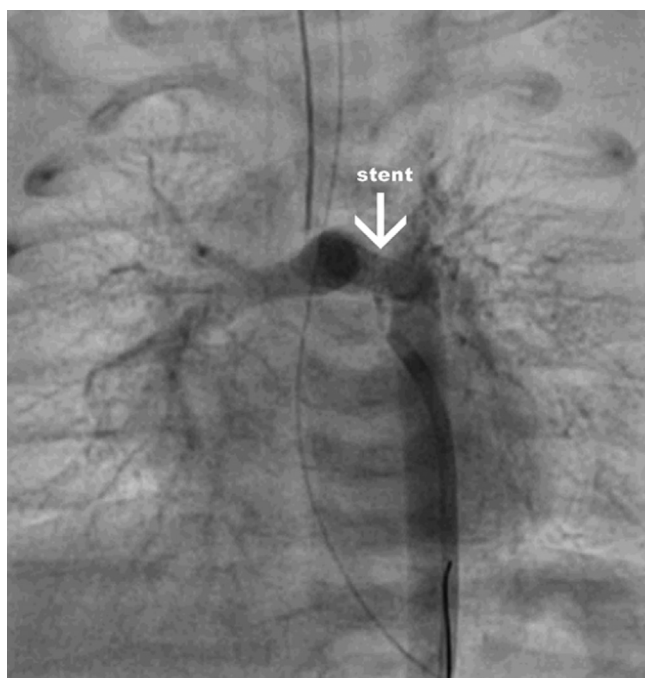
### 2.7. Stent deployment technique

After angiography with 4F right coronary artery (RCA) catheter, PDA was crossed with 0.014 inch percutaneous transluminal coronary angioplasty (PTCA) wire (Balance Middle Weight guide wire, Abott Vascular international BVBA 1831, Diegem, Belgium) and it was parked in either of the branch pulmonary arteries (Fig. 2). RCA catheter was exchanged with 4F long sheath. Pre selected coronary stent was tracked over PTCA wire through the guide and placed across the PDA with its proximal end in the aorta and distal end in branch pulmonary artery. Hand injections were done in guiding catheter to ascertain the position of stent across the ductus. After confirming the position of the stent, it was deployed with initial nominal pressure of 8 atm, then redilated to 12 and 14 atm pressure for better apposition. Balloon was removed after deployment keeping the wire in situ. Hand injection was done again to check the position of the stent, flow across the stent and branch pulmonary arteries (Fig. 3). After achieving satisfactory results, wire was removed. In cases of branch pulmonary artery origin stenosis, we aimed to deploy the stent distal to the stenosed segment.

All the patients were shifted to NICU and extubated on same day. Heparin infusion was given to all patient for 24 h (aPTT was maintained 2–3 times of normal). All the patients were given dual antiplatelets in form of aspirin and clopidogrel immediately after the procedure.

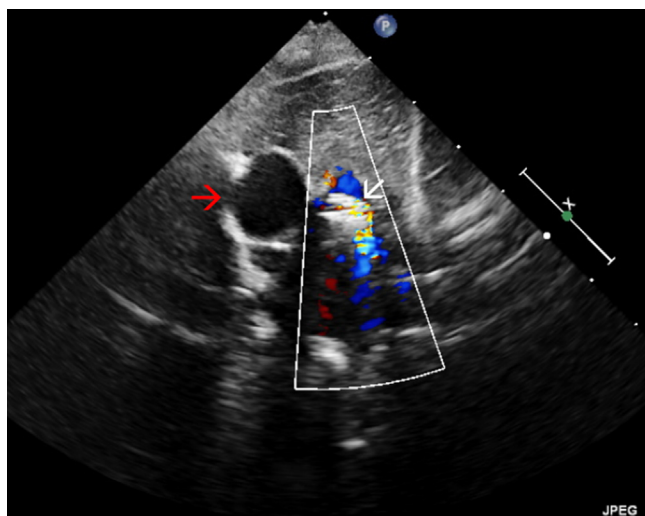
### 2.8. Discharge and follow-up

Patients were discharged on antiplatelets and diuretics. Time interval between shifting of patients from ICU to either primary nursery or step down ICU was recorded. They were followed up



**Fig. 3.** Angiogram done after placement of stent showing good stent position and good flow across both branch pulmonary arteries.

initially after a week and then on monthly basis. During the follow up, patients were monitored clinically for symptoms, weight gain and saturation. 2 D Echocardiography was done during each visit to check for flow across the stent and pulmonary artery, presence of any stenosis in the stent and detailed pulmonary artery anatomy (Fig. 4). Femoral artery Doppler was also done in the first visit to reconfirm the blood flow, presence of any thrombosis or stenosis of the artery. Chest X-ray was done in alternate visit to check for any pleural effusion, size of the heart, pulmonary artery size and pulmonary vascularity in both the lung fields. Patients were subjected to further surgical correction within 6 to 12 months of the procedure depending upon the anatomy of heart defect, growth of the patient and pulmonary artery anatomy (Fig. 5).



**Fig. 4.** 2D Echocardiography in follow up in parasternal short axis view showing stent in situ with flow across the stent (white arrow). Short axis of aorta can be seen (red arrow). (For interpretation of the references to colour in this figure legend, the reader is referred to the web version of this article.)

### 3. Results

From June 2014 to June 2016, we attempted PDA stenting in less than 2 kg weight in 5 patients. All the procedures were performed by femoral artery route. Eight patients who were >2 kg were excluded from study.

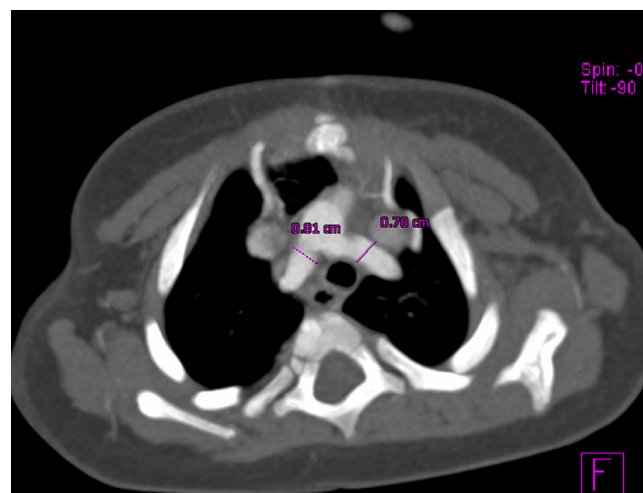
In this group, patient age ranged from 2 days to 16 days and weighed 1.8 kg to 1.97 kg. We chose bare metal, non-drug eluting, pre-mounted coronary stents of different lengths and diameters (Table 1). All the patients had single ventricle physiology, tricuspid atresia, pulmonary stenosis/pulmonary atresia with PDA dependent pulmonary circulation and confluent branch pulmonary arteries without any origin stenosis.

All patients had good post-procedure outcome. One patient had stent malposition from aortic end towards main pulmonary artery which was managed by putting another stent. Single blood transfusion was needed in 2 out of five patients. In 3 patients, no blood transfusion was required. No patient had femoral artery related complications. Total procedure time ranged from 25 to 45 min and fluoroscopy time ranged from 10 to 18 min.

All the patients were discharged within 48–72 h of the procedure either to primary nursery from which they were referred to us or to step down ICU for few days before they were sent home. On follow-up, all the patients maintained saturation above 80% and weight gain was also adequate. There was good flow in stent and good sized branch pulmonary arteries with good flow in 2D echocardiography. One patient was lost to follow-up after 6 months. Last patient is now 5 months old, doing well and waiting for Glenn surgery in another 1–2 months. Rest of the patients have undergone bidirectional Glenn surgery and are doing well.

### 4. Discussion

Palliative procedures, like Blalock Taussig (BT) shunt are being done routinely in neonates and infants prior to definitive repair especially in developing countries. Potential shunt related complications have been reported in as high as 6%–36% of neonates and small children.<sup>1</sup> Pleural effusion, diaphragmatic paralysis, cardiac failure due to excessive pulmonary blood flow, distortion of branch pulmonary arteries, unequal development of branch pulmonary arteries either ipsilateral or contralateral are known complications of shunt surgery.<sup>2–5</sup> PDA stenting is now evolving as a reasonable alternative to surgical shunt<sup>7–10</sup> although performance of PDA stenting is also associated with complications



**Fig. 5.** CT angiogram done after bidirectional Glenn operation showing good sized confluent branch pulmonary arteries. RPA – right pulmonary artery, LPA– left pulmonary artery.

**Table 1**

Details of all the patients including complication and follow-up.

S. NO	Age/ gestational age/ sex	Weight (gram)	Stent size	Procedure time/ fluoroscopy time	Complication	Death before discharge	Early reintervention	Follow-up
1	5 days/ 35+ 5 weeks/M	1850	3.5 × 15	44 min 12 s/ 15 min 25 s	NO	NO	NO	Underwent Glenn surgery at 8 months of age, now 2 years doing well
2	10 days/ 36+2 weeks/ F	1935	3.5 × 15	42 min 30 s/ 16 min 15 s	NO	NO	NO	Lost to follow up after 6 months
3	2 days/ 36 weeks/F	1970	3.5 × 10	34 min 23 s/ 14 min 40 s	NO	NO	NO	Underwent Glenn at 6 months, now 18 months, doing well
4	5 days/ 36+ 1 weeks/F	1890	3.5 × 15, 4 × 15	44 min 35 s/ 17 min 6 s	Stent displaced from aortic end in PDA, another stent was placed	NO	NO	Underwent Glenn at 6 months, now 11 months, doing well
5	3 days/ 35+6 weeks/M	1800	3.5 × 10	25 min 45 s/ 10 min 10 s	NO	NO	NO	5 months old, doing well

like stent embolization, stent thrombosis, re-stenosis, heart failure, pulmonary artery stenosis.<sup>11–14</sup>

In low birth weight babies especially less than 2 kg, complications such as morbidity and mortality increases in cardiac surgery.<sup>6</sup> In 2008, Curzon et al published an important report of the Society of Thoracic Surgeons Congenital Heart Surgery Database where they analyzed outcomes of cardiac surgery in infants with LBW (< 2.5 kg) as compared to normal weight infants (2.5–4 kg).<sup>15</sup> They reviewed over 3000 patients weighing 1 kg to 4 kg from 32 centres around the world. Over 500 infants had low body weight while the rest had normal body weight. Mortality was three times higher in low body weight infants as compared to normal body weight infants in specific operations such as correction of total anomalous pulmonary venous connection (29.2% vs 9.9%), coarctation of the aorta repair (7.1% vs 2.7%), arterial switch procedure (11.8% vs 2.6%), and systemic to pulmonary artery shunt (24.4% vs 6.2%).

Due to high surgical mortality and morbidity in babies less than 2 kg, we decided to electively perform PDA stenting in this high risk group. We selected all the cases with normal ductal anatomy in which stenting could be performed through femoral route.

We could perform all our cases very well with 100% results. There were no major complications and no future re-intervention before definitive surgical correction.

Key steps according to us in performing this procedure in such a high risk group are:

1. Proper patient selection and knowledge of proper anatomy of lesion.
2. Procedure time should be as short as possible including quick arterial access.
3. Proper selection of hardware.
4. Warm catheterization lab, warm saline and maintaining adequate temperature of baby.
5. Careful and smooth movements of hands during performing the procedure.
6. Surgical back-up
7. To apply plan B (surgical intervention) quickly if current plan of management is not working.

## 5. Conclusion

This is a case series of PDA stenting in less than 2 kg babies. Although, the number of patients in our series is only 5, if this procedure is performed very carefully and quickly in such a high risk group, good results can be achieved. We fully believe that more such case series are needed from different centers around the world before reaching to a particular conclusion.

## Financial support and conflicts of interests

None.

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