# TECHNICAL CONSIDERATIONS AND CHALLENGES ENCOUNTERED DURING TRANSCATHETER OCCLUSION OF DUCTUS IN INFANTS

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### ABSTRACT

*Objective:* To focus on the results and the difficulties confronted by the interventionist during therapeutic occlusion of ducts in very small babies and share the experience by using specific devices of specific brands.

Study Design: Retrospective analytical study

*Place and Duration of Study:* The study was carried out at Army Cardiac Center Lahore from May 2014 to May 2015.

*Material and Methods:* A total of 9 infants with patent ductus arteriosus (PDA) with variable sizes and shapes were included in this study. All the patients were selected in outpatient department and the diagnosis was confirmed by transthoracic echocardiography

*Results:* All patients (n=9) had successful closure and included 3 females and 6 males. The weight of the babies ranged from 4-9 kg with a mean of 6.31kg. The minimum angiographic diameter of the PDAs occluded was 1 mm and the maximum was 7 mm with a mean of 3mm. Smallest PDA device occluder used was Occlutech 5-3.5 and the largest size was an ADO1 10-8. We were able to achieve 100% ductal occlusion confirmed on discharge echo color flow Doppler performed 24 hours later. There was no major complication like device embolization, limb ischemia, hemolysis and left pulmonary artery stenosis.

*Conclusion:* Percutaneous device closure of PDA in infants can be accomplished with minimal complications provided the experience gained in deployment, the basic acquaintance on the pros and cons of the various devices and the odds of ending up with likely complications is familiar to the primary operator.

Keywords: Percutaneous, PDA device closure, Infancy.

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# INTRODUCTION

Device occlusion ductus of patent well-recognized arteriosus (PDA) is а therapeutic option thanks to the pioneering Rashkind efforts by Porstmann, and colleagues<sup>1</sup>. Surgical closure of PDA is still an option today but is being offered under special circumstances. Consequent to this disposition, a large number of patients with PDAs of all sizes and morphology including very small babies is likely to be visited by congenital cardiologists<sup>2</sup>. It has thus become centre for the interventionist to achieve mastery over device closure of challenging **PDAs** with unconventional shapes and extreme sizes and in very small patients. Since the alternate but rather more invasive surgical closure of PDA is a simpler technique, and provides permanent solution to the problem<sup>3,4</sup>. The transcatheter occlusion of ducts has to be done just as correctly, aiming for complete occlusion rate without adding any risk, complication or squeal to the patient<sup>5</sup>. Though a wide range of options and apparatus to occlude the PDA is available to the operator in the western world, we in Pakistan are still fraught with limited standard options to occlude the PDA. The purpose of this study is therefore to share experience in occlusion of such ducts, with only standard apparatus available, in infants with weight under 10 kg.

# MATERIAL AND METHODS

All patients following history and physical examination underwent a detailed evaluation by 2D echocardiography using 5MHz probe on Toshiba Nemio echocardiography machine in outpatient department.

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Inclusion criteria: Patients with isolated PDA weighing less than 10Kg: Age Less Than 1 year

Exclusion criteria: Patients more than 1 year age

Patients with PDA with coarctation of aorta or other complex lesion; Patients weighing more than 10 Kg.

The subsequent to a decision to occlude the PDA, written informed consent for percutaneous device closure was taken from all parents. A complete blood picture, chest X-ray and pre-anesthetic evaluation were carried out one day prior to the procedure. All the procedures were carried out under general anaesthesia. The percutaneous arterial and venous access was achieved using a size 22/24

multipurpose or 5F Judkins right were manipulated from the right heart into the pulmonary artery, through the ductus and into the descending aorta. We used 6F to & 7F Mullen sheaths to slide over the exchange length Terumo wire.

Device size selection was 1-2 mm larger than the narrowest angiographic size of the PDA. However other considerations like the shape of the duct, length of the duct, the size of the ampullary space available, the size of the space expected to be taken by the retention skirt at the aortic end and the presence or absence of pulmonary hypertension were also considered. Following device deployment, a check angiogram in true lateral and RAO 30 was

Age (M)	Gender	Weight (Kg)	Morphology	PDA Size (mm)	Brand	Device	Mullen sheath
11	Female	5.5	А	4.5	SHSMA (ADOI)	8/6 mm	7 F
12	Female	6	A2	5	SHSMA (MVSD)	5 MVSD	7 F
12	Female	7	A3	1.5-2	Occlutech	8/6	7 F
6	Male	9	A3	1	Occlutech	6/4	6 F
7	Female	4	A1	1	Occlutech	5-3.5	6F
12	Male	8	D	3.5-4	Occlutech	8/6	7F
11	Male	7	A1	6-7	Occlutech	10/8	7 F
9	Male	6	A1	1-1.5	Occlutech	5-3	6 F
12	Female	5	Е	Е	SHSMA (MVSD)	8 MVSD	7F

Table-1: Summary of results- Trans-catheter device occlusion of PDA in Infants.

G cannula followed by a systemic bolus injection of Heparin 50 IU/kg. Radial sheaths size 5F were used in all patients and aortogram was carried out using 5F pigtail catheter in true lateral 90 degrees and right anterior oblique (RAO) 30 degrees to access the size and morphology of the duct using 1-2ml/kg of contrast at 400 to 600 PSI. The ductus and related measurements were taken using the software of the cath-lab angiographic machine. In some very small babies less than 6 kg, 5 F Judkins Right was used to appreciate the size and morphology of the duct using mildly diluted hand pushed contrast just a 1-2 mm below the ampulla of the duct. Mostly 5F retaken immediately and 5 minutes post deployment. Once satisfied with the location of the device, and with no arch narrowing and with no left pulmonary artery stenosis, the device was finally released from the delivery cable by counterclockwise rotation.

The arterial and venous sheaths were removed on completion of the procedure. A saline flush in the femoral artery followed by a gentle pressure above the points of entry into the groin following removal of arterial sheaths was maintained till such time the bleeding had stopped. The patients were then shifted to the post catheter ward for 24 hrs for observations. The patients were sent home the next day after repeating their echocardiographic evaluation.

# RESULTS

A total of 9 cases with 100% success rate including 3 females and 6 males during the study period. The age varied from 6 months to 12 months and the weight of the babies ranged from as low as 4kg to a maximum of 9 kg with a mean of 6.31kg. The minimum diameter of the PDAs occluded is 1 mm and the maximum was

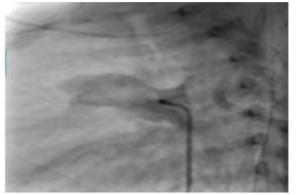


Figure-1: Showing judkins right heart catheter with hand.

7 mm with a mean of 3mm. Smallest PDA device occluder used was Occlutech 5-3.5 and the largest size was an ADO1 10-8. There was no case of left pulmonary artery stenosis. There was no case of device embolization, hemolysis or limb ischemia. All Patients were followed up after 02 weeks, 1 month and at 1 year.

# DISCUSSION

The device closure of PDA has gradually evolved ever since its first trans-catheter closure by Porstmann and colleagues in 1967<sup>1</sup>. Cardiologists have been attempting to develop less invasive transcatheter practice to occlude the PDA of all shapes and sizes<sup>6-9</sup>. Research effort to create a device with material quality that has memory (Nitinol TM wire mesh, 0.007) and which is able to achieve almost complete deployment following with occlusion adaptability and versatility so that it could be used in a wide range of ductal sizes and morphology and in very small patients, has resulted in device deployments in patients with weights of less than 4 Kg and with minimal complications<sup>10-13</sup>. However large ducts in infants with less the 8 Kg weight can still be challenging to occlude due to relative mismatch between the introducers, sheaths and occluders to the small anatomic dimensions available<sup>14,15</sup>. We believe that the first prick in these grossly underweight and "failure to thrive" patients is very important as any swelling in the inguinal area as a result of clumsy technique leads to annoyance and prolongs the procedure time needlessly. For a successful "first prick" arterial or venous access in these small sized patients,



Figure-2: Catheter shaft in the duct to unfold it and helps in size estimation by comparison method.

we preferred vessel entry with 22G/24 G cannulas with a "pubic bone hit technique". Radial sheaths size 5F were used in all patients, however we recommend usage of even smaller sized and shorter sheaths where available in babies less than 5 kg

Aortograms were performed using either 5F pigtail catheters or a hand injected 5F Judkins Right heart catheter. Notice the use of right heart catheter in our cases. This had the advantage of injecting very small amount of contrast at a specific site in the descending aorta in these petite patients and achieving a very similar crisp picture delineating the size and morphology of the duct. Still yet in some cases (type D and type E)<sup>16</sup> a pigtail catheter was passed from the venous side across the ductus and an aortogram was performed in the descending aorta for a clearer unfolded duct Fig-2. A catheter shaft in the duct also allows for accurate size estimation by comparison method when such is in doubt.

We used 6F & 7F Mullen sheaths to slide over the exchange length Terumo TM wire. Generally it is wise to use a sheath one size higher than the manufacturer recommendation. In one case we encountered difficulty in sliding a 7F Mullen sheath across the ductus. The reason could be a very small baby with a very acute bend at the PDA -MPA narrowed junction and thus making the crossing over difficult. We had the option of changing the wire with a recommended Amplatzer ΤM super-stiff exchange length wire and using a smaller sized Mullen sheath or by establishing a venoarterial railroad with taught ends. However we could slide the 7F Mullen sheath across the acute bend by securing the later.

Cooks detachable coils and ADO II occluders were not available to us. Basing our decision on the morphology, size and the space available in the aortic arch, we used ADO I, VSD muscular and Occlutech PDA occluders in

problems with the use of this occluder. The tubular portion tapers or narrows towards the pulmonary end of the device, which encourages the extrusion of the device towards the aorta after its release. Since it has no retention skirt or ring towards the pulmonary end of the device, the initial fixation becomes risky. This configuration in conjunction with increased pressure on the pulmonary end of the ductus, (before the ductus had time to grow into the walls of the ductus), could allow the device to jump back into the aorta upon release as there is nothing at the pulmonary end of the device to keep it in place. This together with limited space in the aortic arch, discouraged us for using it as a first choice in our selection of patients. The Occlutech PDA occluder on the other hand is a softer low profile device with flat aortic retention skirt and thus with a lower chance of obstruction at the aortic end. This



Figure-3: Showing judkins right heart catheter with hand.

our series of patients. Device size selection was 1-2 mm larger than the narrowest angiographic size of the PDA. However other considerations like the shape of the duct, length of the duct, the size of the ampullary space available, the size of the space expected to be taken by the retention skirt at the aortic end were also considered. A device size too small could embolize and a device size to large could lead to a coarctation of the aorta or cause left pulmonary artery stenosis. Device type selection was also based on the presence or absence of high pulmonary artery pressures. We preferred Occlutech PDA occluders in our series of patients to the regular ADOI PDA occluders. Though the ADO I occluder is specially designed for trans-catheter closure of PDA, there are several potential

device has a larger sized pulmonary end compared to the regular ADO I device and so lessening the chances of tipping back into the aorta following release. But there are some inherent problems with this device too. It is a very fragile device and the manufacturer's supplied Cook's teflon loader sleeve is soft and kink-able. This arrangement makes the pushing of the loader sleeve into the supplied Cook's Mullen Sheath back bleed valve oftentimes difficult or clumsy. While pushing the device in the Mullen's delivery sheath care was taken not to rotate the delivery cable in either direction or thus preventing either the premature release or over tightening of the device leading to failure to unscrew the device when so desired. We used two muscular VSD devices in two patients

who had large tubular ducts with high pulmonary artery pressures. Since ADO I with an absent retention skirt and a tapering tubular central body at the pulmonary end could have the possibility of device embolization into the aorta, and ADO II occluders not at our disposal, we selected VSD muscular occluders for our patients. We could achieve 100% occlusion on discharge ECHO performed 24 hrs later.

Retrospective analysis of our data for ducts in a tubular format type E unveiled that squeezing the ADO I device within the duct in such a way that the body along with the aortic retention disc opens within the lumen of the tubular duct rather than providing anchorage by abutting against the ampulla or the aortic wall has not proved to be a sensible option. Since we had two device embolizations into the left pulmonary artery in patients we had attempted in the past, we did not venture to do same in these babies where the such morphology was encountered.

### **CONCLUSION**

Percutaneous device occlusion of PDAs in infants with weights as low as 4 Kg can be performed satisfactorily. However PDA device closure in these very small patients does require a proficiency that exceeds the learning curve acquired as when performing the same procedure on much larger patients

# **CONFLICT OF INTEREST**

This study has no conflict of interest to declare by any author.

### **AUTHORS CONTRIBUTION**

Khurram Akhtar, Nadeem Sadiq, Hajira Akbar and Amjad mehmood, data Analysis, design and interpretition.

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