INTRODUCTION

Patent ductus arteriosus (PDA) is a common congenital heart defect which causes left ventricular volume over load by causing left to right shunt at arterial level. In general, every isolated PDA needs closure beyond 3 months of age except for silent ducts, Eisenmenger ducts and ducts in premature infants. Percutaneously closure of PDA with device is an established modality of treatment worldwide and is regarded as a safe and effective,1-3 even in young infants.4-10 Important determinants of choice of the duct occluder includes age and weight of the patient, size and morphology of the duct and the experience of center and operators. As per traditional approach, the PDA device closure is considered in infants with age beyond 6 months and weight of more than 6 kgs, though successful duct closures in patients weighing less than 6 kgs is also being reported.7,8 Moderate to large PDA poses maximum problems of cardiac failure, increase work of breathing and failing to thrive during infancy. Moreover, device closure in infancy poses special problems pertaining to smaller size of the patients, small aortic ampulla, risks of left pulmonary artery (LPA) stenosis and coarctation of aorta and local access site arterial complications5 as well as technical difficulties in small size children.11

If PDA is directly responsible for congestive cardiac failure, failing to thrive, recurrent chest infections with evidence of left heart volume over load on echocardiography, duct closure is indicated as soon as possible.6 Although, safety and efficacy of PDA device closure in small infants is reported in recent international literature,4,7,9-14 mostly in small series, but such work is not being reported from Pakistan. This study was conducted with specific aim of analyzing the results and complications associated with PDA device closure in infancy in our population.

METHODOLOGY

This quasi-experimental study was prospectively conducted at the Department of Paediatric Cardiology, Armed Forces Institute of Cardiology/National Institute of Heart Diseases (AFIC/NIH), Rawalpindi, Pakistan over a period of 18 months, from December 2010 to June 2012. Consecutive infants, who were taken to the catheterization laboratory with intention of transcatheter closure of PDA, were included. All infants were having echocardiographic evidence of left atrial and ventricular (LA & V) volume over load along with some or all signs and symptoms of cardiac failure, failing to thrive and...
frequent respiratory infections, and not to mention that all infants were on anti-congestive treatment.

Pre-procedural assessment included detailed history, physical examination, blood complete picture, chest X-ray and 2-D echocardiography and Doppler. 2-D echocardiography was done by experienced paediatric cardiologist to determine the morphology, length, narrowest diameters of the duct, pulmonary artery pressures and presence of any associated cardiac anomalies. Infants with no evidence of infections and considered suitable for device closure on 2-D echocardiography were planned to undergo therapeutic cardiac catheterization.

All patients were admitted on the same day of procedure and after written consent; infants were taken to catheterization laboratory. After establishing vascular access (right femoral vein with 5 or 6 F and right femoral artery with 5 F radial sheaths in most cases), intra-atrial Heparin 50 – 75 units per kg was administered. Aortogram was performed with 5 F pigtail catheter in lateral and right anterior oblique projections and duct size, length, narrowest diameter and morphology was determined. If considered suitable, then duct was crossed from venous side and delivery sheaths were parked in the descending aorta. Appropriate device was then selected with reference to narrowest diameter of duct and duct morphology. Device was deployed after careful manipulation and released only if cardiac auscultation and aortogram were satisfactory (Figure 1).

Routine care for next 18 - 24 hours in post-cath wards were given along with echocardiography in evening and next morning. Cases with absent limb pulses were treated with intravenous heparin and streptokinase as per institution protocol. Patients were discharged next morning, if no complications occurred and advised to follow-up after 2 weeks and then 2 months.

Data was entered in computer based statistical programme, Statistical Package for Social Sciences (SPSS) version 17 and descriptive analysis including frequencies with percentages, mean and standard deviations were done. For variables not following normal distribution, median values were calculated. Spearman's rank correlation test used to determine the level of significance of various categorical variables and p-value < 0.05 was considered as significant.

RESULTS

A total of 55 infants were taken to catheterization laboratory with intention of PDA device closure over study period with male to female ratio of 0.8:1, basic parameters are depicted in Table I. Median height was 69 cms and median weight was 08 kgs. Arterial access was established in 1 or 2 attempts in 46 cases (83.6% and median = 1). The number of aortogram performed ranged from 1 - 5 (median = 02) before final decision regarding device suitability. The mean narrowest duct diameter was 2.8 ± 1.1 mm (range = 1 - 6.5 mm).

Out of 55 cases, after doing aortogram, 3 cases were considered unsuitable for device closure and device closure was not attempted, as ducts were either large tubular type with no constriction (n=02) or too tiny to be closed (n=01). Out of remaining 52 cases, procedure was successful in 50 (96.1%) patients. Table II shows various duct occluders / coils used in the study population. Deliveries sheaths used included 6F (n=29), 7F (n=22) and 8F (n=1). The smallest infant in our study was female patient weighing only 3.5 kgs (age 7 months) with narrowest diameter of duct was 2.7 mm and was closed with 6/4 duct occluder, shaping into fish type in the duct (Figure 3). Median procedural time was 30 minutes in the study population. Immediate post-procedural aortogram revealed complete occlusion of the duct in 43/52 (82.7%) cases and echocardiography after 24 hours revealed no residual leak in any of these patients.

Three cases were abandoned after aortogram and device closure was not offered as these ducts were considered as not suitable for device closure (2 cases of large tubular type ducts and one tiny PDA). Out of attempted cases (n=52), 2 cases were unsuccessful. In first unsuccessful case, device was deployed but it resulted in coarctation of aorta (Figure 2) and it was decided to retrieve it. However, during Snare retrieval, device accidently dislodged first into the aorta and then

![Figure 1: PDA device closure in an infant.](image1)
![Figure 2: PDA device causing coarctation, retrieved subsequently.](image2)
![Figure 3: Fish type shape duct device in a small infant.](image3)
Demographic features of study population (n=55).

Table I: Demographic features of study population (n=55).

<table>
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<tr>
<th>Age (months)</th>
<th>Fluoroscopic time (minutes)</th>
<th>Size of PDA (mm)</th>
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</thead>
<tbody>
<tr>
<td>Mean ± Std deviation</td>
<td>10.4 ± 1.9</td>
<td>7.1 ± 6.5</td>
</tr>
<tr>
<td>Minimum</td>
<td>05</td>
<td>03</td>
</tr>
<tr>
<td>Maximum</td>
<td>12</td>
<td>49</td>
</tr>
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Percutaneous device closure of PDA is considered safe and preferred mode of treatment for both children and adults, but in small infants it is an unquestionably a major undertaking. In this study, 52 infants were scheduled for attempted PDA device closure after aortogram revealed device closure feasible with overall 96 success (50/52). Parra-Bravo et al. reported 92.3% success in their small study. Brunetti et al. reported that out of 359 attempted device closure the success was achieved in 357 in patients with mean duct diameter of 2.1 mm. It is worth mentioning that these studies were performed in all age groups while we restricted to infants with almost same success rate. Similarly, Dimas et al. recently reported their experience of 62 infants with weight < 6 kg with 94% success in PDA device occlusion similar to the 93% reported by Sivakumar et al. The smallest infant in this study was an infant girl weighing only 3.5 kgs (Figure 3). Roberts et al. reported their experience of PDA device closure in 10 preterm infants with weight 1.6 - 2.6 kgs and achieved 90% success.

Minor problems related to the local access site included perforation, tamponade or death. One case was not offer an alternative approach to right femoral artery. With the help of vascular surgeon, device was retrieved and duct was surgically interrupted with uneventful recovery. In the second case, while deploying the device, infant went into unexplained sudden cardiac arrest (fortunately recovered with 5 minutes of CPR) necessitating procedural abandonment. Her duct was surgically interrupted next day with uneventful recovery. In the second case, while deploying the device, infant went into unexplained sudden cardiac arrest (fortunately recovered with 5 minutes of CPR) necessitating procedural abandonment. Her duct was surgically interrupted next day with uneventful recovery. Otherwise, there was no cardiac perforation, tamponade or death.

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DISCUSSION

Percutaneous device closure of PDA is considered safe and preferred mode of treatment for both children and adults, but in small infants it is an unquestionably a major undertaking. In this study, 52 infants were
child recovered but procedure was abandoned and next day surgical interruption was performed. Fortunately, both cases eventually discharged home with no residual complications.

PDA device embolization is more common in infants;² PDA device occlusion should only be performed in a set-up where facilities of paediatric cardiac surgery are readily available. In this study, major complications occurred in 2/52 (3.8%) patients and minor in 12/55 (21.8%) of the total patients, with no residual morbidities. All cases except 4 were gone home with no scar mark, or ventilator support, or surgical trauma and after a short hospital stay. These issues do make device closure superior to surgical closure of PDA even in small infants.⁷,²³ There was no case of cardiac perforation or tamponade. A time consuming factor in infants with attempted PDA device closure in the study population was establishing the vascular access which took about 25% of the procedural time. Another important concern was local access site vascular complications that included 09 cases with pulse loss for 2 - 24 hours and 3 patients with pulse loss for more than 24 hours. These cases were successfully managed with intravenous heparin and additional intravenous streptokinase in 5 cases, with no residual problems. One factor in these cases was prolonged procedural time. No local vascular complication was seen in 11 patients where total procedural time was less than 25 minutes, though statistical significance for prolonged procedural time with absence of arterial pulse in the study population could not be established. Abadirs et al. reported 31% minor complications in young infants undergoing PDA device closure.¹²

The mean procedural time was 33 minutes and mean fluoroscopy time was 7.1 minutes, quite comparable to 30 and 10.6 minutes as reported by Karapinar et al.²⁴ Dimas et al. reported mean fluoroscopy time of 34 minutes in comparison to 7.1 minutes in this study.⁴ This disparity may be attributable to vast experience of our operators in last 10 years and the data reported by Dimas was from relatively early experience of PDA device closure.

Limitations of this study was a lack of comparison with surgical interruption / ligation (as very few ducts needs surgical treatment in present era) and lack of follow-up. Nevertheless, in face of its safety and high success rates, the authors consider PDA device closure in infancy as a feasible and attractive therapeutic option.

CONCLUSION

Transcatheter closure of the PDA in infants was effective intervention with high success rate; there was high rate of local access site vascular complications. It should only be done in symptomatic infants with mandatory pediatric cardiac surgical back up.

REFERENCES


