INTRODUCTION

Percutaneous Transcatheter PDA Device Closure in Infancy

Maad Ullah, Mehboob Sultan, Khurram Akhtar, Nadeem Sadiq and Hajira Akbar

ABSTRACT

Objective: To evaluate the results and complications associated with transcatheter closure of patent ductus arteriosus (PDA) in infants.

Study Design: Quasi-experimental study.

Place and Duration of Study: Paediatric Cardiology Department of Armed Forces Institute of Cardiology / National Institute of Heart Diseases (AFIC/NIHD), Rawalpindi, from December 2010 to June 2012.

Methodology: Infants undergoing transcatheter device closure of PDA were included. All patients were evaluated by experienced Paediatric Cardiologists with 2-D echocardiography and Doppler before the procedure. Success of closure and complications were recorded.

Results: The age of patients varied from 05 - 12 months and 31 (56.4%) were females. Out of the 55 infants, 3 (5.4%) were not offered device closure after aortogram (two large tubular type ducts and one tiny duct, considered unsuitable for device closure); while in 50 (96.1%) patients out of remaining 52, the duct was successfully closed with transcatheter PDA device or coil. In one infant, device deployment resulted in acquired coarctation, necessitating device retrieval by Snare followed by surgical duct interruption and another patient had non-fatal cardiac arrest during device deployment leading to abandonment of procedure and subsequent successful surgical interruption. Local vascular complications occurred in 12 (21.8%) of cases and all were satisfactorily treated.

Conclusion: Transcatheter device closure of PDA in infants was an effective procedure in the majority of cases; however, there were considerable number of local access site vascular complications.

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.  
Figure 2: PDA device causing coarctation, retrieved subsequently.  
Figure 3: Fish type shape duct device in a small infant.
Percutaneous transcatheter PDA device closure in infancy

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

<table>
<thead>
<tr>
<th>Age (months)</th>
<th>Fluoroscopic time (minutes)</th>
<th>Size of PDA (mm)</th>
</tr>
</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>
</tbody>
</table>

Table II: PDA occluders used in study population (n=52).

<table>
<thead>
<tr>
<th>Number of cases</th>
<th>Percentage</th>
<th>Cumulative percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coil</td>
<td>01</td>
<td>1.9</td>
</tr>
<tr>
<td>5/4 (AGA)</td>
<td>01</td>
<td>1.9</td>
</tr>
<tr>
<td>6/4</td>
<td>33</td>
<td>63.5</td>
</tr>
<tr>
<td>8/6</td>
<td>15</td>
<td>28.9</td>
</tr>
<tr>
<td>10/8</td>
<td>02</td>
<td>3.8</td>
</tr>
</tbody>
</table>

Table III: Correlation of local vascular complications with gender, patient’s weight, procedural length.

<table>
<thead>
<tr>
<th>No local access</th>
<th>Local access</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>23 (41.8%)</td>
<td>08 (14.6%)</td>
</tr>
<tr>
<td>Male</td>
<td>20 (36.4%)</td>
<td>04 (7.3%)</td>
</tr>
<tr>
<td>Weight</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 06 kgs</td>
<td>07 (12.7%)</td>
<td>05 (9.1%)</td>
</tr>
<tr>
<td>&gt; 06 kgs</td>
<td>36 (65.5%)</td>
<td>07 (12.7%)</td>
</tr>
<tr>
<td>Procedural time</td>
<td></td>
<td></td>
</tr>
<tr>
<td>&lt; 25 minutes</td>
<td>0 (0%)</td>
<td>12 (21.8%)</td>
</tr>
<tr>
<td>&gt; 25 minutes</td>
<td>11 (20%)</td>
<td>32 (58.2%)</td>
</tr>
</tbody>
</table>

Minor problems related to the local access site included 09 (16.4%) cases with pulse loss for 06 - 24 hours (Femoral artery) and 3 (5.4%) patients with pulse loss of more than 24 hours. In these cases, however, no correlation with gender \( r_s = -0.110 \) and \( p=0.425 \) or weight less than 6 kgs \( r_s = +0.254 \) and \( p=0.061 \) was established. Interestingly, no local vascular complications encountered in those 11 (20%) patients, where total procedural time was less than 25 minutes, though not attained statistical significant \( r_s = -0.264 \) and \( p=0.051 \). These cases were successfully managed with intravenous heparin and additional IV streptokinase in 5 (9%) cases, with no residual problems.

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 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. Among 50 successful cases, occluder devices were used in 49, while coil was used only in one case. The maximum size of device used was 6/4 in 33 patients followed by 8/6 in 15 cases (Table II). Similar statistical inference was also drawn by Parra-Barvo et al., concluding 6/4 and 8/6 as the most frequently used devices. Female patients (62%) outnumbered the male, endorsing that PDA is more common in female gender as also reported by Atiq et al. from Pakistan as 2:1 in favour of female in adult patients who underwent PDA device closure; similar observations are also reported by other studies as well. Complete early occlusion (defined as no leak in check aortogram or after 24 hours on echocardiography) occurred in 100% patients out of successful 50 cases which are in accordance to recently reported 98% in children with less than 10 kg of weight, by Park et al.

In this study population, the narrowest duct diameter ranged from 1 - 6.5 mm with mean of 2.8 ± 1.1 mm. In 3 infants, including 2 with tubular type ducts with no constriction point and one with tiny duct, device closure was not offered. This careful approach is necessary to prevent device embolization, which is frequent in large tubular type ducts. In a recent retrospective study, Abadirs from France reported high percentage of complications in 58 infants with weight less than 6 kgs, including a single death. Major complications reported by Parra-Barvo et al. were 10% in their small study with almost 90% success rate. There were two (3.8%) major complication occurred in 52 attempted PDA device closure in this study. In one of these cases, device dislodged during Snare retrieval into right femoral artery, needing emergency exploration by vascular surgeon followed by surgical interruption on the same day (Figure 2). Similar problems of aortic obstruction were also observed by others. In few cases, to avoid coarctation, fish type shape of the device was achieved by opening the larger disc in the duct (Figure 3). In one case, child suffered unexplained sudden cardiac arrest while device was in the phase of deployment, though
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. Abadir\(s\)\( et\)\( al\)\( .\)\( reported\) 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


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