TRANS-CATHETER DEVICE CLOSURE OF HUGE PATENT DUCTUS ARTERIOSUS WITH PRIOR BALLOON OCCLUSION FOR ESTIMATION OF SIZE AND REVERSIBILITY OF PULMONARY ARTERY PRESSURE; IMMEDIATE AND MEDIUM TERM RESULTS

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ABSTRACT

Objective: To assess the accuracy and specificity of balloon occlusion prior to transcatheter closure (TCC) of huge patent ductus arteriosus (PDA) with significantly elevated PHT.

Study Design: Retrospective observational.

Place and Duration of Study: This study was conducted at AFIC/ NIHD Rawalpindi from Sep 2012 to 2014.

Material and Methods: This is a retrospective observational study of 15 patients with very huge PDAs and severe PHT who were referred for device closure. Pulmonary artery pressures were evaluated during cardiac catheterization with transient balloon occlusion of PDAs to decide the reversibility of PHT. Following the device closure, patients were serially followed up to assess the accuracy and specificity of closure and its impact on PHT.

Results: Of 438 patients scheduled for PDA device closure, 30 were found to have PDA with near systemic pulmonary artery pressure. Out of these, 5 patients were found to have irreversible PHT based on hemodynamic data obtained after balloon occlusion of the duct. 25 patients eventually underwent device closure of PDA, had a median age of 9.5 years (range 2 years to 35 years). The weight ranged between 10 Kg to 65 kg (median 13 kg). The PDA closure device size ranged from 16 to 20 mm VSD device. The mean systolic pulmonary artery pressure was more than 65 mm Hg. Duct occluder was muscular ventricular septal defect closure device all patients. The follow up was available in 56 (86%) with a mean follow up period of 65 ± 34 months. All the patients had complete closure of the PDA at 6 months follow up. Mild obstruction of left pulmonary artery (n=) and aortic isthmus flow (n=) was noted at the time of discharge. During the follow up, partial or complete resolution of PHT was observed in all the patients in whom Doppler derived right ventricular systolic pressure was recorded.

Conclusion: Device closure of huge PDA with prior balloon occlusion in severe PHT and significant left to right shunt was found to be accurate and safe in the short and intermediate term.

Keywords: Patent ductus arteriosus, Balloon occlusion, Muscular VSD device, Reversibility of pulmonary artery pressure.

INTRODUCTION

Device closure of large sized Patent ductus arteriosus (PDA) in patients with severe pulmonary hypertension (PHT) is always challenging in catheterization laboratory. In younger age group, PHT is reversible in most of cases, but in elder children and adults having huge ductus exact size and PHT reversibility by calculation of pulmonary vascular resistance (PVR) is mandatory before device closure. Presently there are multiple catheterization techniques for the device closure of very large PDAs however there is little of data on patient selection for prior balloon occlusion, hemodynamic variations during procedures, suitability criteria, and variety of improvised devices for large PDAs, technical considerations, tackling with complications during device closure, and long-term results for these types of patients. With prior balloon occlusion technique the haemodynamic parameters and PAP behavior, duct selection for closure is done and closed in the same setting.

MATERIALS AND METHODS

Between September 2012 to November 2014, 438 patients underwent device closure of PDA. During this period, 30 patients with huge PDA having severe PHT near systemic levels were subjected to balloon occlusion for
estimation of size and reversibility before device closure. Severe PHT was defined as pulmonary artery systolic pressure more than 2/3 of systolic aortic pressure (recorded during cardiac catheterization)². The data was collected retrospectively from the case sheets and the catheterization records. Informed consent was obtained from all patients.

Multiple clinical and investigational parameters were used to determine reversibility of PHT.

Upper and lower limb saturations were recorded at baseline and on exercise when necessary. Post exercise saturation of < 90% was considered as being suggestive of irreversible PVR and when saturation was between 90% to 95% they were subjected to balloon occlusion in cardiac catheterization.

A detailed doppler echocardiographic evaluation was done to define the size and pulmonary artery pressure (PAP) of the PDA. Specifically aortic coarctation and branch pulmonary artery stenosis was ruled out.

General anesthesia (sevoflurane) was used in all patients during the procedure and inspiratory oxygen was maintained between 35% to 50%. At cardiac catheterization, baseline oxygen content and pressures were recorded at the various sites. In those with systolic PAP > 90% of systemic pressure, balloon occlusion (VACS 2) of the PDA was performed and the systemic and PAP were compared before and after the balloon occlusion for 15 min. According to balloon occlusion, the size of VSD muscular device selected was 2 mm larger than size of balloon. Any fall in systolic PAP of > 20% of the baseline pressure was considered as an indicator of significant left to right shunt across duct contributing to PHT. Diagnostic angiograms were performed in left lateral and right anterior oblique 30° to profile the anatomy of PDA which included estimating its diameter at the pulmonary and aortic ends, and its length. The duct size was described as per its diameter at the pulmonary end. If the PDA was found suitable for closure, VSD device (SHSMA) was used in all cases.

The PDA was crossed from the pulmonary end in all the patients. Amplatzer delivery sheath was introduced from the venous route over Amplatzer super stiff guide wire and was parked in the descending thoracic aorta. The device size used was the same as the angiographic size in all patients. Device was delivered as per the standard technique. Aortogram was done at 10 minutes after the release to confirm device position and rule out residual shunt. Post procedure, the patients were monitored in the intensive cardiac care unit for 24 hour. A close watch was kept for any evidence of intravascular hemolysis and device embolization. Patients were discharged on the next day. All patients were given sildenafil for 1 year post procedure to reduce PHT.

All cases were followed at 6 weeks, 6 months and every year thereafter. Improvement in functional class and weight gain were noted. The patients were evaluated clinically for any evidence of worsening of PHT. At follow up echocardiography, the position of the device was confirmed and residual shunt if any was noted. The presence of turbulence in the left pulmonary artery (LPA) and aortic isthmus was looked for and the velocities/ gradients across these structures were recorded. The PAP was estimated with tricuspid regurgitation jet on follow up. Repeat catheterization was not done in any case.

**Statistical Analysis**

The data were entered and analyzed in IBM SPSS Statistics software (version 21). Frequencies and Percentages were calculated for qualitative variables while mean and standard deviation (SD) were calculated for quantitative variables. The p-value of <0.05 is considered as statistically significant.

**RESULTS**

Demographics: During study period, all 30 patients with PDA were found to have severe PHT. Clinical examination, ECG, x-ray chest and 2-D echocardiography (2DE) with color Doppler revealed irreversible PVR in 5 patients. All other patients were considered suitable for PDA closure.
Out of 30 patients who underwent TCC of PDA, there were 8 males and 22 females. The age ranged from 2 years to 40 years (median). The weight varied between 10 to 60 kg (median). All patients were symptomatic PDA was the only hemodynamically significant lesion in all the patients. The duct diameter on echo ranged from 6 to 20 mm (median).

Cardiac catheterization: The mean systolic pulmonary artery and aortic systolic pressures were 66.9 ± 15.3 mmHg and 89 ± 17.2 mmHg, respectively. Angiographically, the PDA size varied from 7 to 22 mm (median). The pulmonary artery systolic pressure was less than 90% of aortic systolic pressure in 21 cases. All of them had predominantly left to right shunt based on clinical and investigational criteria with lower limb saturations of > 95%. They were subjected to TCC without any further evaluation. In all patients, balloon occlusion of PDA was done prior to proceeding with TCC as shown in Fig-1. The pulmonary artery and aortic pressures were recorded at baseline and after 15 min of balloon occlusion. In the 25/30 patients, there was a significant fall in pulmonary artery systolic pressure (>20% of baseline). This was considered as being indicative of reversibility of PHT. The remaining 5 patients in whom the PAP fell by none to < 20% were considered unsuitable for TCC. In all the cases, balloon was stable during the occlusion studies.

All the 25 patients who were considered suitable for TCC underwent successful closure of PDA, there was no incidence of device migration or embolization as shown in Fig-2.

At the time of post deployment angiogram, 3 out of 25 patients showed residual shunt through the device. However, it disappeared over a period of time and there was no residual shunt in any of the patients at the time of the last follow up. Fig-3 shows size of balloon used for estimation of PDA size and systemic/pulmonary artery pressures.

Complications/Problems

In 20 patients PDA device placement was uneventful and the patients were discharged next day. Few problems were noted in remaining 5 patients:

- In 1 patient there was mild residual leakage across the device but the device seemed otherwise stable, however 5 hours after procedure we found that device embolized into left pulmonary artery (LPA). We successfully retrieved the device and 2 mm larger device was deployed with no further problem.
- In 1 patient mild velocity acceleration at proximal LPA was noted with Doppler gradient of 18 mmHg, which did not progress on follow up.
- In one 3 years old child arterial pulses below the right femoral artery where
procedure was carried out, were not present till 24 hours post PDA device placement despite heparin infusion. We administered intra-venous streptokinase 1000 units/kg and about 1 hour the arterial pulses were resumed.

- In 1 patient the duct was extremely difficult to cross from venous end and we crossed the duct from aortic end and snared from venous side resulting in prolonged procedure time (more than 1 hour).
- In remaining 1 patient, there was minor leakage through the device however it was well positioned and on 1 week follow up there was complete closure.

**Follow up**

Follow up is available in all patients for a period of 23 ± 15 months. During the follow up, the PAP could be estimated by tricuspid regurgitation jet. It was significantly lower than the pre procedural PAP. None of the patients showed signs of worsening of the PHT. At the time of the last follow-up, all the patients were either asymptomatic or in the NYHA class I. During the follow up period, none of the patients had any progression in their peak velocities or gradients across the LPA or the aortic isthmus. On the contrary, three patients had velocities less than 1.5 m/s when seen last.

Of 5 patients who were considered to have irreversible PVR, one died after a period of 66 months from the time of catheterization, 2 had gradual worsening of symptoms (from NYHA II to III) over a period of 75 ± 21 months, while two patients remained status quo during the follow up of 44 and 33 months, respectively. All of them were treated with sildenafil and/or bosentan.

**DISCUSSION**

**Case selection and determining reversibility of PHT:**

Patients with large PDAs present with a variable symptomatology in different age groups. Every patient with ductus and severe pulmonary hypertension should be evaluated for evidence of significant left to right shunt utilizing clinical examination, chest X ray, ECG, Echo Doppler and if necessary, hemodynamic assessment at cardiac catheterization to ensure satisfactory long term outcome after device closure, as highlighted by this study as well as by the previous who were excluded due to presumable irreversible PVR. Assessment of PVR at cardiac catheterization after administering 100% oxygen, and after nitric oxide can be underestimated in the presence of pulmonary regurgitation. Temporary occlusion of PDA with balloon or device has been in use to decide on contribution of left to right shunt and proposition in case the PAP does not fall or actually rises. In the setting of PDA with Eisenmenger’s syndrome, pulmonary artery systolic pressure may not fall at all as it happened in 5 of our patients or can actually increase following closure of duct along with or without drop in the aortic systolic pressure. Closure of duct in this scenario can lead to rapid right ventricular failure. When PDA was closed with balloon occlusion and showed no fall in PAP with balloon occlusion, it was decided not to proceed with duct closure. This is a reliable test to exclude Hemodynamic instability during PDA closure.

This is a unique problem seen during the TCC of hypertensive PDAs. Although the exact mechanism of this phenomenon is not known, we hypothesize that the passage of the super stiff wire and/or the delivery sheath into the descending aorta tends to pull it down resulting in pulling up the ascending aorta with a resultant stretch on the right coronary artery producing right/ biventricular ischemia with severe reduction in the cardiac output. The problem is compounded by the presence of pulmonary regurgitation produced by the wire and sheath traversing the pulmonary valve. This may result in acute volume overload of right ventricle in addition to the pressure overload due to severe PHT. The most important thing is to be quick once the super stiff wire goes into the descending aorta. The delivery sheath and the device should be kept absolutely ready for deployment. This helps in shortening the duration of ischemia. Although we did not encounter any serious consequences, it is possible that longer duration of ischemia can be detrimental to the extent of being life threatening. All the resuscitative measures
should therefore be kept in a ready state during this phase of the procedure.

**Device selection:** There is no unanimity on the type of device to be used for closing large PDAs with severe PHT. VSD device was considered best in our study ADO is available up to 16x14 mm. For defects due to equal rims on both sides. In this study, all ducts could be closed successfully without any technical problems. There is a report of successful closure of large ducts using other makes of duct occluder.

**Device size selection in different age groups:** This is of particular importance in order to prevent any obstruction to the flow in the LPA or the aortic isthmus. Worrisome stenosis most often occurs in those where pre-existing LPA stenosis or aortic coarctation that has been overlooked prior to the closure of PDA. It is therefore essential to take a close look at the LPA origin and aortic isthmus as was done in all our patients. Despite this can be partly related to larger duct size and exclusive use of devices in this study. Hemolysis is a rare and well documented complication of incomplete PDA closure with significant residual shunt sometimes requiring complete closure of the shunt with Pulmonary hypertension on follow up.

Fall of PAP in the long term is the hallmark of successful closure of PDA with severe PHT. Though accurate PAP could be estimated by tricuspid regurgitation jet in only 3/25 of cases, none of the remaining patients showed any indirect evidence of worsening of the PHT. This fact supports the use of multiple variables in selecting the patients appropriately.

**Limitations:**

This is a retrospective study and the follow up information was available in all patients. Many of the criteria used for deciding the reversibility of the PAP have been qualitative and have not been compared with the more established variables such as PVR. Patients with presumed irreversible PHT on clinical evaluation did not undergo cardiac catheterization thereby raising the possibility that some patients, who would otherwise have benefited, might have been denied device closure. There is no direct estimation of PAP on follow up since repeat cardiac catheterization was not done in any patient.

**CONCLUSION**

Large PDAs with severe PHT can be closed safely and effectively with prior balloon sizing and estimating PVR in selected group of patients. Use of clinical, radiological, ECG, echo Doppler, and hemodynamic parameters is essential for proper case selection. Test occlusion of PDA with a balloon helps in decision making in borderline cases.

**Conflict of Interest**

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

**REFERENCES**