Percutaneous device closure of patent ductus arteriosus in adult patients with very long term follow up

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OBJECTIVES: We report our 10-year experience with transcatheter closure of Patent Ductus Arteriosus (PDA) in adult using different closure devices.
BACKGROUND: Transcatheter closure of PDA in adults can be challenging because of frequently associated comorbidities. Reports on immediate and intermediate-term results of PDA closure are excellent. This study aimed to provide the outcomes of PDA closure using different devices on long and very long term in adults.
METHODS: Between September 2009 and December 2018, data were retrospectively reviewed from 27 patients who underwent transcatheter closure of PDA. Outcome parameters were procedural success, procedure-related complications, evidence of residual shunt, and improvement in the signs/symptoms for which the procedure was performed. The mean follow-up interval was 72 months.
RESULTS: A device was successfully implanted in 27 of 27 patients (15 females). Median age and weight were 24 years (range: 18-57 years), and 69 Kg (range: 53-102 kg), respectively. The mean PDA diameter was 4.1 ± 2.1 mm. Devices used were Amplatzer Duct Occluder (19/27), Occlutech Duct Occluder (6/27) and PFM Nit-Occlud (2/27). Doppler TTE demonstrated 92.6% of full occlusion at day one, rising to 96.3% at one month. Three procedure-related complications occurred with no death. Among symptomatic patients 26 (96.3%), there was marked improvement in symptoms. Among patients 22 (81.5%) for whom the procedure was performed to address LV enlargement, there was reduction or stabilization in LV size on serial TTEs.
CONCLUSIONS: Transcatheter closure of PDA in the adult patient appears to be safe and effective.
Key Words: *Patent ductus arteriosus; Percutaneous device; Left ventricular enlargement; Transthoracic echocardiogram*

INTRODUCTION

The ductus arteriosus is a vascular structure that connects the LPA near its origin to the descending aorta just after the left subclavian artery; it is an essential fetal structure that closes spontaneously in about 90% of full-term infants during the first 48 hours of life. PDA is considered a form of congenital heart disease (CHD), defined as a persistent patency beyond the third month of life in term infants. The reported incidence of PDA in term neonates is only 1 in 2,000 births, accounting for 5%-10% of all CHD. It can be associated with various other CHD [1]. The prevalence in adulthood is 0.05% and usually as isolated lesion [2].

The presence of a hemodynamically significant PDA with left-to-right shunt may result in LV volume overload with signs and symptoms of heart failure. In patients with evidence of LV volume overload, closure is needed to prevent complications such as LV dysfunction, arrhythmias, and PAH. An additional reason for PDA closure in patients who sustained infective endocarditis it to close the defects to prevent recurrence of infection [3,4].

Surgical closure of PDAs was first performed by Gross and Hubbard in 1939 and has long been considered the gold standard treatment [5]. In most reports, surgical PDA closure allows a complete closure rate of 94-100% with a 0-2% mortality rate [6]. The most common complications of surgical PDA intervention include pneumothorax, bleeding and recurrent laryngeal nerve injury. However, surgical closure in adults can be complicated by the presence of calcified ductus, aortic fragility due to atheromatous lesions, LV dysfunction and PAH. These complications would make the operation more hazardous than when undertaken in the young patients [7]. Surgical closure remains the treatment of choice in the rare patients with a PDA too large for device closure or with unsuitable anatomy, such as aneurysmal PDA.

Transcatheter closure of PDA began by Portsmann in 1967 and became more widespread in 1976 after Rashkind developed a closure device [8,9]. Since then; multiple devices have been developed. The most common devices we use in our practice are the Amplatzer® Ductal Occluder (ADO, St. Jude Medical Inc., St. Paul, Minnesota, USA), the Occlutech® Duct Occluder (ODO, Occlutech, Helsingborg, Sweden) and The Nit-Occlud® PDA (PFM Medical, Cologne, Germany). Transcatheter closure of PDA in adults can be challenging because of anatomical variations, associated findings and complications such as PAH, LV dysfunction, infective endocarditis, calcification and aneurysm formation. Most of the experience with transcatheter PDA closure has been in the pediatric populations. Although some of the pediatric reports included small numbers of adults, a contemporary data focusing on adults are limited. Much of the published data of PDA device closure in adults is focused on ADO [10]. However, there is a paucity of data on the use of other devices in adults. In this study, we report our 10 year experience with transcatheter closure of PDA in 27 adult patients using various closure devices with focusing on safety and efficacy (long term) of device closure in adults with PDA.

MATERIALS AND METHODS

The study was conducted as a retrospective, nonrandomized review of 27 procedures performed on a total of 27 patients by a single operator. The procedures were performed from September 2009 to December 2018 at four medical centers. The patient population consisted of individuals who were referred by their primary cardiologists to a center specialized in the care of patients with CHD. Data were gathered by means of retrospective chart review. All patients provided informed consent regarding the use of their patient data for retrospective analysis and anonymous reporting and the institutions' IRBs approved the study protocol.

The data collected included the following:

Demographics: procedure date, age, gender, height, weight, and BSA.

Clinical data: symptoms, signs, past medical history, and indication(s) for PDA closure.

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Electrocardiography: right/left/biventricular hypertrophy (RVH, LVH, BVH), atrioventricular (AV) block, right or left bundle branch block (RBBB, LBBB), other intraventricular conduction delay (IVCD), as well as any other abnormal findings.

PDA size and type: measured by TTE, cardiac CT, cardiac MRI and angiography.

TTE: LV end-diastolic dimension (LVEDD), left atrial dimension, pulmonary artery size, LV systolic function, presence and quantification of residual shunt(s).

Hemodynamics: Qp:Qs ratio, systolic and mean pulmonary artery pressure, and PVR, Rp:Rs ratio.

Procedural details: fluoroscopy time, device size, device used, and sheath sizes.

Adverse events: details and outcome of any adverse event during the procedure or follow-up period.

TABLE 1
Baseline patient characteristics and findings

Age (years)	**Median 24 (18-57)**
Gender	
Female	15 (55.6%)
Male	12 (44.4%)
Height (cm)	Median 164 (152-190)
Weight (kg)	Median 69 (53-102)
BSA (m²)	Median 1.8 (1.5-2.7)
Associated abnormalities	
Congenital	
ASD	2 (3.7%)
Persistent left SVC to CS	1 (3.7%)
Bicuspid aortic valve	1 (3.7%)
Coronary artery fistula (small)	1 (3.7%)
Acquired	
Coronary artery disease	3 (11%)
Atrial fibrillation	1 (3.7%)
Moderate aortic valve stenosis	1 (3.7%)
Moderate mitral regurgitation	1 (3.7%)
Systemic illness	
Systemic hypertension	2 (7.4%)
Diabetes	2 (7.4%)
Hypothyroidism	1 (3.7%)
Bronchial asthma	1 (3.7%)
ECG	
Normal sinus rhythm	26 (96.3%)
Atrial fibrillation	1 (3.7%)
LVH/Dilatation	6 (22%)
LBBB/RBBB/IVCD	3 (11%)
Non-specific ST-T changes	2 (7.4%)
TTE	
Normal LV function	23 (85%)
Depressed LV function	4 (15%)
LV dilation	22 (81.5%)

Right ventricular systolic pressure (mmHg)	Median 35 (24-65)

Residual shunts were evaluated using color Doppler TTE and classified as trivial (<1 mm), mild (1-2 mm), moderate (2-4 mm), or severe (>4 mm) based on the width of the color jet upon exit from the PDA in a way similar to that used to describe atrial level residual shunts after device closure of atrial septal defects described by Boutin et al. [11].

We used the American Society of Echocardiography guidelines for chamber size and valvular function assessments [12]. Furthermore, PAH was defined in accordance with the standards set forth by the World Health Organization Fifth World Symposium on Pulmonary Hypertension [13].

Patient characteristics

The patients ranged in age from 18 to 57 years with a median age of 24 years. Fifteen (56%) of the patients were female and the remaining 12 (44%) patients were male. Body surface area ranged from 1.5 to 2.7 m^2 with a median of 1.8 m^2. Most of PDAs were isolated not associated with other CHD. Most patients were in normal sinus rhythm (96.3%) except one patient (3.7%) had atrial fibrillation. This patient was elderly and known to have longstanding systemic hypertension. Most of the patients were symptomatic (96.3%). One (3.7%) had history of PDA related infective endocarditis. The majority had TTE evidence of LV volume overload (81.5%) but only a small percentage showed evidence of depressed LV function (15%). The median pulmonary artery systolic pressure was 35 mmHg (range: 24-65 mmHg). Table 1 summarizes the baseline patient characteristics as well as preprocedural TTE findings.

Patent ductus arteriosus

According to the PDA classification adopted by Krichenko et al., 81.5% had type A, 11.1% had type E and 7.4% had type C [14]. The mean PDA diameter on angiography was 4.1 ± 2.1 mm and the mean length was 8.3 ± 3.1 mm. All PDAs were restrictive. The median shunt fraction (Qp/Qs) was 1.8:1 with a range from 1.3 to 2.4:1. Table 2 summarizes the characteristics of the PDAs.

TABLE 2
PDA characteristics (Angiography)

PDA type	
A	22 (81.5%)
E	3 (11.1)
C	2 (7.4%)
PDA size (mm)	Mean ± (SD) 4.1 ± (2.1)
PDA length (mm)	Mean ± (SD) 8.3 ± (3.1)
Hemodynamic data	
Qp : Qs	Median 1.8 (1.3-2.4:1)
PVR (Wood unit)	Median 1.7 (1.3-4.9)
PASP (mmHg)	Median 35 (24-64)
Mean PA pressure (mm Hg)	Median 22 (16–36)

Indications

The indications for PDA closure included signs and symptoms attributable to the defect such as dyspnea on exertion and fatigue. Other indications included the presence of a hemodynamically significant shunt as evidenced by otherwise unexplained LV enlargement or a shunt fraction (Qp/Qs) ≥ 1.5 by cardiac catheterization. Otherwise unexplained deterioration in LV function, recurrent endocarditis, and PAH also constituted indications for PDA closure [15,16]. In most cases, symptoms of dyspnea on exertion and/or unexplained LV enlargement constituted the indications for closure. Table 3 summarizes the indications for PDA closure. It should be noted that many patients had multiple indications for PDA closure.

TABLE 3
Indications for PDA closure

Attributable symptoms or signs	
Dyspnea on exertion, fatigue	26 (96.3%)
Significant left-to-right shunt	
Unexplained LV enlargement	22 (81.5%)
Unexplained deterioration of LV function	4 (15%)
Recurrent endocarditis	1 (3.7%)
Pulmonary Hypertension with PASP <50% of systemic and/or PVR <1/3 systemic Net L-R shunt and PASP 50% or greater systemic, and/or PVR>1/3 systemic	9 (33.3%)

Procedure

Most of the procedures were performed under general anesthesia (74%) while the remaining procedures were done under conscious sedation (26%). Most of the patient requested general anesthesia. A single dose of intravenous antibiotic was administered 30 min before the procedure. Aspirin administered at least 24 hr before the procedure. Femoral arterial and venous access was obtained for all patients following which they received intravenous heparin. After hemodynamic measurements, aortic angiogram was performed in lateral and AP views to visualize the ductus. Antegrade approach was used to cross the PDA in most patients, while snare assisted retrograde approach was utilized in two patients. The choice of the device was depending on the PDA diameter and length. Devices were deployed via venous approach in all the patients. In most cases, the device was successfully deployed in a single attempt. In two instances, two deployment attempts were needed and in one instance three deployment attempts were necessary, in this case the device type was changed from ADO to ODO (long type) in the third attempt [17]. In one case, the tip of the dilator passed the PDA but the rest of the delivery catheter stuck within the PDA due to protruded calcium near the aortic side. In this case we pulled the assembly to main pulmonary artery and we pre-dilated the PDA with 3 × 8 mm coronary non-complaint balloon via another femoral artery access using coronary wire and right Judkins catheter, then the delivery catheter advanced gently. Additional interventional procedures were performed during the same cardiac catheterization in two patients (ASD closure device in one patients and coronary artery stenting in one patient). Table 4 summarizes the procedural data. Post procedure, patients were maintained on aspirin or equivalent antiplatelet therapy for 6 months.

Table 4
Procedural data

General anesthesia	**20 (74%)**
Conscious sedation	7 (26%)
Fluoroscopy time (min)	Median 14 (11-45)
Procedure time (min)	Median 52 (31-90)
Approach for crossing	
Antegrade	25 (92.5%)
Retrograde	2 (7.5%)
Delivery via femoral vein	27 (100%)
Deployment attempts	
One	24 (88.9%)
Two	2 (7.4%)
Three	1 (3.7%)
Device	
ADO	19 (70.4%)
ODO	6 (22.2%)
Nit-Occlud	2 (7.4%)
Combined procedures addressing associated abnormalities	
ASD closure	1 (3.7%)
Coronary PCI	1 (3.7%)

Table 5
Adverse events during and after device closure of PDA

Death	0 (0%)
Device embolization	0 (0%)
LPA or Dao stenosis	0 (0%)
Arrhythmias	1 (3.7%)
Distal cholesterol embolization	1 (3.7%)
Moderate access site hematoma not requiring blood transfusion	1 (3.7%)
Overall	11%

RESULTS

Measured outcome parameters were procedural success, procedure/device-related complications, evidence of residual shunt by TTE, and improvement in the signs/symptoms for which the procedure was performed. Procedural success was defined by device release in appropriate position without embolization. Procedure/device-related complications were determined by chart review. Presence of residual shunt was assessed by color Doppler TTE.

Furthermore, improvement in signs/symptoms for which the intervention was performed was determined by history and serial TTE during follow-up visits. Follow-up occurred at 1, 30, 60, 180, and 360 days with yearly follow-up thereafter with the longest follow up being 10 years for the first few patients. The mean follow up was 72 months.

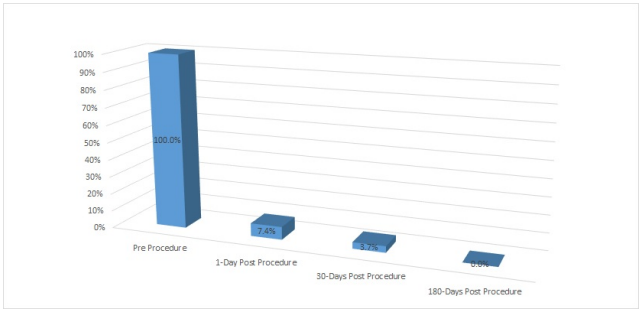

Figure 1) *Echocardiographic shunt status (percentage of patients) pre and post PDA closure. At day one, there were two residual shunts (1 mild, 1 trivial). At thirty days, there was one trivial shunt. At six months, there was no residual shunt*

In all the 27 patients the device was successfully deployed with appropriate position confirmed both by angiography. Device success was achieved with the first chosen device in all except one patient who needed a longer device (the ODO long version). In no procedures did device embolization occur. Also there was no LPA or aorta stenosis occurred related to device protrusion. One patient developed moderate size hematoma at calcified access site that was treated conservatively. In one patient with significant aortic calcification, there was distal cholesterol embolization occurred. It was complicated by acute renal failure requiring no dialysis; also there was distal limbs ischemia and skin discoloration. This treated conservatively by IV heparin infusion. In one week, the renal function and limb ischemia improved to the baseline stat. A third complication of recurrent symptomatic non-sustained ventricular arrhythmia occurred during the procedure in patient with sever LV dysfunction. This patient had ICD implantation before discharge home. Ultimately, no long-term complications were noted. Table 5 summarizes the procedure related complications. Immediate complete occlusion was achieved in 60% on angiography. Doppler TTE demonstrated 92.6% of full occlusion at day one, rising to 96.3% at one month and 100% at six months. Figure 1 summarizes the data with respect to the presence of a residual shunt.

For those 26 (96.3%) patients for whom the procedure was performed to address dyspnea on exertion, all but two noted marked improvement in their symptoms from NYHA class 2-4 to NYHA class 1. The remaining two noted mild to moderate improvement in their shortness of breath from NYHA class 3-4 to NYHA class 2. Of note, one of the two patients suffered from ischemic cardiomyopathy. The other one suffered from bronchial asthma. For those patients for whom the procedure was performed to address unexplained LV enlargement, all experienced reduction or stabilization in LV size on serial TTE. A total of 22 (81.5%) patients had LV enlargement. Eleven female patients had mild-moderate LV enlargement before the procedure (seven patients had mild enlargement with LVEDD of 5.4-5.6 cm with a median of 5.5 cm and four patients had moderate LV dilation with LVEDD of 5.8-6.1 cm with a median of 5.9 cm. On follow-up, the LVEDD normalized in ten patients (3.9-5.2 cm) with a median of 4.9 cm. Most of the improvement occurred in the first 3-6 months and it was sustained during the follow-up period. Only one patient's LVEDD did not improve, instead remaining stable over 4 years follow-up. This patient had hypertensive cardiomyopathy in addition to her PDA at baseline. Among male patients, eleven had evidence of LV enlargement prior to PDA closure. Eight of the eleven men had mild LV dilation with LVEDD ranging from 6.0 to 6.2 cm (median 6.1 cm). The remaining three men displayed moderate LV dilation with LVEDD ranging from 6.6 to 6.7 cm. On follow-up, nine patients experienced normalization of LVEDD (5.0-5.5 cm) with a median of 5.3 cm. Again, most of the improvement occurred in the first 3-6 months following PDA closure and was sustained during follow up. Only two male patients failed to have normalization of the LVEDD, although one LVEDD improved from moderate to mild (6.6-6.3 cm) following PDA closure. Of note, the two patients suffered from a concomitant ischemic cardiomyopathy. Three of the four patients with deterioration of LV function saw marked improvement in LV function following PDA closure. Among those patients with LV dysfunction, the preprocedural LV ejection fraction ranged from 30% to 45%. Following PDA closure, three of the four experienced normalization of the LVEF ≥ 55%, which was sustained during follow-up. The fourth patient with LV dysfunction showed only mild improvement in LV function with the EF improving from 30% to 40%. However, it should be noted that this patient suffered from concomitant ischemic cardiomyopathy. For those patients for whom the procedure was done to address recurrent endocarditis, no further episodes of endocarditis occurred. Regarding the pulmonary artery pressure, the overall Right ventricular systolic pressure by TTE improved from a mean of 44 mm Hg (40 mm Hg invasively) before the PDA closure to 32 mm Hg after the PDA closure. Of note the pulmonary pressure was improved uniformly in all patients including the one with severe pulmonary hypertension. Figure 2 summarizes the follow-up data regarding signs and symptoms.

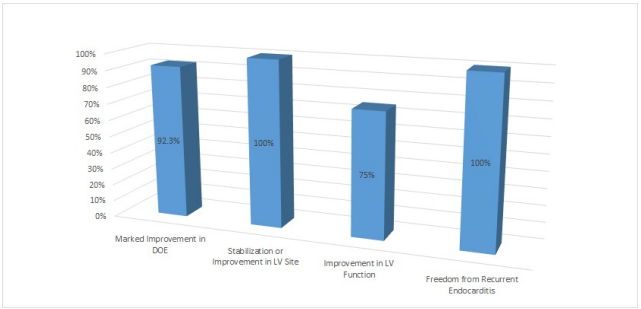

Figure 2) *Percentage of patients on follow-up who experienced improvement in dyspnea on exertion, LV size, LV function, Freedom from endocarditis*

DISCUSSION

PDAs in adult represents special cardiac condition. The impact of longstanding PDA related shunt on adults with probably acquired cardiomyopathies or systemic illness is different from that on pediatric. There is less complaint (stiffer) of LV in adult with/or without cardiomyopathy compared to pediatric [4]. This probably explains why most of the patients were symptomatic throughout the range of shunt degree. This series reports cohort of adult patients with PDAs who underwent transcatheter closure with various devices and very long follow up. The results indicate that transcatheter PDA closure effectively reduces left-to right shunting. The success in eliminating hemodynamically significant shunts appears to have produced stabilization or improvement in the signs and symptoms for which PDA closure was undertaken. All patients with dyspnea experienced improvement in their shortness of breath. The vast majority noted marked improvement in their shortness of breath while two patients with preexisting unrelated cardiomyopathies experienced mild-moderate improvement in their shortness of breath. Furthermore, all patients experienced stabilization in or reduction in their LVEDD on serial TTE following PDA closure. In fact, among those patients with impaired LV function, three of four experienced improvement in the LV ejection fraction. Transcatheter PDA closure therefore appears to ameliorate the pathologic changes that follow from hemodynamically significant left-to-right shunting. The clinical benefits from PDA closure were maintained through the follow up. The complication associated with transcatheter PDA closure in adult clearly related to the presence of atherosclerotic changes at the aorta and the access site. Also, the LV dysfunction put them at risk of arrhythmias during the stress of the procedure. The complication rate was 11%.

Several reports on safety and efficacy of transcatheter PDA closures have been published [18-21]. Most of the reports focused on pediatrics

population with limited number of adults included and the follow up duration was short or medium term at most, different reports focused on different devices [22,23]. Recently, a group published a retrospective review of transcatheter PDA closure in 70 patients, of them 37 adults [24]. Different closure devices were used including coils, ADO and other devices. Devices successfully deployed in all the patients. At 24 hr post-procedure, the success rate of transcatheter intervention was 95.7%. At 6 months follow up, no residual shunt was observed in all the patient. The mean follow up duration was 531 days (range 11-2059 days). No major procedure-related complications reported.

The present study does have several limitations. It is a retrospective review of a nonrandomized population. Furthermore, the data are somewhat incomplete given that the duration of follow-up varied widely among patients. The small sample size also precludes drawing larger conclusions from the data obtained.

CONCLUSION

Based on this series of 27 adult patients who underwent transcatheter PDA closure for indications ranging from dyspnea to LV dilatation, transcatheter PDA closure appears to be safe and effective. No long-term procedural complications were encountered. Furthermore, no significant residual shunt remained with respect to all closed defects. Patients also noted marked symptomatic improvement with TTE confirmation of reduction in or stabilization of LV size and improvement in LV function. The transcatheter approach showed excellent immediate and long-term results and fewer complications. Transcatheter closure should therefore be the preferred method of closure for most anatomically suitable PDAs. Surgical PDA closure in adult carried more risk of of significant complications comparing to transcatheter closures.

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