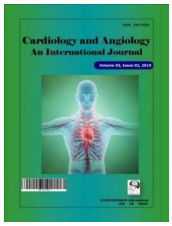

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Challenges of Percutaneous Closure of PDA in Adolescents and Adults: Single Center Experience

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Authors' contributions

This work was carried out in collaboration between all authors. Authors SESM and SHA designed the study, performed the statistical analysis, wrote the protocol and wrote the first draft of the manuscript. Authors RA and AES managed the analyses of the study and the literature searches. All authors read and approved the final manuscript.

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ABSTRACT

Aim: To evaluate the challenges, feasibility, and efficacy of device closure of PDA in adolescents and adults by different types of occluder devices in Sohag University Hospital.
Methods: Between 03/2012 to 06/2017, 33 adolescents and adults were chosen from 174 patients with PDA underwent transcatheter closure in our institute. The diameter of the device was chosen 4 mm larger than the narrowest pulmonary end. A balloon-sizing assisted PDA strategy was used in two patients in whom size of PDA could not accurately delineate. A retrospective review of the procedure, results and adverse events was performed.
Results: Successful device placement was achieved in all patients (100%). The median minimum PDA diameter was 5.5 (2.5-9 mm), median weight 45 (35-80 kg), and median age 16 (13-35 years). Median of mean pulmonary pressure was 29 (9-55) mmHg. Median of fluoroscopy time was 11 min.

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Most of PDAs were closed by ADO I (79%). Four different devices were deployed; muscular VSD, Amplatzer Plug II, ADO II AS and Occlutech® PDA .30 patients had type A PDA. Nineteen out of 33 (81.5%) patients had completed 12-month follow-up.No adverse events encountered in all patients.
Conclusions: Transcatheter closure of PDA is considered safe and efficacious in adolescents and adults. A balloon-sizing assisted PDA and oversizing of occluder strategies should be used to increase safety and feasibility of procedure in the poor delineation of sized of large PDA in this age group.

Keywords: Patent ductus arteriosus; closure; adolescents; adults; adverse events.

1. INTRODUCTION

In the current era, transcatheter occlusion of the patent ductus arteriosus (PDA) using either coils or device transcatheter therapy is considered to be a well-established procedure [1-3]. It is not infrequent for PDA to be diagnosed in adulthood on physical examination or as an incidental finding on transthoracic echocardiography (TTE). Additional problems associated with PDA include pulmonary hypertension, left ventricular volume overload, infective endocarditis, calcification, aneurysm formation, and, rarely, rupture [4]. The mortality rate in adults with untreated PDA is estimated to be 1.8% per year [5].

Transcatheter closure of PDA has greatly replaced the surgical ligation in the management of adult patients with PDA. In case of calcified ductus arteriosus with pulmonary hypertension, transcatheter closure is a low-risk procedure that is frequently preferred over surgical repair [6]. The purpose of this study was to determine efficacy, safety, and challenges of transcatheter closure of PDA in adolescents and adults.

2. MATERIALS AND METHODS

This present cohort study included 33 adolescents and adults patients (female and male) aged ≥12 years with isolated PDA who underwent transcatheter occlusion of PDA at Souhag University Hospital from January 2012 to june2017.The adolescents and adults included in the study represented 18% of the total referred patients 174 patients with PDA (children less than 13 years old were excluded). We retrospectively analyzed medical records, echocardiographic findings, angiographic findings, hemodynamic data, adverse events, and follow-up results of these patients.

Written consent from parents of adolescent patients or adult patients was included in the study and the approval of an ethical scientific committee of Sohag University Hospital was obtained.

The patients who were selected for the device occlusion had clinical and echocardiographic features of isolated PDA except in two patients; One patient had a small subaortic membrane associated with mild subaortic stenosis; and another patient had mitral valve prolapse with mild mitral regurgitation.

The transcatheter occlusion was performed under conscious sedation and local anesthesia in adults and with general anesthesia in adolescents. The heart rate, cardiac rhythm, and pulse oxygen saturation were continuously monitored during the procedure. Access was through the right femoral vein and the right femoral artery. Heparin (100 IU/kg) was administered intravenously after the vein and artery were cannulated. Hemodynamic data including pulmonary artery pressure and the pulmonary-to-systemic flow ratio were recorded. All patients received bacterial prophylactic antibiotic with 40 mg/kg cefotriaxone (maximum 1 g) 30 min prior to catheterization; two subsequent doses were repeated at 8 h and 16 h after the procedure.

2.1 Exclusion Criteria

Associated cardiac anomalies, which would require cardiac surgery.

Descending aortography was performed in the lateral and right anterior oblique (25°) views with a 6F pigtail catheter to define the PDA anatomy. The diameter at the pulmonary and aortic ends and the length of the PDA were measured. The duct size was described according to the diameter at the pulmonary end. The device chosen for closure was 4 mm larger than duct diameter. In case of poor visualization of duct, more angled right anterior oblique (30-45°) was used during angiography. Another technique was

preferred in poor delineation of PDA, balloon sizing of PDA by Amplatzer atrial septal defect (ASD) sizing balloon 24 mm (St Jude Medical Corporation, Plymouth, MN) which can be used for dynamic sizing: Well described previously by Butera et al. [7] (Fig. 1). The technique of device deployment was that of conventional antegrade approach similar to that reported in the literature [8]. Three cases had difficulty One adolescent patient had small PDA that closed retrograde from femoral artery by ADO II AS. Three adult patients had type A PDA had difficulty in crossing PDA by antegrade approach so it was decided to cross it retrograde from femoral artery then creating arteriovenous circuit. After that PDA was closed antegrade by ADO I 6/8 mm and two Occlutech® PDA; 12/15 and 4/6 mm.

Descending aortography was repeated 10 minutes after device deployment. The post-trial residual shunt was classified as follows (as described by Gamboa et al. [9]: trace, if the contrast was slightly opaque at the ductal pulmonary end; mild, if the pulmonary artery was stained without outlining its valve; and moderate, if the whole valvular plane was outlined.

The trial of occlusion of large type A PDA was done in adolescent female patient,had mean pulmonary pressure 55 mmHg. The device chosen was ADO I 12/14 mm. Aortic and pulmonary arterial pressures were measured while the device attached to the cable. The device was released after 10 minutes as pulmonary arterial pressure declined to the half of its measured before device deployment.

Amplatzer duct occluders (ADOs) were used for most PDAs. However, some exceptions to this rule had been applied. The chosen device was 4 mm larger than pulmonary end of PDA.

The fluoroscopy time and procedure time during the procedure were identified.

2.2 Follow-up Protocol

Chest radiography and transthoracic echocardiography were conducted 24 h after the procedure to evaluate the shape and position of the device. Patients had follow up in the Pediatric Cardiology Out-patient Clinic at intervals of 24 h then at 1 month, 6 months, and 12 months after the procedure. Patients were checked clinically for any evidence of cardiac murmur during each follow-up. Complete echocardiographic data (left pulmonary artery, aortic Doppler interrogation and tricuspid regurgitation for measurement of pulmonary hypertension) in addition to evaluation for residual shunting was performed by using a Vivid S5 (GE health care, Norway) echocardiography machine (General Electric).

2.3 Statistical Analysis

Univariate analyses were performed using SPSS Statistics 17.0 (SPSS, Chicago, IL, USA). The patients' clinical characteristics and outcome were expressed as median and interquartile range for all continuous variables and frequency with percentages for categorical variables.

3. RESULTS

The demographic and catheterization data of the patients undergoing transcatheter closure of PDA are listed in Table 1. The median pulmonary end of PDAs was 5.5 mm by angiography. The median pulmonary-to-systematic flow ratio was 2.4:1. The mean pulmonary pressure was 29 mmHg. The device was successfully deployed in all 33 patients.

Angiography at the end of the procedure showed complete occlusion in 12(36%) patients and residual shunt in 21(63%) patients had a trivial residual shunt with foaming through the device and with contrast jet <1 mm. On the following day, the leak disappeared completely in all cases as evaluated by echocardiography.

The median fluoroscopy time was 11 min and the median total procedure time was 43 min (Table 1).

Using the classification adopted by Krichenko et al. [10], 30 patients had type A, two patients had type E; one had large PDA that closed by Amplatzer muscular VSD10 mm and another one had small PDA that closed by ADO IIAS 5/6, and one adult patient had type D PDA that closed by Amplatzer plug II.

Amplatzer duct occluders (ADOI) were used for most PDAs (79%). However, some exceptions to this rule had applied; Amplatzer muscular VSD devices 10 mm and 12 mm (AGA Medical Corporation, Golden Valley, Minnesota) were used in two adolescent; one patient had type C PDA and the other was Down syndrome and had type A PDA with moderate pulmonary hypertension (mean pulmonary pressure 38 mmHg) (Fig. 2). Amplatzer ADO II 5/4 was used in small PDA of adolescent patients. Amplatzer

plug II deployed in an adult patient, had type D. (Fig. 3). Recently, three Occlutech® PDA devices 12/10, 15/12 and 4/6 were used in three adolescents and adults who had type A PDA (Fig. 4).

Table 1. Demographic and catheterization data

Variable	Median (range) or Number (%)
Age (years)	16(13-35)
Sex(F/M)	(26/7)(78%/22%)
Weight	45 (35-80)
Intracardiac disease and PDA	2
Minimum lumen diameter of PDA (mm)	5.5(2.5-9)
Mean pulmonary pressure (mmHg)	29(19-55)
Qp/Qs	2.4(1.9-2.6)
Fluoroscopy time(min)	11 (7-15.3)
Procedure Time	43 (35-67)
Follow up duration(months)	32 (1-47)

Qp/Qs:Pulmonary-Systemic flow ratio

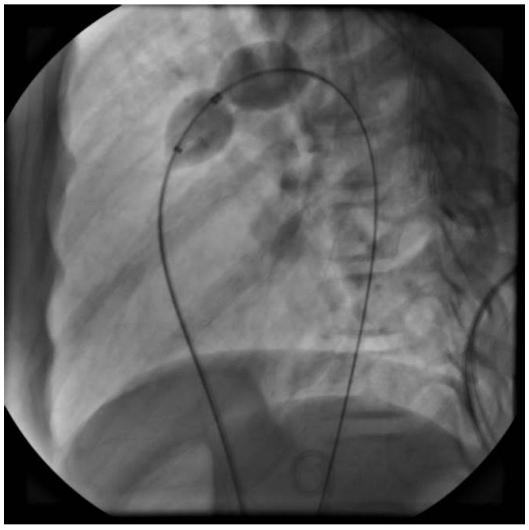

Fig. 1. Fluoroscopic view in lateral projection. A waist appeared in sizing balloon when pulling back done from descending aorta through PDA

All patients were discharged home 1 day after the closure and no patient had residual shunt on color Doppler echocardiography after 24 h.

Nineteen out of 33 (81.5%) patients had completed 12-month follow-up and all patients were found nearly asymptomatic with complete closure with no evidence of device migration, recanalization, thromboembolic episodes, wire fracture, hemolysis, or endocarditis.

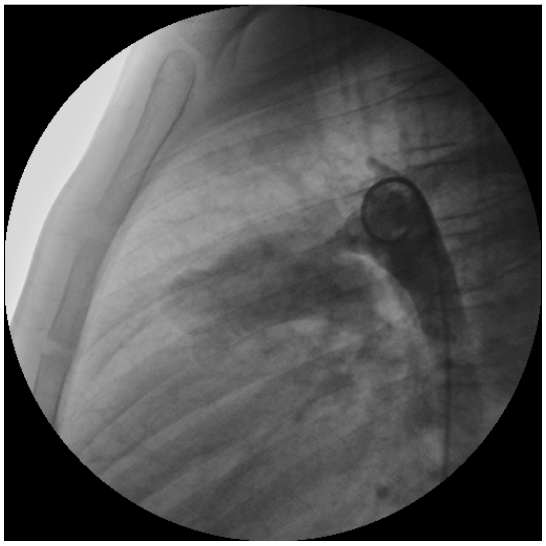

Fig. 2,A

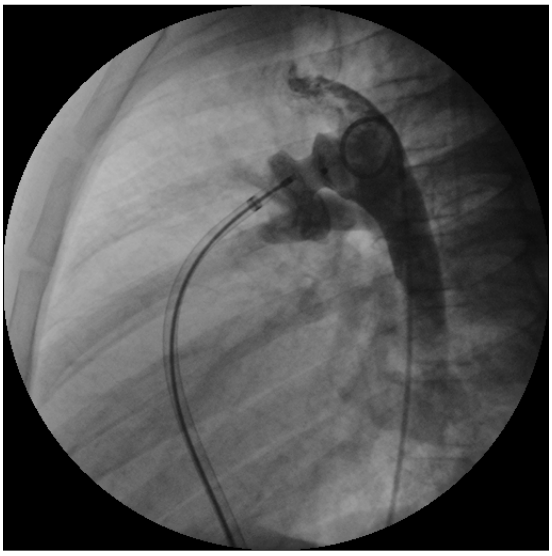

Fig. 2,B

Fig. 2. Transcatheter closure of the patent ductus arteriosus in Down patient. (A, Descending aortogram in lateral view showing a 9-mm ductus. B, Trace residual shunt after closure of PDA by Amplatze muscular occluder 12 mm)

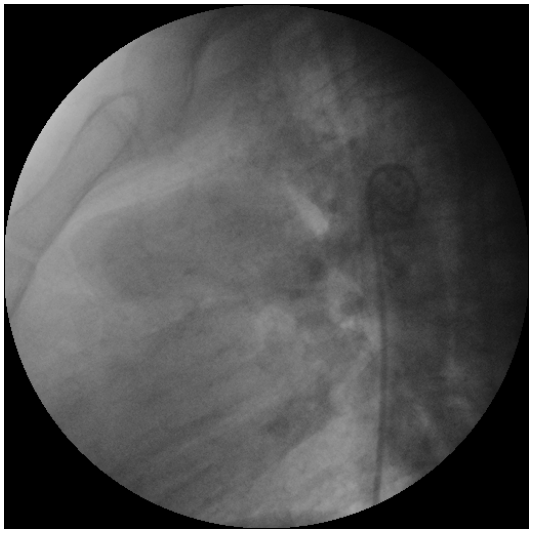

Fig. 3,A

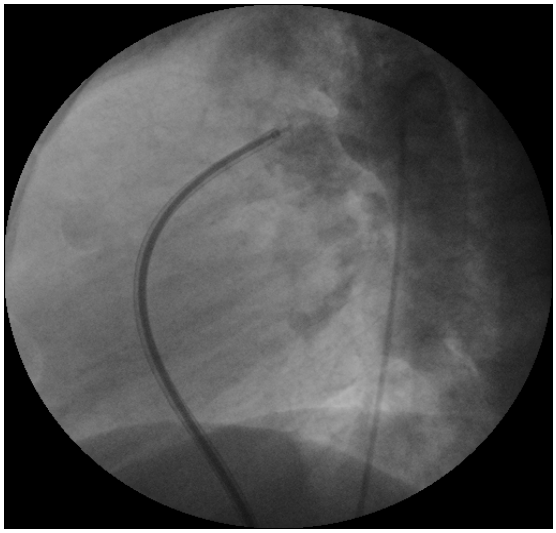

Fig. 3,B

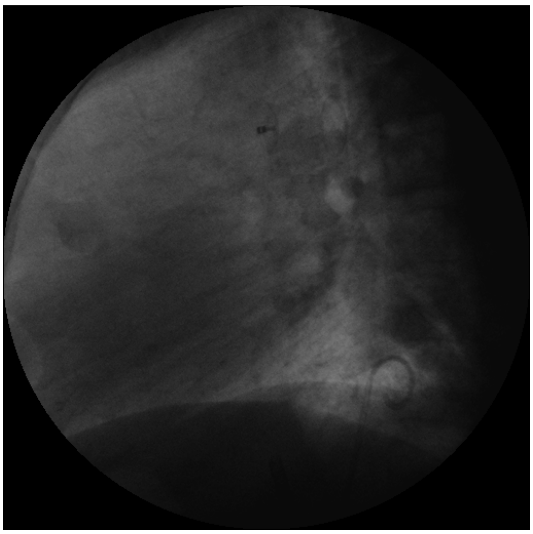

Fig. 3,C

Fig. 3. Transcatheter closure of large PDA in adult patient A. Descending aortogram in lateral view showing an 8-mm ductus. B. The ductus was closed with trace residual shunt by Occlutech® PDA 12/15 mm. C. Completely released Occlutech® PDA occluder

4. DISCUSSION

Isolated PDA accounts for 6% to 11% of all CHD cases. Sometimes PDA has an asymptomatic nature, so it often escapes clinical detection until adulthood when PAH or congestive heart failure develops [11,12].

The percutaneous closure of adult PDA has many Challenges. The important one is difficult delineation of the ductus through conventional angiography. This is particularly due to deformation of anatomical relationship between aorta and pulmonary artery and associated calcification can make quite difficult a proper evaluation of PDA size.

Alternative to the left-lateral traditional view, the right anterior oblique view may improve visualization of the PDA as suggested by Garg and Moorthy [13]. In our series, two lateral and RAO views were used as a routine in performing angiography of descending aorta in all cases.

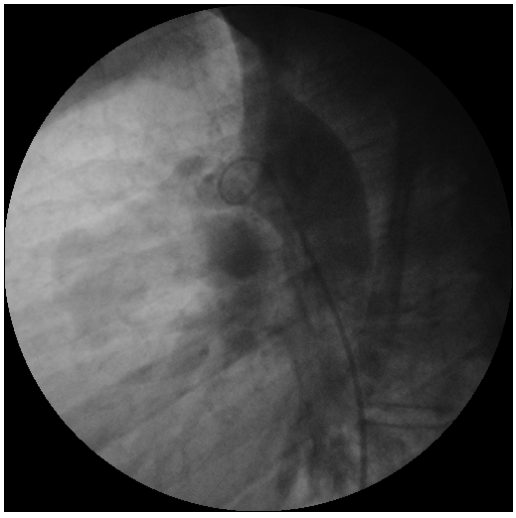

Fig. 4,A

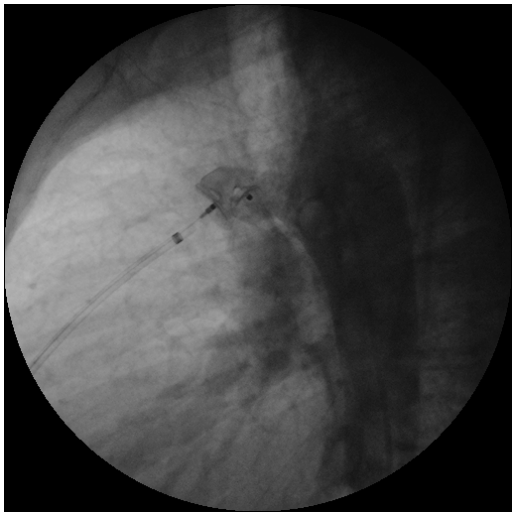

Fig. 4,B

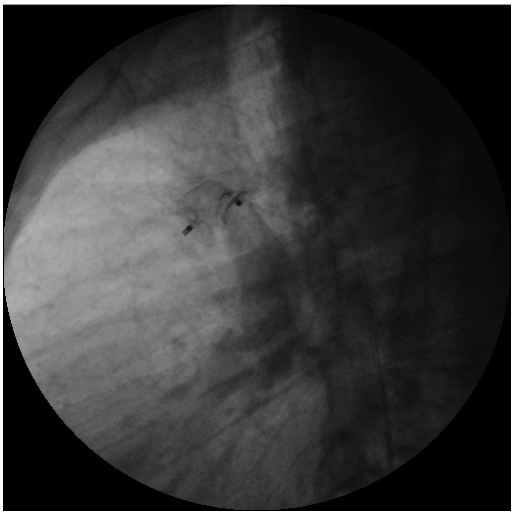

Fig. 4,C

Fig. 4. Transcatheter closure of type D in adult patient A. Descending aortogram in lateral view showing an 6-mm ductus. B. The ductus was closed with trace residual shunt by Amplatzer plug II 12 mm. C. Amplatzer plug II well seated in PDA after release

However, there were two cases balloon-sizing assisted PDA as described by Buttera, et al. [7] was needed to assess the size accurately. Amplatzer plug II 14 mm and ADO I 12/14 mm devices were successfully implanted in those two patients (St Jude Medical Corporation, USA).

Difficulty in crossing PDA antegradely was another challenge that had been encountered in a total of three patients of our series. We overcame this problem by crossing PDA in a retrograde manner by changing the wire that was snared in the pulmonary artery, creating arteriovenous circuit and advancing delivery sheath and closing PDA antegradely. PDAs were closed in those three patients by ADO 16/18 and Occlutech duct occluder (12/15 and 4/6).

We propose that oversizing of devices about 4 mm more than pulmonary end of PDAs increases safety of procedure and prevent embolization. Also there is no fear of obstruction of descending aorta or left pulmonary artery in adolescents or adults. This is concordant with the study of Francisco, et al. [14] and Zhang, et al. [15].

Table 2. Description of devices used for closure

Device	Size	Number
ADOI	14x12	2
	12x10	9
	10x8	8
	8x6	5
	6x4	2
Amplatzer muscular VSD (MVSD)	10mm	1
	14mm	1
Amplatzer plug II	14mm	1
ADO II	5x4	1
Occlutech Duct Occluder (ODO).	12x15	1
	12x10	1
	4x6	1

ADO: Amplatzer Duct Occluder, MVSD: Amplatzer muscular VSD device

In fact, Zhang, et al. studied occlusion of large PDA in patients with pulmonary hypertension. The study was conducted on 137 patients (age ≥12 years) and oversizing of the occluder was preferred and the device chosen for closure had a diameter at the aortic end that was twice the duct diameter.

In our case series we preferred using muscular VSD occluder in closing large PDAs with pulmonary hypertension or large tubular PDAs as reported previously in other literature [15].

Our present results demonstrate a 100% success rate with no major adverse events (e.g., accidental device embolization, significant aortic or pulmonary obstruction, endocarditis, hemolysis or vascular injury) [10].

5. STUDY LIMITATIONS

A major limitation that only three patients had moderate PH and one patient had severe PH and most of the patients had near normal pulmonary pressure. Second limitation of this study was its retrospective nature and their relatively small number of patients. More studies with a larger number of patients and older patients are needed to analyze the safety and efficacy of transcatheter closure of PDA in this age group.

6. CONCLUSION

Transcatheter closure of PDA is considered to be safe and efficacious in adolescents and adults. A balloon-sizing assisted PDA and oversizing of occluder strategies should be used to increase the safety and feasibility of procedure especially in the poor delineation of large-sized PDAs in this age group.

CONSENT

As per international standard or university standard, patient's written consent has been collected and preserved by the authors.

ETHICAL APPROVAL

As per international standard or university standard, written approval of Ethics committee has been collected and preserved by the authors.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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