Original Article

INHOSPITAL OUTCOME OF PATENT DUCTUS ARTERIOSUS DEVICE OCCLUSION IN THE ADOLESCENT & ADULT POPULATION

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Author's Contribution

AUR:Conducted the study and wrote the article. AQ: Helped in review the article. AB: Re-arranged data and corrected article. AC: Tables and figures and made corrections.

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ABSTRACT

BACKGROUND: Patent ductus arteriosus (PDA) in adults is different compared to children in many ways. Although the indications of closures are almost same in all age groups but can have long impact like many patients can turn into Eisenmenger syndrome if not treated. Device closure is safe and prevents such complications when treated early.

OBJECTIVE: This study was conducted to see the outcome of device occlusion in adult patients presented with PDA.

MATERIAL AND METHODS: We conducted a retrospective study in a tertiary care referral centre. All adult patients with PDA were included. These were patient who presented with PDA and were attempted to close percutaneously. Clinically Eisenmenger due to PDA were excluded. Patients having near systemic pulmonary artery (PA) pressure were balloon occluded, before occlusion.

Results: A total of 109 patients underwent for PDA device occlusion from October 2010 to December 2019. Females were 85.3% (n=93) and 14.7% (n=16) were male. The age ranged from 16 to 60 years (mean age 24.5 ± 10 years). Endocarditis was present in 8 patients at first presentation and 1 patient presented in the postpartum period. Occlusion was successful in 95.4% (n=104) and 5 were abandoned (3 due to irreversible pulmonary hypertension and 2 due to non-availability of appropriate sized device). There was no pulmonary hypertension (mPAP<25mmHg) in 34% (n=37); mild pulmonary hypertension (mPAP=25-40mmHg) in 50% (n=55); moderate pulmonary hypertension (mPAP=41-55mmHg) 4 % (n=4) and severe pulmonary hypertension (mPAP>55mmHg) 12 % (n=13). The narrowest point of PDA on angiography ranged from 3 to 15mm (mean 5.72mm ±2.53mm).

Duct occluder1 was used in 85.5 % (n=89) and 9.6 %(n=10) required reverse shank occluder to occlude the duct, 1 required muscular VSD device, ASD device was used in 1 patient and in 3 patients post infarction VSD device. The size of the device compared to narrow point was bigger by 2-8mm (mean 4.3 ±1.3mm). There was no reported device embolization in our study.

CONCLUSION: Device closure is possible in almost all patients, as different types and bigger devices can be used. In this study we found that a considerably bigger size can be safely taken in adolescents and adult age group which appears to be safer with minimal risk of complications.

KEYWORDS: Patent ductus arteriosus, PDA device closure in adults, PDA and pulmonary hypertension.

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INTRODUCTION:

Patent ductus arteriosus (PDA) accounts for 5-10% of all congenital heart diseases. The prevalence of PDA is 0.05% in adults.[1] It is usually diagnosed and treated at an early age. But in countries like Pakistan, where congenital heart services have been established over the last 3 decades, a large number of adult patients with PDA are being diagnosed late or even in old age. Along with morbidity, untreated patients have mortality (irrespective of size of the PDA) of ≈ 1.8% per year.[2]

The natural history of PDA depends on the size of duct and magnitude of the shunt as well as the status of the pulmonary vascular disease. Small PDAs usually have a good prognosis, but have increased risk of endocarditis. Moderate to large ducts lead to significant left ventricular volume loading, risk of heart failure or irreversible pulmonary hypertension.[3] The ACC/AHA 2018 guidelines recommend (class I) the closure of PDA in adults with significant left atrial or left ventricular loading attributable to PDA, with a net left to right shunt with pulmonary artery (PA) systolic pressure <50% systemic and PVR less than 1/3rd systemic.[4]

PDA surgical closure was done by Gross and Hubbard in 1939 and was considered the gold standard treatment.[5] However, surgical closure in adults can be complicated because of calcified ductus, aortic fragility due to atheromatous lesions, LV dysfunction and PA hypertension. These complications make the operation more hazardous in adult patients[6]. Percutaneous occlusion is now the first line treatment with excellent medium and long term results.[6] Transcatheter closure of PDA in adults can be challenging because of anatomical variations. Different devices has been used for occlusion, Amplatzer® Ductal Occluder ADO, muscular VSD and Pmi VSD devices (St. Jude Medical Inc., St. Paul, Minnesota, USA), the Occlutech® Duct Occluder, reverse shank ODO (Occlutech, Helsingborg, Sweden)

This study was conducted to see the outcome of device occlusion in adult patients presented with PDA.

MATERIAL & METHODS:

This is a retrospective cross-sectional study from a single tertiary care referral cardiology centre. All adult patients who were diagnosed with an isolated PDA were enrolled for percutaneous closure. Patients diagnosed with severe pulmonary hypertension, who had a PDA shunting left to right, were given oral pulmonary vasodilators for six month before closing the PDA. The patients who had Eisenmenger syndrome clinically or who demonstrated severe irreversible pulmonary hypertension (PHT) due to PDA were excluded.

Prior to the procedure, all patients underwent full clinical assessment, ECG, X-ray chest and echocardiography. Informed and written consent was taken from all patients. The procedure was performed under local anaesthesia. IV antibiotic was given 30 minutes prior to the procedure and 2 subsequent doses were given IV as well. During the procedure, once arterial access was obtained the patient was given IV heparin 100 IU/kg up to a maximum of 5000 IU. Aortogram was done in 90 degree lateral to measure the size and morphology of the duct. If this was not informative, it was repeated in 30 right anterior oblique (30 RAO). Full hemodynamic assessments were done prior to selection of device. PDA was crossed from PA using multipurpose catheter and wire. In few patients PDA was crossed from aortic side and wire was snared from PA to femoral vein.

Patients, who demonstrated PA pressures near systemic systolic pressure underwent complete balloon occlusion by a low profile soft balloon for 15 minutes with simultaneously O_2 inhalation at rate of 10 L/min by face mask. Pressures from PA and aorta were recorded to assess for significant drop in PA pressures. Occlusion device was selected taking into consideration the size, morphology of duct and PA pressure. Device was deployed in usual way in antegrade fashion.

Patients remained admitted for 24 hours to observe any complications and to ensure haemostasis. They were discharged after trans thoracic echocardiogram was performed.

RESULTS:

There were total of 109 patients in our study group who met the selection criteria from October 2010 to December 2019.

The age ranged from 17yrs to 60 yrs (mean 24.5 yrs ±10 yrs) and median age of 21 yrs. The gender distribution of our data set showed 14.7% (n=16) males and 85.3% (n=93) females.

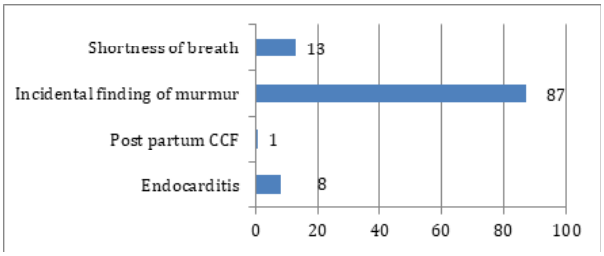
The majority of the patients 79.83% (n=87) presented to the cardiology clinic for evaluation of cardiac murmur. 7.34% (n=8) of the patients presented clinical evidence of infective endocarditis. 11.9% (n=13) patients presented with shortness of breath and 1 of the patients had postpartum congestive cardiac failure.

Transthoracic echocardiogram was done to assess the size of the PDA; presence and severity

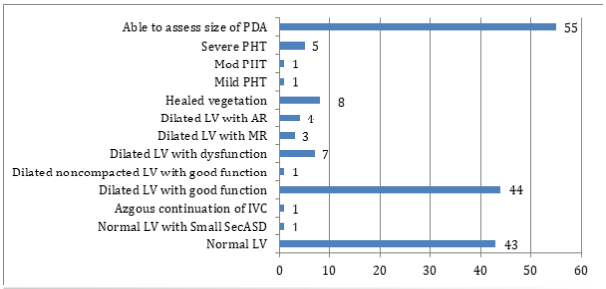
of PHT; size and function of ventricle and exclude other abnormalities. We were able to assess the size of the duct on echo in 50.4% of the patients. Small size duct was present in 45.9% (n=50), moderate size duct 36.7% (n=40) and large size duct in 17.4% (n=19).

The ducts were classified after angiographic delineation using Krichenko classification. It was found to be of Type A in 73% (n=80), Type B in 7% (n=8), Type C in 7% (n=7), Type D in 2% (n-=2) and Type E in 11% (n=12).

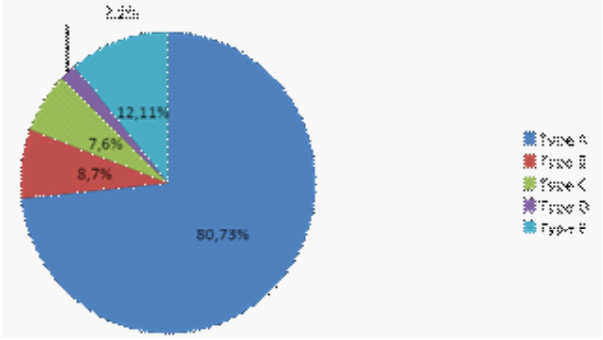
Pulmonary hypertension was classified as mild, moderate and severe according to clinical and investigative criteria. There was no pulmonary hypertension in 34% (n=37) of the patients, mild pulmonary hypertension was present in 50% (n=55), moderate pulmonary hypertension in 4% (n=4) and severe pulmonary hypertension in 12% (n=13). Out of the 13 patients who were diagnosed as having severe pulmonary hypertension, 3 patients were abandoned after hemodynamic assessment which showed irreversible pulmonary hypertension. 10 of the patients with severe pulmonary hypertension underwent device closure.



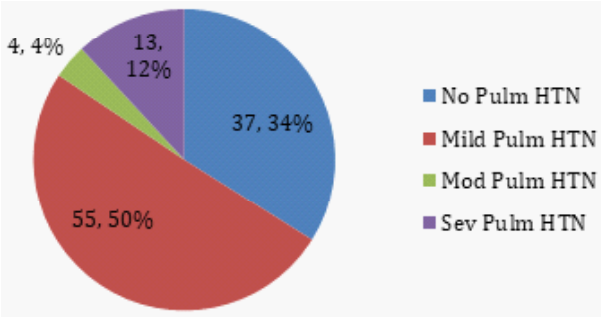
Clinical Presentation Distribution



Transthoracic echocardiography Findings



Distribution of Angiographic Types of Duct



Distribution According to PA Pressure

We were able to cross the duct from PA in 96.2% (n=100)patients who underwent device closure. Duct was crossed from aortic side antegrade in 3.8% (n=4) and wire was snared from PA using goose neck snare and brought out from femoral vein. All these 4 patients had small duct.

The size of the duct range between 2-15mm with a mean of 5.95mm ±2.91mm. The size of the device selected was bigger by a mean of 4.2mm± 1.5mm from the pulmonary end/narrow point of the duct.

Severe pulmonary hypertension was present in 13.5 % (n=14) of patients with PDA. In hypertensive PDAs, if simultaneous aortic and PA systolic pressure was > 30% -40% difference in systolic pressures of aorta and PA, they were not given O_2 and balloon testing. Seven patients were tested for balloon occlusion and simultaneous O_2 inhalation for 15 minutes. Of 4 showed drop of PA pressure >30 mm in systolic and mean pressure. Rest of

Table-1:Hemodynamic data where septal occluder used Ao (Aorta), PA (Pulmonary Artery

Age	Sex	Pressure in Air (mmHg)	Pressures in O_2(mmHg)	Pressures after balloon occlusion	Device Used Size & Type of Device	Duct/device size (mm)	Pressure after device occlusion
20	F	**Ao**=122/80-100 **PA**=85/50-60			20mm pimVSD	13/22	**Ao**= 140/80-100 **PA**-45/27-33
24	F	**Ao**=115/70-85 **PA**=115/67-83	**Ao**=115/70-85 **PA**=100/60-70	**Ao**=123/80-94 **PA**=68/22-37	24mm pimVSD	16/24	**Ao**=111/75-87 **PA**=84/52-63
20	M	**Ao**=161/79-108 **PA**=141/77-98			14mm mVSD	10/14	**Ao**=157/78-104 **PA**=109/59-76
20	M	**Ao**=150/65-93 **PA**=115/64-81			20mm ASD	11/20	**Ao**= 150/65-93 **PA**=105/58-74

3 showed minimal or no pressure drop. So later were abandoned for device occlusion. Mean drop in mean PA pressure after occlusion was 36.1± 15 mmHg which was well below the mean aortic and pre occlusion PA mean pressure, so it was considered safe to occlude the duct.

Remaining 89 of the patients underwent occlusion using ADO1 Amplantzer duct occluder, 10 required the reverse shank duct occluder, 1 had muscular VSD device, 3 had post infarction muscular VSD device and 1 had an ASD device implanted. 2 patients were abandoned due to lack of appropriate device. Immediate outcome showed mild residual leak in 12 patients, mostly with large PDAs.

There was no major complication or death. Minor hematoma was present in 3 patients that did not require any treatment. All patients were discharged next day morning after clinical examination and transthoracic echo.

The echocardiogram performed at 24 hours post procedure showed no residual leak in 96 patents (92.3%), small residual leak in 7 patients (6.7%), moderate residual leak in 1 patient; dilated LV with good function in 22, LV dysfunction in 10, AR in 4 and MR in 3 patients. 7 out of the 8 patients with residual leak had a ductal narrow point >6mm

DISCUSSION:

The first PDA closure without thoracotomy was described by Portsman et al in 1967. There are many studies that demonstrate the safety and efficacy of PDA device closure in children but much in adult population. Our study group is the one of the largest adult population study so far previous series are small reported from other parts of the world, because the condition is usually diagnosed and treated early in life.

Majority of patients in our set up were females (6:1 ratio unlike usual 2:1). As per recommendations of AHA 2018 for closure of PDA, episode of infective endoarteritis is a definite indication for PDA closure. This is a significant infective complication in our region [3] and 7.3% of patients presented with Infective endocarditis justifying closure of PDA in all patients, justifying duct closure.

Most of studies showed use of ADO1 for ductal occlusion and there is relatively small number chort using other devices [8,11]. Alkashkari used ADO1 and Nit Occlude coil to occlude in 27 adult patients successfully in relatively moderate size PDAs with mean diameter of 4.1 ± 2.1 mm[10]. Since then, multiple types of devices have been employed for transcatheter closure of PDA with varying success.

Type of device depends on duct morphology and PA pressure. Type A was the most common type of duct found on angiogram as it has been documented in other studies.[13] ADO was the commonest device used followed by reverse shank device in 9.6% and muscular VSD in 2%. We used Amplantzer devices i.e. duct and septal occluders and reverse shank devices due to ease of use and excellent results to ensure occlusion of the duct in maximum patient without complications.

In few patients 3.8 % (n=4) the duct was crossed antegrade and the wire was snared from pulmonary artery to bring out from femoral vein. This makes procedure time long and add significant cost to the procedure. This issue has been seen in few cases with small PDA, demonstrated by few studied where they used ADOII to occlude the duct, we fear to use Amplatzer duct occluder II (ADOII), being more softer and risk of embolization [9,10].

Several studies have shown how to work up and mange hypertensive PDAs, but most studies have mixed population from small children to adult patients[13,14].Duan Z et al used predominantly pressure parameters to determine suitability in relatively older children [15], comparing pulmonary systemic pressure ratio. We found that PA pressure did not fall in safe range ie, 33.5±10 mmHg. To achieve complete occlusion ductal narrow point to device waist was 1:1.75, to minimize the chance of embolization

Pre discharge transthoracic echo, done at 24 hours post procedure showed complete occlusion in 92.3%. Only 7.7 percent patients has small residual leak. These were patients where septal occluders were used to occlude large PDAs. This percentage is far less as compared to the data shown in previous studies with different devices. Gamboa R et al showed a variable occlusion from maximum of 91% with ADO1 and minimum to 50 % with Nit-Occlud coil after 24 hours of occlusion[16].

Complication rate in device closure has been reported from 2% to 20 % in different studies[17,18]. Serious complications may occur after PDA device occlusion like inguinal hematoma, obstruction of LPA, obstruction of descending aorta, embolization and significant hemolysis[19,20,21]. Most studies have shown almost no complication per device occlusion except hematoma formation. So was our study, no major complication except small inguinal hematoma and no device embolization. As adults have

gained their growth potential they accommodate bigger devices like VSD and ASD without obstructing the surrounding structures to ensure complete occusion of the duct.

CONCLUSION:

Percutaneous closure is safe and effective.Almost complete occlusion can be achieved in 95.4% by using different devices other than duct occluders without significant complications.

Extra hardware like snare, balloon and using septal occluders in few patients add significant cost of the procedure. Risk of infective endocarditis justifies closure of PDA in all patients. A comprehensive haemodynamic study should be part of evaluation prior to PDA device closure to assess for reversibility in hypertensive PDAs.

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