ABSTRACT

Background: Patent ductus arteriosus (PDA) is a common form of congenital heart disease and forms about 5-10% of congenital heart diseases. Surgical closure is safe and effective; however, certain patients may experience some morbidity. Recently, transcatheter closure of PDA using the Amplatzer duct occluder has been shown to be safe and efficacious.

Objectives: To evaluate whether transcatheter closure with this device offers an alternative to surgical closure of PDA.

Patients and Methods: Between July 2006 to July 2008, 149 patients (98 females and 51 males) with PDA underwent cardiac catheterization in an attempt to close their PDA by transcatheter approach using Amplatzer duct occluder device.

Results: The patient’s age ranged from 4 months to 45 years (median 5 years). Successful PDA closure was achieved in 136 patients (91.2%) with 100% complete closure rate within 24 hours after the procedure. Thirteen patients (8.7%) had unsuccessful attempts, 11 (7.3%) of them had failure of deployment of the device, while embolization of the device occurred in two of the patients (1.3%).

Conclusions: Amplatzer duct occluder device is safe and effective for closure of different types and sizes of PDA with low rate of complication.

Key words: ADO devices, cardiac catheterization, congenital heart disease

INTRODUCTION

Patent ductus arteriosus (PDA) is a common form of congenital heart defect with an incidence of one in 2500 to 5000 live births.[1] The presence of volume overloading of the left atrium and left ventricle is an indication for closure of the defect. The risks of endocarditis, aneurysm of PDA, and pulmonary vascular disease are also indications for closure.

Closure eliminates left-to-right shunting volume overload of the left-sided circulation, and the risk for pulmonary hypertension and endocarditis. Surgical closure of PDA is safe and effective,[2] however, certain patients may experience some morbidity, including bleeding, inadvertent left pulmonary artery (LPA) ligation, recurrent laryngeal nerve damage, and residual shunting.[3-5]

PDA was the first example of congenital heart disease to be treated by transcatheter closure, which becomes an established form of treatment for the majority of patients with PDA and as a safe alternative to surgery.

The percutaneous technique was first described by Porstmanur et al.,[6] since then various devices such as Rashkind PDA umbrella,[7] button device,[8] PDA coils[9] and most recently the Amplatzer duct occluder (ADO) have been introduced.[10,11] The ADO device was designed to provide the most desirable characteristics for a percutaneous closure device that can be used in most if not all patients with PDA. These include user-friendly delivery system, high complete closure rate, small delivery system (allowing its use in small infants), transvenous delivery route, ability to adapt to various PDA sizes and types, and the ability to retrieve or reposition the device prior to release from a secure delivery system.

This study was carried out to evaluate the safety and efficacy of Amplatzer device for the transcatheter closure of PDA in Iraqi patients.
PATIENTS AND METHODS

This retrospective study was carried out in Ibn al-Bitar center for cardiac surgery-Baghdad, from July 2006 to July 2008, during which 149 patient who underwent cardiac catheterization in an attempt to close the PDA by transcatheter approach using amplatzer duct occluder device, were evaluated. The patients were diagnosed to have persistent patency of ductus arteriosus (PDA) based on evaluation with a physical examination, CXR and transthoracic Echo/Doppler study were planned to undergo cardiac catheterization to close the PDA by transcatheter occluder device. Patients with PDA who had cardiac catheterization as diagnostic procedure only were excluded.

Although, the manufacturer exclusion criteria were body weight of less than 5 kg and associated cardiac anomalies, which would require cardiac surgery, exception is made for severe medical condition that necessitate early closure of PDA.

General exclusion criteria include pelvic vein or inferior vena cava thrombosis, sepsis (local and generalized), any type of serious infection less than one month prior to procedure, malignancy with life expectancy less than three years and demonstrated intracardiac thrombi on echocardiography.

Procedure Protocol

Procedure is usually done under general anesthesia, except in adult patient, where sedation with local anesthesia is given. Access in the femoral vein is obtained with placement of a 5-7 F sheath. A 5-F sheath is placed in the femoral artery. Heparin is used according to the operators’ preference. All of our patients were done without heparin.

Main PA pressure and aortic pressure is recorded with pull back gradient from ascending to descending aorta and PDA obtained to rule out any obstruction. Angiogram in the lateral projection is then performed with a catheter in the proximal descending aorta to calcify the PDA. The PDA size is measured and the PDA is classified by its shape.12

The device is selected so that the smaller end is at least 2 mm larger than the narrowest portion of the PDA. An end-hole catheter is passed from the main PA through the PDA into the descending aorta. A stiff exchange guide wire is placed with the tip in the distal descending aorta.

A 5-7F long sheath is then passed over the wire into the descending aorta. The appropriate-sized device is then screwed onto the delivery cable and pulled into the loader under water to prevent air entry into the device or sheath.

The device is then advanced to the tip of the sheath in the descending aorta without rotation of the cable. The sheath and device are then pulled back into a position just distal to the ampulla. The position of the device is confined with repeated angiograms in the descending aorta and adjusted until the retention skirt is well seated in the ampulla.

When good position is achieved, the sheath is retracted further and the tubular part of the device is opened within the PDA.

Another angiogram is performed in the descending aorta to confirm final device position up to this step, the device can be repositioned or retrieved if the angiogram showed significant residual flow; sometime a repeated angiogram is performed in the descending aorta ten minutes after. If device position is satisfactory, the pin vise is then fixed onto the delivery cable, and the device is released with counter-clockwise rotation.

Repeat pull back pressures are obtained from the left PA to the main PA and ascending to descending aorta to evaluate for possible pressure gradient.

The patient receives intravenous antibiotics for 24 hours and usually discharged on second day after evaluation by CXR, and echo-doppler study and kept on oral antibiotic for 5 days.

Observation of subacute bacterial endocarditis prophylaxis is recommended for six months or until complete closure is obtained. Patients are instructed to avoid contact sports for one month.

Follow-up the patient includes clinical evaluation, transthoracic echocardiography and CXR done after one month, six months, and one year after occlusion.

RESULTS

Of 149 patients included in the study, there was 98 female and 51 male, female to male ratio is 1.9:1. The patients ranged from 4 month to 45 years (median 5 years). Their body weights ranged from 4 Kg to 75 Kg (median 15 Kg) successful PDA closure from 149 patients with ADO device had been achieved in 136 patients (91.2%), unsuccessful attempts was because of failure to deploy the device in 11 patients (1%) and the embolization of the device which occurred in 2 patients.

Table 1 shows the PDA classification (A, B, C, D, E, and F); Type A was the most common in 94 patients.

In three patient it was not possible to classify the type certainly, because of the unusual orientation or the poor visualization even with repeated angiogram with views other than the standard views used in PDA like (right anterior oblique), and it is in those patients balloon was used to choose the proper size of the device.

PDA was the isolated heart defect in 128 (86%) patients. The other 21 (14%) patients had associated cardiac anomalies with the PDA. [Table 2].

The VSD was the most common associated anomaly 7 patients (4.6%). One patient had an ASD which was occluded by amplatzer septal occluder in transcatheter approach before referring for PDA occlusion, another 2 years old patients had coaractation of aorta with balloon aortic angioplasty done to him 1 year before referral to cardiac catheterization, no residual gradient was found between descending and ascending aorta and PDA.
successfully occluded without residual gradient.

One patient had stenosis at the origin of left PA before device deployment and the pressure gradient was obtained between main and left PA after effective PDA occlusion. In one of the patients who had interruption of inferior vena cavae with Azygous continuation to the superior vena cavae a difficulty was in advancing the sheath and dilator to pass the PDA to the descending aorta, this problem was overcome by using a snare to capture and pull the a guide wire from arterial side into position in the descending aorta.

One 36 year old female patient who had recanalized PDA after surgical ligation and with systolic and mean PA pressure of 40 mm and 10 respectively was successfully occluded by the device.

PA pressure was measured during cardiac catheterization in 105 patients. Their median mean PA pressure was 25 mm Hg (range 10-100 mm Hg) and the mode was 15 mm Hg. The remaining 44 patients, a record of systolic PA pressure was obtained from echo/Doppler study, which the median systolic PA pressure was 35 mm Hg (range 25-70 mm Hg) mode mm Hg.

Table 3 demonstrates that moderate size devices were used more frequently, i.e., size 8/6 9 10/8 in 46 9 28 patients, respectively, in two patients size 18 muscular VSD amplatzer device needed to be used to close PDA owing to their large PDA (wider than the largest ADO device available by manufacturer).

Failure of Deployment

Unsuccessful attempts to close the PDA were occurred in 11 patients. Two patients had severe pulmonary hypertension, because of their hemodynamic date before and after balloon closure of PDA they were considered not fit for PDA closure. As mentioned earlier.

In four patients the PDA was very large in size that even the largest available device prolapsed from the PDA, those considered not fit for device closure and were referred to surgery.

One 5-months-old infant with PDA measuring 4 mm A angiographically: A 6/8 mm. device prolapsed through the ductus, the next available size (8/10 mm) caused pressure gradient across aorta of 15 mm Hg, which was considered significant and the device removed before its released. Significant pressure gradient (more than 5 mm Hg) was encountered between the main and left PA after device deployment in 4 patients, for which the device was also removed [Table 4].

A few technical difficulties were encountered in several patients during the procedure. Kinking of the sheath at the right ventricular out flow tract or in pulmonary artery near the PDA, which led to difficulty in advancing the device. This was overcome either by reintroducing the dilator inside the sheath to straighten it again or by further advancing the sheath with the device inside it to pass the site of the kink, another problem faced is the difficulty to introduce the device into the sheath, size which recommended by the manufacturer for that device which needed to replace the sheath with larger one. None of these minor difficulties had led to revise the procedure. Complete angiographic closure of PDA, i.e., no residual shunt immediately or 10 minutes after device deployment was achieved in 96 (70%) patients, the remaining 40 patients had minimal residual shunt through device by angiography. All patients who underwent successful device deployment had complete closure and no residual shunt could be recorded 24 hours following the procedure by echo-Doppler study. Also no shunt could be detected on echo-Doppler examination in any patient at follow up.

Follow up the average duration of follow up is 3-9 month. Seventy-five patients were followed for one month, 39 patients had followed up after 1 and 6 months and 20 patients had followed after 1, 6 months, and 1 year following the procedure. The follow-up included clinical examination, CXR, echo/Doppler study. Of these patient 100% had complete closure documented by Doppler study, no evidence of device related

Table 1: Anatomical classification of patent ductus arteriosus (PDA) patients

| Type of PDA | Type | No. (%) | Type | No. (%) |
|-------------|------|---------|------|---------|
| Ventricular septal defect (VSD) | 7 (4.7) | Coarctation of aorta | 1 (0.67) |
| Mitral valve prolapse | 3 (2) | Right side aortic arch | 1 (0.67) |
| Aortic stenosis | 3 (2) | Aortic regurgitation | 1 (0.67) |
| Atrial septal defect | 2 (1.34) | Azygous continuation of IVC | 1 (0.67) |
| Mitral regurgitation | 1 (0.67) | Stenosis of origin of the left pulmonary artery | 1 (0.67) |

Table 2: The distribution of patients with associated cardiac anomalies participated in the study

| Type | No. (%) |
|------|---------|
| Size of device | No. (%) |
| 6/4 | 24 (17.3) |
| 8/6 | 46 (33.3) |
| 10/8 | 28 (20.2) |
| 12/10 | 25 (18.1) |
| 14/12 | 7 (5) |
| 16/14 | 6 (4.3) |
| VSD Occluder size 18 | 2 (1.3) |

Table 3: The size of the devices used in the study

| Patient No. | Cause of failure |
|-------------|-----------------|
| 4 | Larger than available device |
| 4 | Left PA stenosis |
| 4 | Aortic obstruction |
| 2 | Severe pulmonary hypertension |
obstruction, recanalization, thromboembolic episode, or clinical evidence of hemolysis.

Complications: Complications were encountered in 5 patients (3.3%) during or following procedure. Embolization of the device occurred in two patients. One three years old patient in whom the device embolize into the descending aorta immediately after release, while in the other seven years old patient with large PDA (14/12) device embolized to the pulmonary artery on the next day of closure. In both patients the device was successfully retrieved by snaring under fluoroscopic control.

The second five years old patient with severe pulmonary hypertension and large PDA, had pressure gradient between ascending and descending aorta after PDA occlusion of 10 mm Hg, which was considered not significant (any gradient of 10 mm Hg or less across aorta is considered to be non-significant) his femoral pulses was normal. On follow-up one month and six months later same gradient recorded on Doppler study.

The third patients developed residual pressure gradient between the main and left PA of 5 mm Hg was recorded after 8/6 sized device deployment in 1.5 years old patient on follow-up after one month, his CXR showed equal pulmonary vascular marking bilaterally and Doppler study could not pick up any pressure gradient.

The fourth complication was seen in a three years old female patient who had fever (38.5 degree centigrade) for three days following successful occlusion. No focus of infection could be catched clinically; here laboratory tests (including CBP, ESR, blood culture, and urine exam) were normal, the temperature fall down spontaneously after 5 days. No death related to use of device was reported in our series.

DISCUSSION

Since Portsmann et al. placed first Evalonfoam plug prosthesis in 1967, every effort had been done to develop a perfect transcatheter method for PDA occlusion. Diverse devices have been designed and some undergone modification according to the experience in their use and effectiveness. The use of these devices avoids the complications related to surgical procedure, diminishes hospitalization time by immediate recovery. It considers that ideal device is the device that uses catheters of low caliber, that has the capacity of retrieving, that with a delivery system which is effective and easily handled, besides to have the smaller percentage of residual shunts. The amplatzder duct occluder device was designed to provide the most desirable characteristics for percutaneous closure device. Many studies had been done worldwide to assess the safety and mid-term follow-up effectiveness of the ADO device and to compare it with other devices, in closure of PDA.

This study was designed to analyze the safety, efficacy, and follow-up results of percutaneous closure of PDA after reviewing the result of two years work and experience in using amplatzder duct occluder device as alternative to surgical closure of PDA. The results of this work are compared with the corresponding results of various published works.

Regarding the age of the patients different age groups included, even the two challenging extremes, i.e., infants and adults. Nine patients (6%) were less than one year of age and the least age was 4 months, in all except one (five months old baby the device caused aortic obstruction and removed before release) the PDA was successfully occluded and this is in agreement with the Fishers et al. study,[13] who considered transcatheter closure of PDA with ADO device in twelve patients under one year of age and showed possible to use this device successfully in the infant age group as duct closure was achieved in all but two symptomatic babies who were abandoned because of excessive procedural and fluoroscopy time; however, they experienced some specific technical difficulties involving kinking of the long sheath at the angle of the right ventricular outflow tract of the PA,[13] While in Butera et al. study,[14] in which 16 symptomatic children with mean age of 18.8 ± 10 months were included and their PDAs were successfully occluded by ADO device and without any complication. So they concluded that closure of moderate to large PDA in very young, symptomatic children is safe and effective technique and resolves the patient’s clinical problems.[14]

In adults, surgical closure poses challenges not encountered in pediatric patients. Friability and/or calcification of the ductus, atherosclerosis, and aneurysm formation may provide technical challenges[15] and the presence of other unrelated co-morbid conditions such as coronary atherosclerosis and renal disease may adversely affect the peri-operative risk.[16] From 12 (8%) adult patients included in this study, 11 (91.6%) had successful device deployment and the only one patient who excluded had so large PDA that the largest device did not fit inside. Those who had successful device placement, neither immediate nor later complication were seen. Similar favorable results in adult patients were encountered by Lee et al.,[17] Arora et al.[18] In their series of 5 adults with PDA, Lee et al.[17] reported a procedural success rate of 100% and there were no complications. Similarly in a series of 27 adults with PDA, Arora et al.[18] reported only one unsuccessful placement of ADO device. In Hong et al.,[19] series, out of 37 adults with PDA of wide variety of sizes 36 (97%) patients had successful deployment of ADO and in one patient the ductus could not be crossed so they concluded that the AOD device is both safe and effective for the closure of PDAs of all sizes in adults.

Although the manufacturer does not recommend the use of ADO in patients with body weight of less than 5 kg, two patient were included under that weight (4, 4.5 kg) in the treatment cohort, the procedure was achieved successfully in 6 months, 4.5 kg patient without
complication. However, the 5 months 4 kg patient, device placement caused a significant pressure gradient across aorta and it was abandoned. Although the device can be used in patients with less than 5 kg body weight, care must be taken for careful measurement of pull back pressure between ascending and descending aorta and from left to main PA to detect any obstruction that may result from device placement. This is in agreement with the manufacturer recommendation.

Other studies had included patients with weight less than 5 kg, the same agreement recorded in Fischer et al., series\textsuperscript{[13]} which include 7 patients under that weight (from 2.6-4.4 kg). In all except 2 patients Fischer et al., were successful in placing the ADO and there was subsequent complete occlusion with good result on follow-up. However, the procedure was not successful in two small infants of 2.6 and 4 kg body weight because of technical difficulty (kinking of the sheath at right ventricular outflow tract) and excessive procedural and fluoroscopy time.\textsuperscript{[13]}

Another paper by Bilkis et al.,\textsuperscript{[20]} reported experiences with ADO in 209 patients, among whom 27% were infant weighting less or equal to 5 kg. Kinking of the delivery sheath occurred in only one infant to the extent that device delivery was impossible. In another infant, mild aortic narrowing was caused by retention disc of the device.

Closure of PDA by ADO device can lead to favorable results, when associated cardiac anomalies with left to right shunt is present, 7 patients included had associated VSD two of them had significant pulmonary hypertension. Their PA pressure was declined significantly in all after device placement. A patient with ASD closed by transcatheter amplatzer septal occluder, had undergone transcatheter closure of his PDA by ADO device. Therefore, PDA occlusion could be helpful in either reducing surgical risk or even obviating the need for surgery in some patients, when PDA is associated with certain cardiac defects.

Regarding the 11 patients (7.3%) in which the device could not be deployed - Two patients were excluded because of severe pulmonary hypertension which made them unfit for PDA closure (i.e., not related to the device itself), in 4 patients with large PDA in which size 16/14 device (which is the largest device provided by the manufacturer) was prolapsed from the PDA. Manufacturing a larger sized device probably could solve this problem.

Although, size 18 mm muscular VSD amplatzer occluder device was placed successfully in 2 patients with large PDA in which size 16/14 was not fit, but the shape of the VSD device may not fit in all types of PDA, besides the VSD device is more expensive than the PDA devices, which make placing VSD device in a PDA not a practical solution. In the remaining 5 patients, because of their large PDA, placing device size suitable for PDA resulted in obstruction of aorta or left PA, and the device had to be removed by retrieving it into the sheath before release. This advantage of ADO devices to be retrieved, allows the devices to be removed if any complication was occurred from its placement.

Similarly, two unsuccessful attempts were mentioned in Shrivastava et al.,\textsuperscript{[21]} study from 41 attempts of PDA closure by ADO, 4 months old patient, because of aortic obstruction; Another one year old (4.8 kg) patient in which her PDA was considered too big for the device, considering her age and low weight, while in Hong et al.\textsuperscript{[19]} study,\textsuperscript{[13]} only 1 from 37 patients was excluded because the PDA couldn’t be crossed. In Fischer et al.\textsuperscript{[13]} study the procedure was unsuccessful in 2 out of 12 infants because of the technical problems (kinking the sheath) which resulted in excessive procedure time. While no unsuccessful attempts were mentioned in Waight et al.,\textsuperscript{[15]} Butera et al.,\textsuperscript{[14]} Bockeria et al., studies.\textsuperscript{[22]}

Regarding technical difficulties, kinking of the sheath was encountered in a number of our patients but none of the technical problems were severe enough to discontinue the procedure. In the Fischer et al. series\textsuperscript{[13]} kinking of the long sheath at the right ventricular outflow tract had occurred in 9 of the 12 infant (75%), and in five of 25 older patients 20% included in the series. They overcame this problem by snaring the long sheath from systemic arterial side, or by exchanging the long sheath by larger cook sheath, despite that two small infants were excluded because of this technical difficulty. While in Bilkis et al. study\textsuperscript{[20]} which included 209 patients kinking the delivery sheath occurred only in one infant to the extent that device delivery was impossible.

Complications had occurred in five patients (3.5%), of which device embolization was most important. In the first patient the device which was size 10/8 embolized just after release from delivery cable to the descending aorta, while in the other patient the device embolized 24 hours after the procedure to the PA. In both, the device removed by sneering without surgery. The embolization was probably because of large distensible PDA, improper device size used or improper fixation at the PDA. Both cases occurred in the few weeks after starting the work with ADO device. This complication not recorded in later weeks probably because of buildup of experience with device use. Embolization was reported as a cause of death in Bilkis et al. study,\textsuperscript{[20]} while in our study the embolized device was removed by snaring and no complication later on. The other two complications were residual gradient across. The aorta of 10 mm Hg in one patient and across left PA (5 mm Hg) of the other patient. The same aortic gradient recorded in the patient during 6 month follow up, but the PA gradient could not be picked up by Doppler study after one month. Although we considered this insignificant gradient as a complication, in Hong et al. series\textsuperscript{[15]} he recorded pressure gradient after closure was up to 11 mmHg in aorta and up to 4 mm Hg at the PA, which was considered as part of procedure and not complication.
Several complications had been encountered by other series. A significant aortic obstruction, requiring surgical removal of the device was reported by Duke[20] in 2 years old girl after ADO device deployment. In Fischer et al. study[13] complications related to the procedure such as blood loss needed transfusion (one patient) or femoral artery thrombosis (one patient) only occurred in under one year age group. While in Hong et al. study[19] complications were encountered in four patients (from 37 Patients), one had AV fistula of femoral artery, two had groin hematoma and one had allergic reaction, none were attributed to device implantation, but rather the catheterization procedure itself. In Waight et al., study[11] only one patient was noted to have post procedural complication of mild coarctation of the aorta requiring stent implantation (total complication rate was 1.2%). Other studies did not record any complications.[14,15] In published results of the international clinical trial with ADO reported 15 procedure related complications in 316 patients who underwent attempted transcatheter closure of PDA. Complication included hemolysis, left PA stenosis, device protrusion into aorta, causing coarctation, device misplacement, and one death following device embolization.[11,24] No late complications were recorded on follow-up in this study or any other study related to device implantation. In Bilkis et al.[20] series they reported one death following device embolization, while no death recorded in other series.[11,24]

CONCLUSION AND RECOMMENDATION

ADO device is effective alternative for PDA occlusion. It meets with most of the desirable characteristics of percutaneous closure device that can be used in most if not all patients with PDA. However, care must be taken when the device used in patient less than 5 kg body weight especially those with large PDA because of their small aortic size, to avoid any complication that might result.

Although ADO device has low early complication rate and no recorded complication on intermediate follow-up, we emphasis on care needed during cardiac catheterization for pressure recording in aorta and pulmonary artery, before and after device placement, and careful angiographic assessment of the device position, particularly the position of aortic ring, before and after detaching the device from its delivery system.

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