

TRANSCATHETER CLOSURE OF PATENT DUCTUS ARTERIOSUS USING THE AMPLATZER DUCT OCCLUDER AT QUEEN ALIA HEART INSTITUTE: MEDIUM-TERM FOLLOW-UP

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ABSTRACT

Objectives: Transcatheter closure of patent ductus arteriosus is a well-established procedure. The aim of this study was to assess the medium term results of patent ductus arteriosus closure using the Amplatzer Duct Occluder.

Methods: From January 1998 to January 2005, 204 cases (77 males and 127 females) underwent an attempt of transcatheter closure of their patent ductus arteriosus at Queen Alia Heart Institute using the Amplatzer Duct Occluder™ device. Their median age was 3.5 years (range 0.8-13 years), their median weight 14kg (range 6-32kg), their mean Qp/Qs was 2.3 ± 0.6 , their mean systolic pulmonary artery pressure was 38.44 ± 7 mmHg. The mean narrowest diameter of the pulmonary end of the patent ductus arteriosus angiographically was 4.2 ± 0.8 mm (range 3-8mm). The devices used were (6-4, 8-6, 10-8 and 12-10mm) delivered antegrade via 5-7 French sheaths. All patients had chest X-ray and color flow echocardiographic follow-up at 24 hours, one, three, six months and yearly thereafter.

Results: There was immediate and complete closure of the ductus in 180 (88.24%) of cases. The remaining 24 (11.76%) patients had a trivial residual shunt through the device mesh. Follow-up color flow Doppler echocardiography revealed complete closure of patent ductus arteriosus in 96% of cases at 24 hours, and complete closure at one month follow-up in 100% of cases. One patient developed aortic obstruction where the duct joined the aorta at a more acute angle, which was retrieved surgically. Otherwise no other complications were reported. Neither thromboembolization nor hemolysis or recanalization of the ductus was reported. Furthermore, chest radiographs and Doppler echocardiography follow up revealed no evidence of wire fracture or device disruption or any episodes of infective endocarditis.

Conclusion: Since the initial clinical experience in 1998, the transcatheter closure of patent ductus arteriosus using the Amplatzer Duct Occluder has proven to be an easy procedure that could be mastered quickly but with caution and at the same time it is an effective procedure that has almost replaced surgery in our center. Longer follow up will be needed to precisely define the safety and indications of this device.

Key words: Amplatzer Duct Occluder, Patent ductus arteriosus, Medium term follow up

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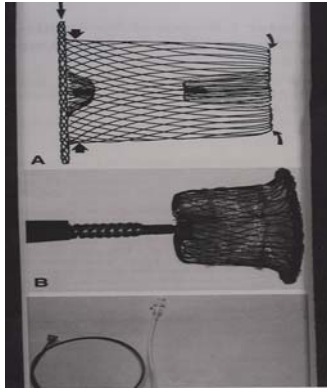


Fig. 1. The Amplatzer Duct Occluder device

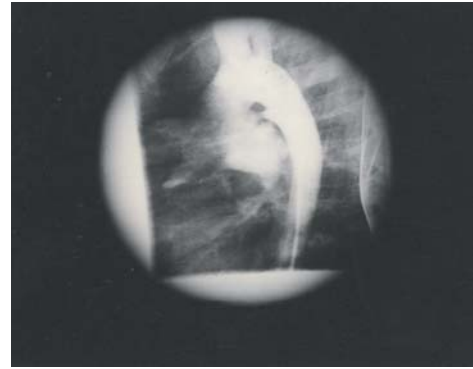


Fig. 2. Angiogram in the descending aorta shows the patent ductus arteriosus between the descending aorta and the left pulmonary artery



Fig. 3. Angiogram in the descending aorta shows the deployment of both aortic and pulmonic discs of the device in the ampulla of the ductus

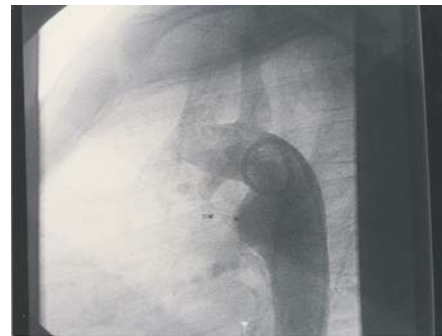


Fig. 4. Angiogram in the descending aorta after release of the Amplatzer Duct Occluder device shows complete closure of the ductus arteriosus

Introduction

Isolated patent ductus arteriosus (PDA) is the second most common congenital heart disease⁽¹⁾ accounting for 10-18% of cardiovascular malformations.⁽²⁾ Closure of PDA even with small shunt volumes in asymptomatic patients is recommended because of the risk of endocarditis (1.5% per year) and the potential development of congestive heart failure or pulmonary hypertension.⁽³⁾ Transcatheter occlusion of persistent ductus arteriosus has replaced surgery as the treatment of choice⁽⁴⁾ and became a well established technique with low morbidity and no reported mortality.^(1,5) The aim of the study was to assess the short and intermediate results of the transcatheter closure of PDA using the self expandable, self centering and repositionable Amplatzer Duct Occluder Device (ADO) at Queen Alia Heart Institute (QAHI).

Methods

From January 1998 to December 2005, 204 patients (77 males and 127 females) with PDA underwent an attempt of transcatheter closure of their PDA at QAHI using the ADO device. Their median age was 3.5 years (range 0.8-13 years), their median weight 14 Kg (range 6-32Kg). All patients had clinical and echocardiographic evidence of a PDA. Patients who were excluded from the study are those who had small PDA's <3mm who underwent coil closure and those with large PDA's >8mm who were sent for surgery. Most of our patients were asymptomatic, 15 patients presented with failure to thrive, and 45 patients with recurrent respiratory symptoms. Informed consent was obtained from all patients or their guardian.

The ADO device that was used is a self expandable, mushroom-shaped device that has been described in details in previous studies^(5,6) (Fig. 1).

The sizes of the devices that were used were: 6-4, 8-6, 10-8 and 12-10mm, which were delivered antegradely via 5-7 French sheath. The technique of transcatheter closure was similar to that described by Masura *et al.*^(6,7) (Fig. 2,3,4).

Prophylactic antibiotics with second-generation cephalosporin were given during the procedure to every patient in a dose of 25mg/kg every eight hours for three doses. After 24 hours the patient was discharged home on no medications. Follow up of patients was done by doing serial Chest X-Rays in postero-anterior and lateral positions, and 2D-echo with color flow mapping which were done at 24 hours, one, three and six months after the closure then yearly thereafter in order to assess; position of the device, presence of residual ductal flow, recanalization, left pulmonary artery stenosis, coarctation of the aorta, and wire fractures.

Results

According to the classification that was adopted by Krichenko *et al.*⁽⁸⁾ One hundred sixty seven patients had PDA type A, two patients had PDA type B, 17 patients had PDA type C, six patients had PDA type D and 12 patients had PDA type E. The mean systolic pulmonary artery pressure was 38.44 ± 7 mmHg. The mean Qp/Qs was 2.3 ± 0.6 . The mean narrowest diameter of the pulmonic end of the PDA angiographically was 4.2 ± 0.8 mm. Complete and immediate angiographic closure was present in 180 patients (88.24%). The remaining 24 patients had a trivial residual shunt. In one patient, who had a PDA type E according to Krichenko *et al.* classification, the duct joined the aorta at more acute angle than usual, so during the deployment of the aortic retention disc it ended projecting into the aortic lumen, obstructing more than half of its lumen, which was confirmed by 2D-echo and was retrieved later on surgically. This patient was excluded from our follow up plan. No patient required blood transfusion. At 24 hr, color Doppler flow revealed complete closure in 196 patients (96%). At one month follow up it showed a complete closure in the 203 patients (100%). Follow up data were available to 195 patients at three, six months after the closure, and yearly thereafter with no evidence of wire fracture, device migration or recanalization, evidence of hemolysis, thromboembolism or endocarditis. The symptomatic patients improved dramatically after the closure;

regarding their weight gain and respiratory symptoms.

Discussion

Since Porstmann *et al.* success in closing PDA by transcatheter route using an Ivalon plug in 1969,^(6,9) numerous different occluding devices and coils have been used with satisfactory results,^(10,16) leaving the conventional surgical ligation of the PDA reserved for symptomatic preterm infants or large ducts.⁽¹⁷⁾ The ideal device has been chased for decades since Porstmann *et al.* introduced the Ivalon plug nearly 37 years ago. The ideal device should possess the 'wish-list' characteristics⁽¹⁸⁾ including: low cost, ease of delivery using smaller introducer sheaths, should achieve high complete closure rate, lower morbidity and mortality compared to surgical closure.⁽¹⁶⁻¹⁸⁾ Rashkind occluder device was once accepted and used widely, but its high cost, the large transvenous sheath, the high incidence of late residual shunt with the significant risk of LPA stenosis led to the continuous search for alternatives.^(10,12,17,18) Recently, Gianturco coils have been used on a wide scale to close PDA's non-surgically due to its low cost, ease of delivery using smaller catheters, and its high closure rate approaching 98%-100%.^(5,16,18) The coil has disadvantages, the most important one is the lack of a controlled-release mechanism, that once they are released they cannot be retrieved back. Recently, controlled-release coils have been developed⁽¹⁹⁾ and are available for use, but still not in our center. Another disadvantage is its unsuitability for use in large PDAs. So, the drawbacks of these devices namely; the high incidence of residual shunts, the sometimes complex delivery system and their unsuitability for large PDA's and infants^(6,18,20) had led to the newly introduced ADO device which has a number of plausible features;⁽¹⁷⁾ namely retrievability up to the point of deployment and the ease of the delivery system using 5F to 7F long sheath, its suitability for all sized PDA's.^(5,17,21) Several studies reported the immediate and short term results of transcatheter closure with ADO regarding the 100% occlusion rate, yet still significant complications had occurred including death, hemolysis, device embolization, device misplacement and significant blood loss during the procedure.^(10,17,18,22) In our series of 204 patients the closure was successful in all of our patients. One

significant complication had occurred as mentioned before; the device had obstructed more than half of the aortic lumen causing pseudo coarctation, constituting 0.97% of patients which could have been avoided with careful selection of patients and careful implantation of the device. Otherwise no late minor or major complications such as bleeding, hemolysis, deaths, device embolization or displacement, and wire fracture had occurred including. The symptomatic patients improved dramatically. The youngest patient who underwent PDA closure was eight months of age with body weight of 6kg. Our future challenge is to try to close PDAs in younger patients with weight of less than 5kg since the experience in neonates and younger patients is limited worldwide.^(7,17)

Conclusion

Since the initial clinical experience in 1998, the transcatheter closure of PDA using the ADO has proven to be an easy procedure that could be mastered quickly but with caution and at the same time effective procedure that it has almost replaced surgery in our center. Longer follow up will be needed to precisely define the safety and indications of this device, especially in younger patients.

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