The initial experience and outcomes of patent ductus arteriosus closure at Nelson Mandela Academic Hospital, Mthatha, Eastern Cape

Zongezile M. Makrexeni and L. Bobotyana

Department of Paediatrics and Child Health, Faculty of Medicine and Health Sciences, Walter Sisulu University, Mthatha, South Africa

Address for correspondence:
Professor Zongezile M. Makrexeni
Paediatrics and Child Health
Head Clinical Unit - Paediatric Cardiology
Nelson Mandela Academic Hospital and Walter Sisulu University
Nelson Mandela Drive
Mthatha
5100
South Africa

Email:
mmmaso30@gmail.com

Zongezile M. Makrexeni ID: https://orcid.org/0009-0007-3903-5891
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ABSTRACT

Background: Transcatheter closure of the patent ductus arteriosus (PDA) is a common intervention worldwide. An initial experience and outcomes in percutaneous closure of patent ductus arteriosus in a new catheterisation laboratory at Nelson Mandela Academic Hospital (NMAH) in Mthatha was reviewed.

Methods: Data regarding ductal closure using the Amplatzer Duct Occluder type I (ADO1) and Amplatzer Vascular Plug II (AVP II) were reviewed and prospectively collected. Demographics, haemodynamics, angiographic patent ductus arteriosus type, complications and outcomes were documented.

Results: A total of 26 patients underwent percutaneous patent ductus arteriosus closure from September 2019 - August 2021(1year 11 months). There were 17 females and 9 males. The median age of the patients was 23 months (range 3 - 60 months) and the median weight was 8.3kg (range 3.6 - 14kg). The mean pulmonary vascular resistance was 4 Wood unit (WU).

Seven patients had Krichenko Type C Duct (27%) and 15 (58%) patients had Type A Duct. The ductal size (narrowest diameter at the pulmonic end) mean was 6mm for the Type C Ducts and 3.5mm for the Type A Ducts. Fluoroscopy time was mean was 18 minutes and the radiation dose was about 450 microGreys.

Out of the 26 patients that were done catheterisation, 4 patients were not done patent ductus arteriosus closure. Of the 4 patients, 2 patients had tiny PDAs that could not be closed percutaneously, and the other 2 patients had associated coarctation of the aorta.

Six of the 7 patients with Type C Duct were closed successfully with Amplatzer Vascular Plug, and 1 patient had device embolisation. Fifteen patients with Type A Duct were closed successfully with Amplatzer Ductal Occluder 1 with no complications. Complete ductal occlusion was achieved in 21 patients on day 1 and only 1 patient had residual ductal flow following the ductal closure.

Conclusion: Percutaneous ductal closure with Amplatzer Duct Occluder at Nelson Mandela Academic Hospital is comparable to other centres in South Africa in terms of safety and outcomes. SA Heart® 2025;22:56-60

INTRODUCTION

Nelson Mandela Academic Hospital is situated in the former Transkei region of the Eastern Cape. The hospital services around 6 million people and is the only referral hospital for the former Transkei region. For the longest time it had no paediatric cardiologist until 2019. There is a new catheterisation lab with a Phillips machine that was bought previously and was never used because there were no cardiologists at the time. Since September 2019, we started using the catheterisation lab to do diagnostic and intervention catherisations.

Percutaneous closure of the patent ductus arteriosus (PDA) is the main therapy for this congenital heart defect. The PDA incidence is around 11.9% - 15.6% of all congenital heart defects.[1-2] Over 2 decades, a wide range of devices have been employed for transcatheter closure of the PDA from small infants to adult patients.[3-15]

The Amplatzer Duct Occluder (ADO 1) has proven to be an elegant device that allows moderate and large sized ducts (up to 11mm in diameter) to be successfully occluded by the percutaneous approach. It combines ease of implantation with a high occlusion rate and a low rate of procedure related complications.[16-17] The procedure can be safely carried out in infants >3.5kg in weight with symptomatic PDA.

METHODS

The data of patients who have undergone patent ductus arteriosus closure was collected. Patients' age, sex and weight were documented during the time of PDA closure. Haemo-

dynamic characteristics were documented and included quantification of the left to right shunting, Qp/Qs, and pulmonary vascular resistance (PVR) before ductal closure. Angiographic data including ductal size (narrowest diameter at the pulmonary end), aortic ampulla, ductal length, and the shape or type of the PDA were recorded.

The duct was defined as small if the narrowest diameter was <2mm; moderate size, if the narrowest diameter was 2 - 3.5mm in patients with symptomatic heart failure; and large if it was >3.5mm in symptomatic patients or >4mm in asymptomatic patients.[18]

The ductal shape was classified using the Krichenko angiographic morphological classification.[19] Device type and size, screening time, including complications and outcomes were noted. Presence of other congenital heart disease was also documented. Values were reported as mean and range.

The follow-up plan involved review at 7 days post PDA closure, 1, 3, 6, 12 months and finally 2 years following percutaneous ductal closure.

DEVICE DESCRIPTION

Amplatzer Duct Occluder

The Amplatzer Duct Occluder (AGA Medical Corporation, Golden Valley, MN) is a self-expanding and self-centering device, made from 0.0004 to 0.0005-inch Nitinol wire mesh. It is mushroom-shaped with a low profile and consists of a flat retention disc and a cylindrical main body, into which polyester fibers are sewn. Platinum marker bands are laser welded to each end and a steel sleeve with a female thread is welded into the marker band (Figure 1).

The retention disc is 4mm larger than the main body, which itself has a conical structure. The delivery system consists of a delivery cable, a Mullins-type sheath, loader, and a pin vice. The device comes in different sizes, requiring sheath sizes from 5-7F for delivery. The size of the device chosen is generally such that the diameter of the pulmonary end of the device is at least 2mm larger than the narrowest diameter of the duct.

The device sizes are categorised according to the diameters of the aortic and pulmonary ends of the device. The standard device sizes are 6/4, 8/6, 10/8, 12/10, 14/12, and 16/14mm respectively, where the first number refers to diameter of the aortic end and the second number to the pulmonary end of the conical shaped device. The devices are all 7mm long. They can be delivered through sheath sizes ranging from 5F (for devices up to 8/6mm) to 7F for devices larger.

The AmplatzerTM Vascular Plug II (AVP II)

The AVP II is a multi-layered mesh designed to increase density and flow disturbance. It has 6 planes of cross-sectional coverage resulting in rapid occlusion of the vessel (Figure 2). When you preparing to close the duct, you must select a device that is 30% - 50% larger in diameter than the diameter of the vessel.

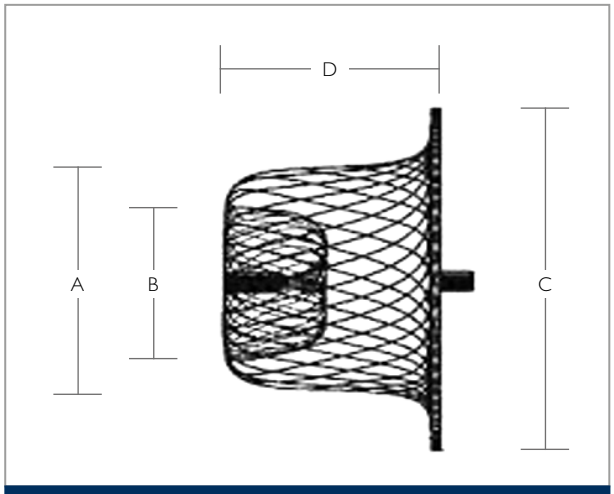

FIGURE 1: A: Device diameter at descending aorta. B: Diameter at pulmonary artery. C: Retention skirt diameter. D: Device length. (Figure used with permission from Abbott Cardiovascular, 5050 Nathan Lane, North Plymouth, MN 55442).

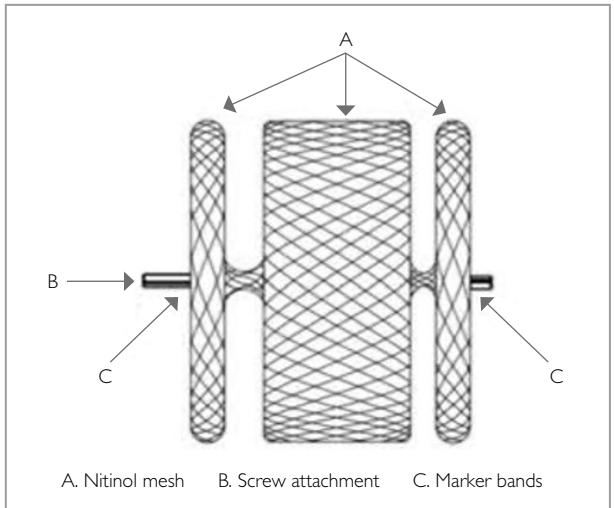

FIGURE 2: Amplatzer Vascular Plug. (Figure used with permission from Abbott Cardiovascular, 5050 Nathan Lane, North Plymouth, MN 55442).

PATENT DUCTUS ARTERIOSUS OCCLUSION PROCEDURE

The patient is usually prepared for routine cardiac catheterisation. Under sedation, the patient is scrubbed and draped. Femoral arterial and venous access is achieved, using standard vascular access short sheaths. About 50IU/kg of heparin is given. Descending aortography in the straight lateral view is performed. The size and the shape (type) of the PDA are then determined and classified using the Krichenko classification. The ductal anatomy information is used to select the device size compared to ductal size and device length (long shank vs. short shank).

Approximately, 1 - 3mm larger device than ductal size is chosen to occlude the duct. Standard left and right cardiac catheterisation procedure is performed. Calculations to ascertain the extent of left-to-right (or right-to-left) shunting and pulmonary vascular with systemic vascular resistances are done. Following angiography and haemodynamic data, the decision to or not to close the PDA is made. If the PDA is amenable to percutaneous closure based on the size and length of the duct, an appropriate device is selected using the manufacturer's device selection table as a guide.

The delivery system is flushed using heparinised saline. A 0.035" guide wire is passed across the PDA using an end-hole catheter. A size 6F - 9F Cook's Mullins long sheath is used as a delivery system and this sheath is passed across the PDA over the guide wire. Blood is allowed to flow through the side connector, to purge all air from the system. The delivery wire is passed through the loader. The device is attached to the delivery wire using a screw mechanism. Under water, the device is retrieved into the loader so that its distal radiopaque end is at the tip of the loader. The loader is then firmly introduced into the delivery sheath. Under fluoroscopy, the device is advanced into the sheath using the delivery wire until it reaches the tip of the delivery sheath. At this stage, the whole assembly is repositioned until the operator is satisfied to deploy the distal (aortic) disk. Once the distal disk is well positioned and conforms to the vessel wall, the shank is deployed.

Angiography may be performed at any stage of device deployment using the Cook's side connector and an angiographic catheter to check for device positioning in the duct, pulmonary, and aortic positioning. The device is released, repositioned, or retrieved as the operator deems fit. The patient receives an intravenous antibiotic and may receive infective endocarditis prophylaxis for 6 months. The patient is followed up at 1 day, 1, 3, and 6 months, 1 year, and 2 years following transcatheter closure of the PDA using this device, to look for complications that may arise from the catheterisation procedure or the device itself.

RESULTS

Over a period of 1 year and 11 months (September 2019 - August 2021), 26 patients underwent PDA percutaneous closure using Amplatzer Duct Occluder (ADO 1) and Amplatzer Vascular Plug (AVP II). Of the 26 patients that were taken for PDA closure, 4 of them were not closed. Two patients had small PDA of 1mm and could not be closed. The other 2 patients had associated coarctation of the aorta with the large PDA and were refereed for surgical closure of the PDA and coarctation repair.

Patient basic characteristics are presented in Table I.

The angiographic data, basic haemodynamics, device selection and outcomes are presented in Table II.

The smallest device used was a 6/4mm ADO, and the largest device was a 14mm AVP. The average device size was 8/6mm ADO and a 12mm AVP. Only 2 patients required upsizing of the device due to severe residual flow on angiogram prior to release of the device.

There was only 1 patient who had a PDA and a restrictive perimembranous ventricular septal defect (VSD) which was treated conservatively.

Only 1 patient had a device embolisation on day 5 of device closure. This was a 12-month-old baby with a large 5mm tubular duct. The baby weight was 6kg. Due to the size of the PDA on angiogram measurements, we opted for the 10mm AVP for closure of the duct. Post device release there was a significant residual left to right shunting of the contrast on angiogram and echocardiogram. We opted to observe the patient because the device was holding well despite some leak that was seen. Five days later we discovered that the device had embolised into the left pulmonary artery with a good pulmonary blood flow into the lung. The device embolised due to under-sizing of the duct.

TABLE I: Patient basic characteristics / demographics.

Number of patients	Sex	Age	Weight
26	Male - 9	Median - 23/12	Median - 8.3kg
	Female - 17	Range - 3 - 60/12	Range - 3.6 - 14kg

TABLE II: Angiographic data, basic haemodynamics, PDA sizes, device used and outcomes.

PDA Type	Number	Diameter	QP / QS	PAP	PVR	Device used	Outcome
Type A	15	Mean - 3.5mm	Mean - 1 - 2: 1	Mean - 30mmhg	Mean- 4WU	ADO I	100% limmediate closure
Type C	7	Mean - 6mm				AVP II	1 device embolisation 6 successful closures

All the patients had complete ductal occlusion on day 1 of the procedure and on discharge. Patients were followed up on day 7, 1, 3, 6, 12 months and some are due for the 2 years follow-up soon.

DISCUSSION

In the period of the study, which is September 2019 - August 2021, we managed to successfully close 22 PDA with only one complication. This is for the first in Mthatha, Nelson Mandela Academic Hospital, Walter Sisulu University, that we have done this intervention.

So far, the unit has been using the Amplatzer devices because of the consignment that we have with the company. We were unable to use other devices due to unavailability of the agreement between the hospital and the other companies. Also due to the lock-down levels 3 - 5 that we had in 2020 during the outbreak of the COVID-19 in South Africa, our Cath lab was closed, and we could not do any cases for a period of 6 - 8 months and that has affected the number of cases that we did in 2020.

The average age at ductal closure was 23 months. The youngest patient was 3 months old. This shows that most of the patients were diagnosed very late with the PDA and therefore could only be closed at almost 2 years of age. This data is almost like what Prof L. Pepeta, et al. described in their study of the ductal closure using Occlutech Duct Occluder in Port Elizabeth.[20] Due to the late presentation of the patients to the cardiology clinic and delayed ductal closure, most of the patients had high pulmonary artery pressures and a high PVR at the time of closure.[20]

In terms of the weight at the time of closure, the smallest patient was 3.6kg and the biggest was 14kg. The 3.6kg baby was the youngest of the cohort with symptomatic PDA. The average weight at closure was 8.3kg. Therefore, most of our patients presented late with advanced age compared to some of the other studies of PDA closure in small babies. This was partly because previously the cardiac clinic at NMAH was run by junior non-cardiologist doctors and sometimes the patients are missed in the district hospital.

Most of the patients had Type A Duct, and few had a tubular duct. There were no patients with Type D and E Ducts in our cohort.

The Amplatzer Duct Occlude device is known to have a high occlusion rate of about 99% within 6 months of device deployment with minimal complications.[16-17] This was also the case in our cohort, 100% of our patients had complete occlusion of the duct on discharge and 6 months later the duct was still closed. There were no significant complications on the Amplatzer Duct Occluder group of patients.

The determinants of success with the Amplatzer Duct Occlude in our cohort was multifactorial:

- Correct diagnosis and measurement of the PDA.
- Correct selection of the device type and the device sizes based on the type and size of the PDA.
- Doing the procedure of PDA closure following all the steps as described in the manuals.

The Amplatzer Vascular Plug 11 has been used for the closure of selected patent ductus arteriosus types more especially Type C Tubular Duct with good outcomes. The device can also be used in other morphological types of the duct and in small patients. It is a low profile, easily repositioned, and has excellent results.[21]

Out of the 22 patients that were occluded with Amplatzer Duct Ocluder and Vascular plug, there was only one device embolisation and 21 successful PDA closures with no complications. There was a 100% ductal closure on day 1 of ductal occlusion and on follow up until 6 months.[22]

The only patient that had a device embolisation was a 1-year-old child with failure to thrive weighing 6kg. The patient had a large tubular duct of 5mm on angiographic measurements. The decision was to use size 10mm AVP to close the duct based on

the angiographic measurements that were repeated more than twice. Following the placement of the device in the duct, there was a good closure on the first angiogram before the device was released. The device was eventually released completely, and a follow up angiogram was done. There was a shift in the positioning of the device following release and there was a residual left to right shunt about 2.5mm in size. The echo-cardiogram was done which also confirmed a 2.5mm residual duct and the device was in situ. The decision was to observe the patient and see if the leak will get better overtime or not.

The patient was kept in the ward and the follow up echos done to confirm the positioning of the device and to monitor the leak. On day 5 post device deployment, the echo was done which showed significant PDA flow and the decision was to take the child for repeat Cath and device retrieval and to upsize and use a bigger device. The device had embolised into the left pulmonary artery at the time. The positioning of the device in the pulmonary artery made it difficult for the device to be retrieved in Cath lab because the screw was against the wall of the LPA and facing towards the branch pulmonary artery. The patient was referred for surgery removal of the device.[20]

CONCLUSION

The Amplatzer Duct Occluder can be used successfully in patients as small as 3.5kg and above in carefully selected patients with minimal complications. The initial experience and outcomes in PDA closure in the new Cath lab in Mthatha are satisfactory.

Conflict of interest: none declared.

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