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COMPLEMENTARY TECHNIQUES OF PERCUTANEOUS CLOSURE OF DUCTUS ARTERIOSUS USING DETACHABLE COOK COILS AND AMPLATZER DEVICES

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COMPLEMENTARY TECHNIQUES OF PERCUTANEOUS CLOSURE OF DUCTUS ARTERIOSUS USING DETACHABLE COOK COILS AND AMPLATZER DEVICES

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ABSTRACT

Background: Patent Ductus Arteriosus (PDA) is a common cardiac malformation whose treatment locally has been surgical ligation via a lateral thoracotomy. Device closure of the ductus was first performed at the Mater hospital in 1999 in a ten year old male using a five millilitre detachable cook coil. In 2000 the Amplatzer device was introduced to close larger ducts. Subsequently these devices have been used interchangeably to close both small and large ducts. We report this single centre experience of percutaneous PDA closure in a resource-limited setting; utilising the two techniques.

Objective: To describe our experience of trans-catheter closure of small and large ducts using either the detachable Cook coils or the Amplatzer occluders at the Mater Hospital Nairobi.

Design: A descriptive retrospective cohort study.

Setting: The Mater Hospital, Nairobi, Kenya.

Subjects: Patients with clinical and echo-cardiographic features of patent ductus arteriosus who underwent cardiac catheterisation and angiography followed by device embolisation of the ductus.

Results: From April 1999 to October 2009 a total of ninety eight subjects were recruited into the study. Sixty nine (70%) of these subjects had the ducts closed using the Amplatzer devices, while twenty nine (30%) were embolised using the cook detachable coils. Three of the subjects in the coil group had the ducts embolised using the double technique while the rest were embolised using single coils. Various coil sizes four to eight millimetres were used in patients with small to medium ducts (two to seven millimetres) whereas the Amplatzer duct occluder was successfully used in all the duct sizes. The Amplatzer atrial septal occluder device was used to close very large ducts in two of the patients. The overall success rate was 93.1%, but the coil group had higher failure rate of 6.9% compared to the Amplatzer group of 3%. One patient in the Amplatzer group had a late embolisation requiring surgical retrieval at one month post occlusion. There were no mortalities.

Conclusion: Transcatheter device occlusion of PDA is a safe and alternative to

surgery associated with minimal morbidity and no mortality

INTRODUCTION

Patent ductus arteriosus (PDA) is a common congenital heart disease occurring in 1:2000 neonates delivered at term. As an isolated malformation it accounts for 10 to 18% of all cardiovascular malformations and is more common in females. Left untreated PDA can be complicated by failure to thrive, recurrent chest infections, cardiac enlargement and failure, bacterial endocarditis and endarteritis (1) and sadly in this environment irreversible pulmonary hypertension due to late presentation. A diagnosis of PDA therefore constitutes an indication for treatment. Locally, treatment of PDA has been surgical ligation through a lateral thoracotomy. This simple surgical

procedure can be complicated by bleeding, recurrent laryngeal nerve palsy, thoracic duct damage and chylothorax and in some instances recanalisation of the ductus (1).

The cardiac catheterisation unit of the Mater hospital was established in 1995. In April 1999 a ten year male child with recurrent recanalised ductus from two previous surgical ligations had successful embolisation of his ductus using a 5 mm detachable cook coil. The same year in August, five more patients with small ducts were successfully closed using detachable cook coils. The Amplatzer device was first used in the unit in 2000 initially for closing larger ducts of 5mm and more. Later the use was extended to close smaller ducts of 3 to 5 mm, however with time due to the erratic local supply and the expense, the multiple coils were used to close

larger ducts either through the arterial route or a combination of trans-venous and trans-arterial routes. We hereby report our single institution experience of the complementary use of either type of devices to close small and larger ducts at the Mater hospital.

MATERIALS AND METHODS

This was a descriptive retrospective cohort study conducted from 1999-2009. Patients with clinical and echo-cardiographic features of patent ductus arteriosus who underwent cardiac catheterisation and angiography followed by device embolisation of the ductus were selected. The diagnosis of PDA was based on characteristic clinical and echo-cardiographic features. Selection for cardiac catheterisation was not randomised but depended on size of the duct at echocardiography and the size of device available in the cardiac laboratory at the time of diagnosis. During cardiac catheterisation deep sedation was given to infants and children up to 12 years while local anaesthesia and conscious sedation was given to older children and adults. Intra-venous Cefuroxime was used for anti-biotic prophylaxis in all the patients and intra-venous heparin at 100 units/kg body weight was given once vascular access was obtained. After catheterisation, angiography was performed to confirm the echo-cardiographic findings followed by device embolisation using either the cook coils or Amplatzer devices. The extracted included patients baseline parameters of age, sex, weight and height, echo-cardiographic parameters including size of ductus, pulmonary pressures, catheterisation data including size and type of device, technique of

embolisation, outcomes and complications of the procedure. After the initial learning curve from a constant visiting interventional cardiologist the procedures were performed by the same local doctors except for double coil embolisation. Premature babies, patients with very large ducts and those with clinical and echo-cardiographic evidence of severe pulmonary hypertension including Eisenmenger physiology were excluded from the study. Ethical clearance was obtained from the hospitals standard and ethics committee

Techniques of implantation: The coil group; Two techniques were used to close the PDA using coils, the single coil technique and the double coil technique

Single coil Technique: The single coil method was performed retrograde through femoral artery using 5 or 6f introducer sheath. An aortogram was performed in the lateral- lateral position to profile and measure the size of the PDA for purpose the appropriate size of coil (Figure 1A). A Judkins right coronary 5 or 6F was used to enter duct from the descending aorta. A suitable coil, connected to delivery wire was then inserted into catheter and advanced into pulmonary artery. The mandil was then withdrawn to produce loop in the duct, then the catheter withdrawn to extrude coil in ductal ampulla (Figure 1B). The coil was then detached and post delivery angiograms were performed (Figure 1C). The final position was confirmed in the antero-posterior view (Figure 1D). Post procedure chest X-ray and echo-cardiogram performed before releasing the patient to the High dependency unit for monitoring.

Figure 1 (A-D)

Figures showing the procedure for embolisation of the duct using single coil technique assessed from the descending aorta

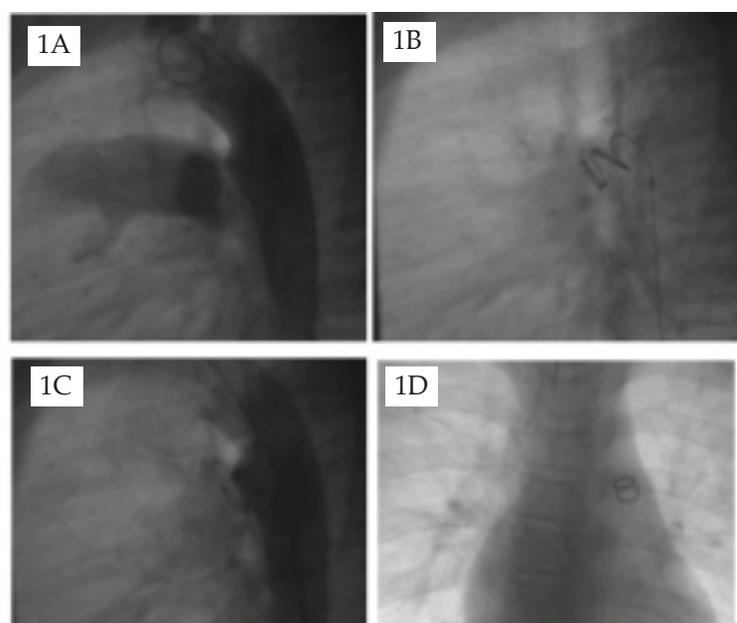


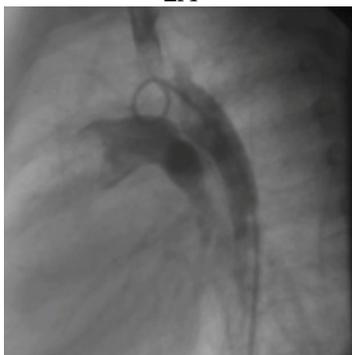
Figure 1A aortogram in the lateral view to profile the ductus B coil loop extruded in the ductus,C an aortogram to confirm the occlusion and D a chest radiograph showing the coil in the ductus.

Double coil technique: Instances when an aortogram showed a larger duct, the double coil procedure was chosen. In technique of implantation both antegrade cannulation of the ductus from the femoral vein and retrograde from the femoral artery was used to cross the duct as shown in Figures 2. After profiling the ductus (Figure 2A), it was crossed both from the inferior venacava and the descending aorta (Figure 2B). The aortic coil was first mounted (Figure 2C) followed by the coil from the pulmonary artery (Figure 2D), then both coils released. A final aortogram was performed in the lateral position confirming complete occlusion (Figure 2E) before an antero-posterior radiogram to show the final position of the coil (Figure 2F)

Figure 2A-2G

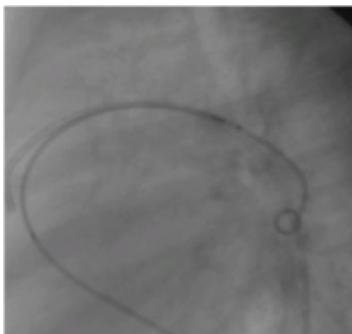
Showing the antegrade and retrograde techniques for double coil occlusion for smaller to moderate size ducts

2A



Large duct profiled using an aortogram in lateral position.

2B



Both catheters in the ductus with dual entry from the right and left heart

2C



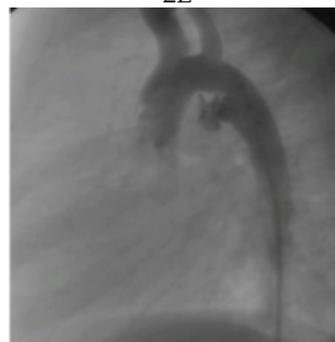
Antegrade coil mounted into duct.

2D



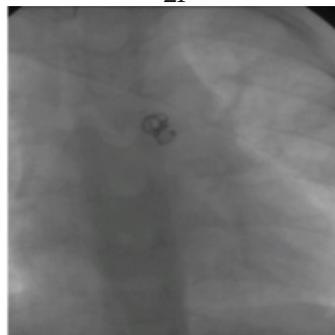
Both in the ductus before release.

2E



An aortogram in lateral-lateral position showing complete occlusion of the ductus

2F



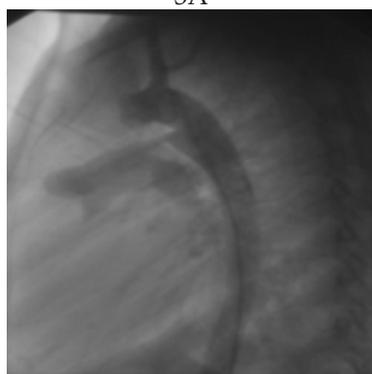
Final appearance of the coil in plain chest radiograph

Technique implantation Amplatzer device: This technique involves right and left heart cannulation from the right femoral vessels. After profiling the ductus via an aortogram in the lateral-lateral position (Figure 3A), a right coronary catheter was used to cross the ductus from the venous side into the descending aorta where it was exchanged for long guide wire (Figure 3B). A long sheath Mullins was then passed over guide wire into the descending aorta and the inner shaft removed. The device was then loaded into the delivery system and mounted into the Mullins sheath in the descending aorta. Together these were drawn into the ductus using the tracheal bifurcation as a guide (Figure 3C). Pre deployment aortogram was performed to assess the extent of occlusion before (Figure 3D) and a post deployment radiograph to document the final position of the device made (Figure 3E)

Figure 3

Serial photographs showing techniques of duct embolisation using the Amplatzer duct occlude device

3A



Initial aortogram profiling the ductus

3B



Exchange guide wire crossing the ductus into the descending aorta

3C



Device mounted into the delivery system in the descending aorta.

3D



An aortogram in the lateral-lateral position before release of the device showing complete occlusion.

3E



The final position of the device on a chest radiogram.

RESULTS

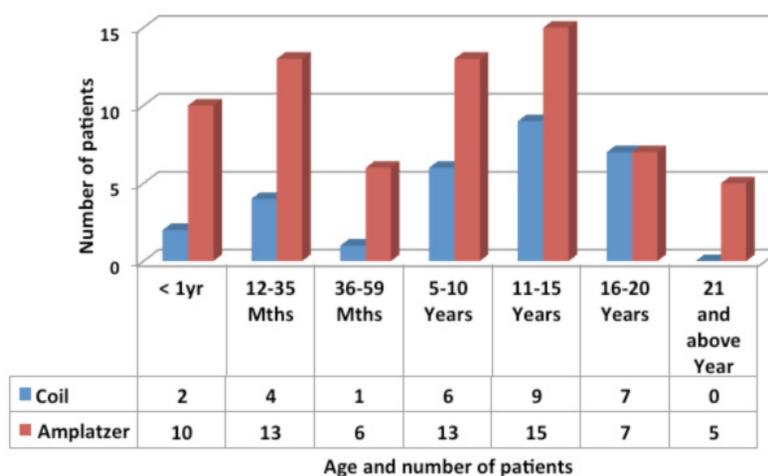
Of the 103 patients who underwent diagnostic catheterisation five patients were excluded from embolisation. Of these, two had very tiny ducts and no further interventions were offered while three had very large ducts and were sent for surgical ligation. The remaining 98 patients underwent duct embolisation using either a coil or Amplatzer device.

Twenty nine (29.6%) had their ducts embolised by the coils while 69(70.4%) were embolised using the Amplatzer devices. The overall mean age was six years with a range of two months to 22 years and a female preponderance of 2:1. Most infants(age less

than one year) had their ducts embolised using the Amplatzer device, 14.5% compared to only 3%of coils used. However with advancing age of ten and above both devices were used in similar proportions (Figure 4).

Figure 4

Age category versus the type of device used (N = 98)



Comparatively, patients who had their ducts embolised using the coils had a higher mean weight and age (30 kg and 7.8 years) compared to the Amplatzer group (19 and 5.9 years) five patients (5%)

were suffering from congenital Rubella. The overall success rate of 93% with a slightly higher rate in the Amplatzer group 97% compared to the coil group of 93% (Table 1).

Table 1

Profiles of patients undergoing Amplatzer and coil embolisation

	Amplatzer	Coil
No. of Patients	69	29
Patients below one year	10(14.5%)	2(3%)
Mean Age(yrs)	5.9	7.8
Male: Female	1:2	1:3
Mean Weight	19.15kgs	30.8kgs
Mean Height	107 cms	102 cms
Mean PDA size	8mm	5mm
Congenital rubella	2(3%)	3(10.3%)
Complete Occlusion	64(92.8%)	27(93.1%)
Residual shunts	2(3%)	1(3.4%)
Failed / abandoned	3(4.5%)	1(3.4%)

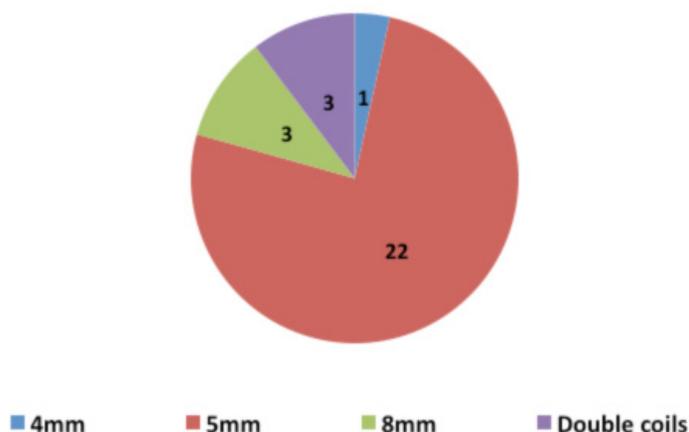
Coil group (total 29): Although this group were of a mean older age, they had no clinical, echocardiographic and catheterisation evidence of pulmonary hypertension. There was a history of recanalised ducts from previous surgery in three patients, congenital rubella in another three and

small ventricular septal defects in two patients. Two of the patients had failed embolisation from another institution. The majority 22 (75.6%) had the ducts embolised using 5 mm coil, while three (10.3%) had 8 mm coil, and one (0.3%) using a 4 mm coil. The double coils (Figures 2) were used in three patients

two sets of 5 mm coils and one set of 5 mm and 4 mm coil (Figure 5). All three patients had total occlusion of their ducts. In two patients there was embolisation of the coil to the distal left pulmonary artery branch but both were successfully retrieved with subsequent placement of a bigger size 8 coil while the other was

closed using an Amplatzer device. There was residual shunting seen in 3.4% of the subjects. While in one with a small ductus were totally failed occlude the duct despite numerous attempts. This was one of the patients with congenital Rubella syndrome

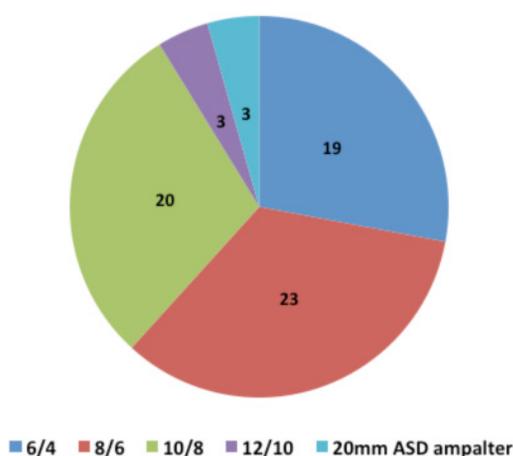
Figure 5
Number of patients against the size of coils (n=29)



The Amplatzer group (total 69): This group included a wide variety of duct sizes ranging from small 3mm to very large ducts of 12mm. One patient had an atypical ductus connecting the right pulmonary artery to the right brachiocephalic trunk. Moderate pulmonary hypertension was encountered in one patient, while two had congenital rubella syndrome. Additional

findings included one patient with pulmonary valve stenosis associated with moderate size ductus. Two cases in this group had very large ducts requiring larger devices so we used 20 mm Amplatzer ASD occluder device (Figure 6), of these one had full occlusion while the other failed and was taken for surgical ligation.

Figure 6
Number of patients Vs size of Amplatzer device (n=66)



Follow-up and complications: Follow-up echo cardiograms were done at discharge, then at intervals of one three and six months. Majority of the patients were discharged from follow-up after two years but some who had additional lesions like congenital Rubella, ventricular septal defects and pulmonary

valve stenosis have been followed for longer periods up to ten years. There was one late embolisation into the iliac bifurcation after three month in a four year old female embolised using size 8/6 of the Amplatzer group. She underwent surgical retrieval of the device. There was no echo-cardiographic evidence of left

pulmonary stenosis on follow-up. The younger patients less than two years who had larger ducts had their devices protruding into the lumen of the descending aorta but no coarctation of aorta was noted on follow-up. Persistent resting bradycardia was noted one patient (coil) group immediately post embolisation which resolved within six months of follow-up. No case of infective endocarditis was observed although two patients developed rheumatic heart disease, mild aortic and mitral regurgitation in one while the other had mild mitral regurgitation. Both were in the Amplatzer group.

DISCUSSION

The PDA remains a common congenital heart disease. As an isolated lesion it forms about five to ten percent of all congenital cardiac diseases. Prior to 1999 all cases diagnosed with PDA locally were treated with surgical ligation through a thoracotomy irrespective of age of the patient or size and shape of the PDA. Although thoracotomy is a relatively safe procedure, it requires extended hospital stay and convalescence. Some complications have been encountered including bleeding, atelectasis and lung collapse, damage to recurrent laryngeal nerves, chylothorax and occasionally death. Recanalisation has also been a frequent observation. In April 1999 a ten year old male who underwent thoracotomy twice and still had significant residual shunting of a recanalised ductus underwent successful percutaneous embolisation of the duct using a 5 mm detachable cook coil. This excitement led to further closure of five more patients three of which had previous surgery and recanalised ducts. This experience was presented to the Kenya cardiac society annual scientific conference in 2000 (2). Further experience into the year was still limited to smaller ducts but in August 2000 the Amplatzer duct occluder was introduced into the unit making it possible to close larger ducts. Irrespective of the duct size we are now able to interchange the coils and the Amplatzer devices in a complimentary manner.

Transcatheter closure of PDA was first described by Portsman *et al*, (3) and thereafter several devices and techniques have been described and perfected. These include the Rashkind's double umbrella technique (3), the Sideris button device (4), Cooks detachable coils (5) and most recently the Amplatzer duct occluder (6).

Although patients in the coil groups were older (mean age of eight years) none had pulmonary hypertension due to a smaller PDA size averaging 5 mm. The rationale for selecting this treatment modality was because the procedure was found less cumbersome. The presence of additional lesions small Ventricular septal defects in three of the twenty six patients did not affect the outcome of the procedure and no concomitant intervention

was offered apart from advising on antibiotic prophylaxis for infective endocarditis during dental and surgical procedures. A total of five patients who had congenital Rubella and small ducts were treated, two with the Amplatzer device and three with coil embolisation. Complete occlusion was achieved in four of the five patients while the remaining patient failed to totally occlude the duct with the coil. Patent ductus arteriosus is commonly associated with congenital rubella occurring in 50% of cases. Local encounter of PDA and congenital Rubella has been that of large ducts associated with pulmonary hypertension and treatment has been surgical ligation. However, Bergum in Bangladesh reported two cases of congenital rubella with large PDA successfully occluded with the Lifetech PDA occluder device (11). Our cases were small ducts of 5 mm and less.

The double coil technique (Figures 2) was used for larger ductus, at a time when we had run out of the Amplatzer device in the unit. None of these patients had residual shunting on follow-up. We also did not find any branch pulmonary stenosis especially the left pulmonary artery. During the initial experience our tutor deliberately embolised the coil into the left pulmonary and taught us how to retrieve it, with this tutorship any coil which embolised to the pulmonary tree was successfully retrieved and repositioned and non in this group required surgical intervention. Although the technique for the coil embolisation was that of controlled release when the duct ampulla allowed, some coil was implanted without the delivery system

The Amplatzer group was a much younger and lighter population with a mean weight of 19 kg compared to the coil group of 30 kg and had a higher occlusion rate. Despite the fact that this method of embolisation was learnt later after the coil the learning curve was very short only two weeks and we had a higher occlusion rates. The duct sizes were variable from very small to very large ducts with 65% of patients having moderate size duct hence the use of 8/6 and 10/8 devices, an experience described by others (8,9,10). Only one patient had moderate pulmonary hypertension the rest had basically normal pulmonary pressures. Subsequent follow-up of the pulmonary pressures at six months and two years showed regression of the pressures to mild pulmonary hypertension. Pulmonary hypertension is considered a contraindication to Amplatzer device embolisation. We did not use these devices in patients with severe pulmonary hypertension.

There was a higher rate of residual shunting in the coil group (3.4%) compared to the Amplatzer group of 1.5% (Table 1). One would have used additional coils to completely eliminate the shunts however no further treatment was offered due to limited choices of the coils and devices. Bacterial endocarditis and haemolysis are known complications of these

procedures (12). We did not observe any of these during the brief and long term follow up. However in this environment endo-cardial involvement from rheumatic fever is common and two patients developed rheumatic heart disease during the follow up period. They have been retained on long term follow-up for purposes of disease prophylaxis and monitoring for any risk of long term infective endocarditis. The mean duration of hospitalisation was one day for older patients and two days for younger patients and those who had general anaesthesia. This did not differ between the types of devices used.

Our main challenges were the patients who had very large ducts at angiography which at echocardiographic selection were of moderate size. In two of these patients the 20 mm Amplatzer ASD occluder devices were used. One had complete occlusion but the other had significant residual shunting. When comparing the techniques of occlusion the coil patients and the Amplatzer patients the coil group had a longer learning curve than the Amplatzer group. The cost of coil devices is four to five times cheaper than the Amplatzer devices and this would be a reasonable option to close the ducts especially in resource scarce settings.

Study limitations: The selection of patients was dependent on echo-cardiographic assessment to match the device available in stock however selection of the size and type of device was determined by the angiography of the duct. This led to the exclusion of patients after undergoing angiography due to lack of appropriate devices.

In conclusion, complementary transcatheter use of Amplatzer duct occluders and detachable cook coils for closure of ducts feasible even in resource scarce settings and is a safe alternative to surgery. The use of multiple coils is feasible in patients with small to larger ducts, whereas, the Amplatzer devices can be successfully used in all the duct sizes.

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