

# Patent ductus arteriosus closure using Occlutech® Duct Occluder, experience in Port Elizabeth, South Africa

Lungile Pepeta, Adele Greyling, Mahlubandile Fintan Nxele, Zongezile Masonwabe Makrexeni

Department of Paediatrics and Child Health, Division of Paediatric Cardiology, Dora Nginza Hospital, Walter Sisulu University, Port Elizabeth, South Africa

## ABSTRACT

- Background** : Percutaneous closure of patent ductus arteriosus (PDA) has become standard therapy. Experience with the Occlutech® Duct Occluder is limited.
- Methods** : Data regarding ductal closure using Occlutech® Duct Occluder were reviewed and prospectively collected. Demographics, hemodynamic and angiographic characteristics, complications, and outcomes were documented.
- Results** : From March 2013 to June 2016, 65 patients (43 females and 22 males) underwent percutaneous closure of the PDA using Occlutech® Duct Occluder. The median age of the patients was 11 months (range, 1–454 months) and the median weight was 8.5 kg (range 2.5–78 kg). The mean pulmonary artery median pressure was 27 mmHg (range, 12–100 mmHg) and the QP: Qs ratio median was 1.8 (range, 1–7.5), with a pulmonary vascular resistance mean of 2.7 WU (standard deviation [SD]  $\pm$ 2.1). Thirty-two patients had Krichenko Type A duct (49%); 7, Type C (11%); 4, Type D (6%); and 22, Type E (34%). The ductal size (narrowest diameter at the pulmonic end) mean was 3.5 mm (SD  $\pm$  1.9 mm). The screening time mean was 17.3 min (SD  $\pm$  11.6). Out of 63 patients with successful closure of the PDA using Occlutech® Duct Occluder, there were 15 patients with small PDAs; 25 with moderate PDAs, and 23 with large PDAs. In one patient, the device dislodged to the descending aorta, and in two patients, to the right pulmonary artery immediately following deployment, with successful percutaneous (two) and surgical (one) retrieval. Complete ductal occlusion was achieved in all 63 patients on day one.
- Conclusion** : The Occlutech® Duct Occluder is a safe and effective device for closure of ducts in appropriately selected patients.
- Keywords** : Occlutech device, patent ductus arteriosus, percutaneous occlusion

## INTRODUCTION

Percutaneous closure of patent ductus arteriosus (PDA) is mainstay therapy for this congenital cardiac defect. PDA incidence is about 11.9%–15.6% of all congenital heart defects.<sup>[1,2]</sup> The very first report of catheter-based closure of the PDA was in 1967 by Porstmann, *et al.*<sup>[3]</sup> Over two decades, a wide variety of devices have been employed

for transcatheter closure of the PDA from small infants to adults.<sup>[4–16]</sup> There is a limited number of studies that have reported successful closure of PDA using Occlutech® Duct Occluder (Occlutech, Helsingborg, Sweden).<sup>[17–20]</sup> Therefore, we report short- to medium-term results from a single center.

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

**For reprints contact:** reprints@medknow.com

**How to cite this article:** Pepeta L, Greyling A, Nxele MF, Makrexeni ZM. Patent ductus arteriosus closure using Occlutech® Duct Occluder, experience in Port Elizabeth, South Africa. *Ann Pediatr Card* 2017;10:131-6.

Access this article online	
Quick Response Code: 	Website: <a href="http://www.annalspc.com">www.annalspc.com</a>
	DOI: 10.4103/0974-2069.205144

**Address for correspondence:** Prof. Lungile Pepeta, Faculty of Health Sciences, Building 7, 1<sup>st</sup> Floor, R0126, Summerstrand Campus (South), Nelson Mandela Metropolitan University, Port Elizabeth 6001, South Africa. E-mail: lungile.pepeta@gmail.com

## METHODS

### Patients

Following clearance from the Research Ethics and Bio-safety Committee of Walter Sisulu University regarding research in humans; prospective data collection and retrospective review of records of patients that had undergone percutaneous closure of PDA in a tertiary care setting in South Africa were performed.

Patients' age, sex, and weight at the time of closure were documented. Hemodynamic characteristics were documented and included quantification of left-to-right shunting, patients' pulmonary artery to systemic arterial blood flow ratios ( $Q_p: Q_s$ ), and pulmonary vascular resistance (PVR) before ductal closure. Angiographic data including ductal size (narrowest diameter usually at the pulmonic end), aortic ampulla, ductal length, and shape of the PDA were also recorded. The duct was defined as small, if the narrowest diameter was  $<2$  mm; moderately sized, if it was between 2 mm and 3.5 mm in patients with symptomatic heart failure and between 2 mm and 4 mm if there was no heart failure; and large if it was  $>3.5$  mm in symptomatic patients or  $>4$  mm in asymptomatic patients.<sup>[17]</sup> The ductal shape was classified using the Krichenko angiographic morphological classification.<sup>[21]</sup> Device type and size, screening time, complications, and outcomes were also noted. Presence of other or associated congenital heart disease was documented as well. The follow-up plan involved review (including echocardiography) at 1, 3, and 6 months, 1 year, and finally 2 years following percutaneous ductal closure.

Values were reported as median (range) and mean ( $\pm$  standard deviation).

### The Occlutech® Duct Occluder device

The device is made of a meshwork of self-expandable combination of nickel and titanium (nitinol) wire. Its shape is reminiscent of a "champagne cork." On the aortic side, there is a flat disk which is attached to the body ("shank") of the device through continuous nitinol

braiding. On the pulmonic end, the shank "flares up" and as such, has a diameter 1.5–4 mm bigger than the aortic end [Figure 1a and b]. Inside the shank, there are polyethylene terephthalate threads which are thought to enhance ductal closure rate. The devices are currently delivered through 6F to 9F Cook's delivery system, depending on device size [Table 1].

### The Occlutech® Duct Occluder transcatheter delivery protocol (Occlutech, Helsingborg, Sweden)

The patient is usually prepared for routine cardiac catheterization. Under sedation, the patient is scrubbed and draped. Femoral arterial and venous access is achieved, using standard vascular access short sheaths. About 50 IU/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.<sup>[21]</sup> The ductal anatomy information is used to select the device size compared to ductal size and device length (long shank vs. short shank). Approximately, 1–3 mm larger device than ductal size is chosen to occlude the duct. Standard left and right cardiac catheterization 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 hemodynamic 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 [Table 1].

The delivery system is flushed using heparinized saline. A 0.035" guidewire 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 guidewire. 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

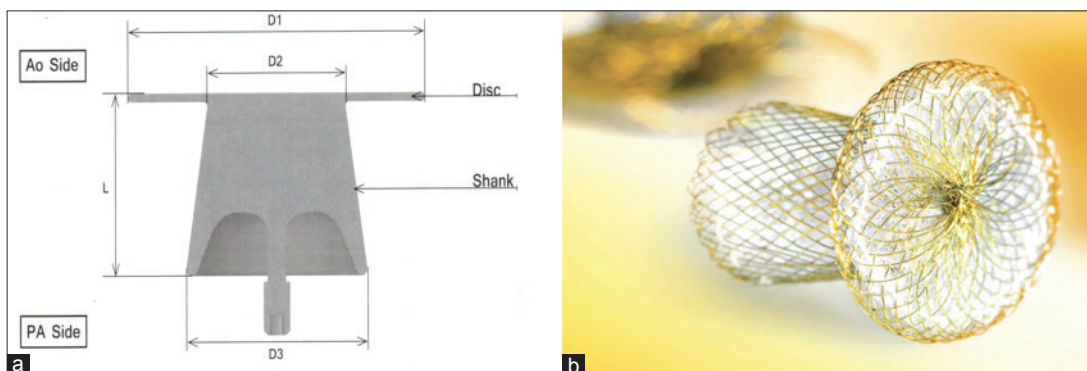


Figure 1: Occlutech® patent ductus arteriosus occluder showing the dimensions of the device (a), and nitinol braiding with polyethylene terephthalate (b) (used with permission from Occlutech, Helsingborg, Sweden)

**Table 1: Manufacturer’s guidelines regarding device size choice in relation to the patent ductus arteriosus size and length (Occlutech, Helsingborg, Sweden)**

PDA Occluder Cook’s Delivery System		D2	D3	D1	Device Length
Product No.	Delivery system size (F)	(mm)	(mm)	(mm)	(mm)
Occlutech Patent Ductus Arteriosus Occluder® with Short Shank					
42PDA05	6	3.5	5	9	4.25
42PDA06	6	4	6	10	5.00
42PDA07	6	5	7	11	6.05
42PDA08	6	6	8	13	6.30
42PDA10	7	8	10	16	7.00
42PDA12	7	10	12	18	12.00
42PDA15	8	12	15	20	14.00
42PDA18	9	14	18	24	16.00
Occlutech Patent Ductus Arteriosus Occluder® with Long Shank					
43PDA05L	6	3.5	5	9	7.00
43PDA06L	6	4	6	10	7.50
43PDA07L	6	5	7	11	8.50
43PDA08L	6	6	8	13	9.00
43PDA10L	7	8	10	16	10.50

D1: Retention Disk, D2: Aortic side of the Shank, D3: Pulmonic side of the Shank, F: French

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. It has been reported that the Occlutech® Duct Occluder may assume one of three positions when deployed, and these include position 1 where the aortic retention disk is pulled into the ampulla, position 2 where aortic disk abuts the aortic end of ampulla, and position 3 where the pulmonic end of the shank closes the narrowest ductal diameter rather than the narrowest (near the aortic disk) of the shank.<sup>[18]</sup> 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 catheterization procedure or the device itself.

**RESULTS**

Over a period of 3 years and 3 months (March 2013 to June 2016), 65 patients underwent PDA closure using Occlutech® Duct Occluder. Demographic, hemodynamic, and angiographic data are presented in Table 2. Almost

**Table 2: Demographic, haemodynamic and angiographic data presented as median (range) or mean (standard deviation)**

Age in months	11 (1-454)
Weight in kilograms	8.5 (2.5-78)
Qp: Qs	1.8 (1-7.5)
Rp in Wood units	2.7 (±2.1)
Mean PA in mmHg	27 (12-100)
PDA narrowest diameter in millimeters	3.5 (±1.9)
PDA Length in millimeters	11.5 (±5)
Radiation exposure in minutes	17.3 (±11.6)

Number of patients (n) and sex distribution: n=65; F=43; M=22 F: Females, M: Males, Qp: Pulmonary blood flow, Qs: Systemic blood flow, Rp: Pulmonary resistance, PA: Pulmonary artery

two-thirds (66%) of the patients were females. Regarding age at closure of the PDA, the youngest patient was 1 month old and the oldest was 37 years old. The weight of patients that underwent closure of their PDAs using the Occlutech® Duct Occluder ranged from 2.5 kg to 78 kg (median, 8.5 kg), and about 23% (n = 15) of patients had a body weight <5 kg. The cohort had significant pulmonary hypertension (mean PAP median = 27 mmHg, range: 12–100 mmHg). The QP: QS ratio was also significant at a median of 1.8:1 (range: 1–7.5). However, the PVR mean was normal at 2.7 wood units. Pertaining to ductal size, type, and device choice, 15 patients had small PDAs, 25 with moderately sized, and 25 with large PDAs. Thirty-two patients had conical PDAs (Type A); 22, conical but long PDAs (Type E); 7, tubular ducts (Type C); and 4, complex ducts with more than one narrow areas (Type D). There were no patients with short and tubular ducts (Type B). About the device choice, 34 patients were occluded using the short shank device and 31 patients using the long shank. The choice of a device with either long or short shank was based on the

ductal length and the size of the ampulla compared to the size of the device. Ten patients were occluded using size 3.5 × 5, ten with 3.5 × 5 L, three with 4 × 6, three with 4 × 6 L, eight with 5 × 7, six with 5 × 7 L, five with 6 × 8, five with 6 × 8 L, three with 8 × 10 L, six with 8 × 10 L, three with 10 × 12 L, one 10 × 12 L, and two with 12 × 15 L. Fourteen out of 15 patients with small ducts had closure of their PDAs using the smallest devices (3.5 × 5 or 3.5 × 5 L devices). When it came to positioning and readjustment of the device during deployment, the device was pulled to abut against the ampulla (position 2) in forty patients (61%), the device was pulled into the ampulla (position 1) in 22 patients (34%), and in three patients (5%), the pulmonic end of the device was responsible for ductal closure (position 3). Only three patients required upsizing of the device due to unsatisfactory positioning of the device with large residual left-to-right shunting on angiography and high index of suspicion that the device might embolize.

Three patients had other congenital heart diseases. Two patients had restrictive perimembranous ventricular septal defects, and it was presumed these would close spontaneously. One patient had absent left pulmonary artery with a right-sided aortic arch and PDA. This patient had a moderately sized PDA of 3.1 mm with significant but reversible pulmonary hypertension with a PAP mean of 40 mmHg, QP: QS of two, and Rp of 3.4 wood units. This patient had closure of the PDA using a size 6 × 8 L Occlutech® Duct Occluder.

Two patients with Krichenko Type A PDAs and one with Type C PDAs had device embolization. In one patient, the device dislodged into the descending aorta, and in two, into the right pulmonary artery (RPA). In the first embolization, the PDA was 4.8 mm, with an ampulla of 6.1 mm and length of 18.9 mm. A size 6 mm × 8 mm short

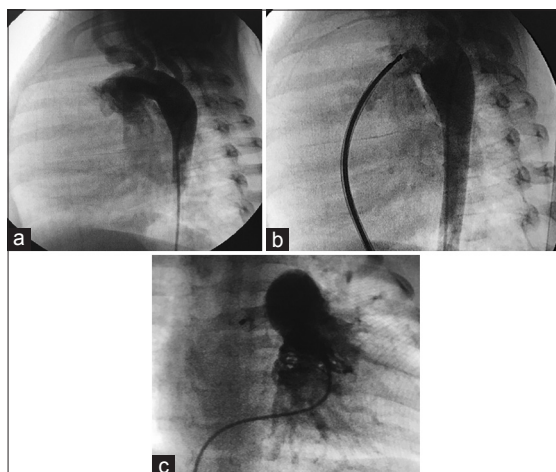
shank device was deployed initially. The deployment and release of the device before the pulmonic end of the device was on the pulmonic side of the duct across the narrowest ductal diameter resulted in embolization of this device in the first patient. This was the second device to be deployed in this cohort, and therefore inexperience and poor judgment contributed in embolization of this device. Another device which was larger and longer (8 × 10 mm long shank) was deployed appropriately with good result. In the second patient, the PDA was 10.5 mm, with an ampulla of 31.9 mm and length of 22 mm. A size 12 × 15 was chosen to close the PDA. The device assumed position 1 in this patient. The device dislodged to the RPA as a result of undersizing of the PDA. A size 14 × 16 mm Amplatzer® Duct Occluder (ADO) was used to close the PDA successfully in this patient, as there was no size 14 × 18 Occlutech® Duct Occluder at the time in the cardiac catheterization laboratory. The last embolization had the device stuck in the RPA origin with the aortic disk [Figure 2]. The pulmonic disk with the screw was in the distal RPA. Attempted percutaneous removal was unsuccessful. This patient had surgical removal of the device and surgical closure of the PDA.

Immediately after ductal closure, 37 patients out of 63 (59%) had complete ductal closure. There was 97% (n = 63) closure rate on day 1 (discharge) in all patients that had a successful deployment of Occlutech® Duct Occluder. The follow-up range was 1–2 years with a median of 2 years. Thirty-eight patients have already been discharged from the follow-up clinic as they have completed 2-year follow-up period as per protocol.

## DISCUSSION

The Occlutech® Duct Occluder was introduced in our unit in March 2013, and 63 patients had successful closure of their PDAs using this device. To the best of our knowledge, this is the highest number of cases published on closure of PDAs using the Occlutech® Duct Occluder. Our findings are in keeping with other published data on percutaneous PDA occlusion using other devices including Cook's® coils, ADO I, II, and additional sizes, and Nit-Occlud® device.<sup>[10-13,15,16,22]</sup> Our experience also compares with the experience in other units that have used the Occlutech® Duct Occluder for PDA closure.<sup>[17-20]</sup> This device is able to close small, moderately sized, and large ducts in appropriately selected patients.<sup>[17-20]</sup> In our case series, the majority of the small ducts were closed with the smallest devices.

Regarding body weight, the device was used to close ducts in patients <5 kg. The smallest weight was 2.6 kg. Compared to other published studies, only one study reported closure of PDAs in patients <5 kg, and the smallest weight reported in this study was 3.1 kg.<sup>[20]</sup> The



**Figure 2: Tubular patent ductus arteriosus (a), occlutech patent ductus arteriosus occluder *in situ* before release (b), right ventriculogram showing occlutech patent ductus arteriosus Occluder® stuck in the right pulmonary artery origin with the aortic disk (c)**



reasons why smaller ducts are a challenge to close with these devices might be that the delivery system measures 6F–7F in size and the smallest aortic retention skirt has a 9 mm diameter, which might increase the risk for vessel injury or bleeding at access site and coarctation of the aorta, respectively. Loss of femoral artery following closure of PDA using Occlutech® Duct Occluder was reported in the study by Kudumula, *et al.*<sup>[18]</sup> This was restored by continuous heparinization of the patients over a period of about 2 days. Coarctation of the aorta has been reported with the ADO I and the ADO II.<sup>[16]</sup> These complications were not seen with the use of this device in our cohort.

The largest PDA closed in our unit was 8.8 mm, and this was successfully closed with a size 12 × 15 device. The design of the device with a “flare” on the pulmonic side together with an aortic disk offers stability to the device once deployed and released. The largest PDA that has been reported to have been successfully closed in literature was a size 11 mm. Moreover, a size 14 mm × 18 mm was used to close this PDA.<sup>[19]</sup>

Majority of the ducts were conical (Krichenko Type A). Of note, there was no aortopulmonary-like PDA (Krichenko Type B) that was closed using this device. The longest duct was 22.4 mm. Attempted closure with Occlutech® Duct Occluder 8 mm × 10 mm long shank (10.5 mm long device) resulted in embolization of the device. This long PDA was successfully closed using a size 12 mm × 15 device, which is 14 mm long. The Occlutech® Duct Occluder has one advantage of having a variety of short and long shank devices available even for moderately sized and large PDAs. When the ampulla is large enough to accommodate the aortic retention skirt, a shorter device than ductal length may be chosen, as long as the device is released with the pulmonic disk deployed on the pulmonic side of the PDA. Majority of our patients had ductal lengths longer than the device chosen to close the PDA.

Regarding other complications, embolization was the main complication noted in our series. Embolization of Occlutech® Duct Occluder has been reported.<sup>[19,20]</sup> In one patient, the device was retrieved successfully percutaneously, and the patient was sent for surgery. In another patient, the device was stuck in the right pulmonary origin with the pulmonic end with the screw deep in the pulmonary artery. Like in our patients, attempts to retrieve the device percutaneously were unsuccessful. This patient had a surgical removal of the device and PDA closure. Perchance, a redesign of the Occlutech® Duct Occluder with a metal protuberance on the aortic disk side could assist with retrieval of this device upon embolization.

Regarding the outcomes, studies have reported delayed closure rates when using the Occlutech® Duct Occluder.<sup>[17-20]</sup> There are no long-term follow-up complications noted so far.

## CONCLUSION

Short- and medium-term results have shown that the Occlutech® Duct Occluder is a safe and effective device for closure of ducts in appropriately selected patients including patients with adequate ductal length, ductal ampulla to accommodate the aortic disk, and even patients who are <5 kg. A randomized clinical trial is suggested to ascertain as to whether this device is superior to ADO in ductal closure. Further experience is warranted in small patients <5 kg to determine the safety and efficacy of this device.

## Acknowledgment

The authors wish to thank Ziyad M. Hijazi, MD, for his critical review of the manuscript.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

## REFERENCES

1. Dickinson DF, Arnold R, Wilkinson JL. Congenital heart disease among 160 480 liveborn children in Liverpool 1960 to 1969. Implications for surgical treatment. *Br Heart J* 1981;46:55-62.
2. Carlgren LE. The incidence of congenital heart disease in children born in Gothenburg 1941-1950. *Br Heart J* 1959;21:40-50.
3. Porstmann W, Wierny L, Warnke H. The closure of the patent ductus arteriosus without thoractomy. (preliminary report). *Thoraxchir Vask Chir* 1967;15:199-203.
4. Rashkind WJ, Mullins CE, Hellenbrand WE, Tait MA. Nonsurgical closure of patent ductus arteriosus: Clinical application of the Rashkind PDA occluder system. *Circulation* 1987;75:583-92.
5. Rao PS, Sideris EB, Haddad J, Rey C, Hausdorf G, Wilson AD, *et al.* Transcatheter occlusion of patent ductus arteriosus with adjustable buttoned device. Initial clinical experience. *Circulation* 1993;88:1119-26.
6. Verin VE, Saveliev SV, Kolody SM, Prokubovski VI. Results of transcatheter closure of the patent ductus arteriosus with the Botallooccluder. *J Am Coll Cardiol* 1993;22:1509-14.
7. Moore JW, George L, Kirkpatrick SE, Mathewson JW, Spicer RL, Uzark K, *et al.* Percutaneous closure of the small patent ductus arteriosus using occluding spring coils. *J Am Coll Cardiol* 1994;23:759-65.
8. Hijazi ZM, Geggel RL. Results of antegrade transcatheter closure of patent ductus arteriosus using single or multiple Gianturco coils. *Am J Cardiol* 1994;74:925-9.
9. Tometzki A, Chan K, De Giovanni J, Houston A, Martin R, Redel D, *et al.* Total UK multi-centre experience with a novel arterial occlusion device (Duct Occlud pfm). *Heart*

- 1996;76:520-4.
10. Uzun O, Hancock S, Parsons JM, Dickinson DF, Gibbs JL. Transcatheter occlusion of the arterial duct with Cook detachable coils: Early experience. *Heart* 1996;76:269-73.
  11. Tometzki AJ, Arnold R, Peart I, Sreeram N, Abdulhamed JM, Godman MJ, *et al.* Transcatheter occlusion of the patent ductus arteriosus with Cook detachable coils. *Heart* 1996;76:531-5.
  12. Podnar T, Masura J. Percutaneous closure of patent ductus arteriosus using special screwing detachable coils. *Cathet Cardiovasc Diagn* 1997;41:386-91.
  13. Masura J, Walsh KP, Thanopoulous B, Chan C, Bass J, Goussous Y, *et al.* Catheter closure of moderate- to large-sized patent ductus arteriosus using the new Amplatzer duct occluder: Immediate and short-term results. *J Am Coll Cardiol* 1998;31:878-82.
  14. Masura J, Gavora P, Podnar T. Transcatheter occlusion of patent ductus arteriosus using a new angled Amplatzer duct occluder: Initial clinical experience. *Catheter Cardiovasc Interv* 2003;58:261-7.
  15. Bhole V, Miller P, Mehta C, Stumper O, Reinhardt Z, De Giovanni JV. Clinical evaluation of the new Amplatzer duct occluder II for patent arterial duct occlusion. *Catheter Cardiovasc Interv* 2009;74:762-9.
  16. Baspinar O, Irдем A, Sivasli E, Sahin DA, Kilinc M. Comparison of the efficacy of different-sized Amplatzer duct occluders (I, II, and II AS) in children weighing less than 10 kg. *Pediatr Cardiol* 2013;34:88-94.
  17. Abdelbasit MA, Alwi M, Kandavello G, Che Mood M, Samion H, Hijazi ZM. The new Occlutech® PDA occluder: Initial human experience. *Catheter Cardiovasc Interv* 2015;86:94-9.
  18. Kudumula V, Taliotis D, Duke C. The new occlutech duct occluder: Immediate results, procedural challenges, and short-term follow-up. *J Invasive Cardiol* 2015;27:250-7.
  19. Dedeoglu R, Bilici M, Demir F, Demir F, Acar OÇ, Hallioglu O, *et al.* Short-term outcomes of patent ductus arteriosus closure with new Occlutech® duct occluder: A multicenter study. *J Interv Cardiol* 2016;29:325-31.
  20. Boudjemline Y. The new Occlutech® patent ductus arteriosus occluder: Single centre experience. *Arch Cardiovasc Dis* 2016;109:384-9.
  21. Krichenko A, Benson LN, Burrows P, Möes CA, McLaughlin P, Freedom RM. Angiographic classification of the isolated, persistently patent ductus arteriosus and implications for percutaneous catheter occlusion. *Am J Cardiol* 1989;63:877-80.
  22. Pepeta L, Dippenaar A. Ductal closure using the Amplatzer duct occluder type two: Experience in Port Elizabeth hospital complex, South Africa: Cardiovascular topic. *Cardiovasc J Afr* 2013;24:202-7.