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Original Study

Percutaneous transcatheter occlusion of the patent arterial duct using the pfm DuctOcclud Coil® via a trans-aortic and trans-pulmonary approach

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Abstract Occlusion using coils is now the treatment of choice for closure of the patent arterial duct. The DuctOcclud (pfm AG, Cologne, Germany) device is a relatively new retrievable coil for such trans-catheter closure. This study expands on previously reported experience with this device, summarizes the advantages of the device, and compares trans-pulmonary and trans-aortic delivery in 47 patients. There were 27 females. The mean, and median, ages were 4.6, and 2.85 years, respectively. The youngest patient was aged 9 months, weighing 7 kg. A trans-aortic delivery was used in 41 cases, and a trans-pulmonary approach in 6 cases. Of the 47 procedures, 45 (96%) were successful at the first attempt. The other two patients were treated successfully at the second attempt, giving a 100% rate of success. The technical characteristics of the coil allowed for its repeated maneuvering until an optimal position was obtained prior to release. Closure was confirmed by lack of ductal flow by echo-doppler on follow- up echocardiography. No short- or long-term complications of the procedure were noted in any of the patients. We conclude that the DuctOcclud device is an effective and safe method for closure of the small-to-moderately patent arterial duct. In a large proportion of patients, trans-aortic delivery is the preferred approach.

Keywords: Patent ductus arteriosus; DuctOcclud; paediatrics; coil; trans-catheter; occlusion

OCCLUSION USING COILS INTRODUCED THROUGH catheters has now become the treatment of choice for closure of the patent arterial duct in the western world,[1,2] although surgical ligation and division are still the prevalent techniques used world-wide for this condition. Limited literature exists concerning the use of the DuctOcclud pfm coil (pfm AG, Cologne, Germany), a retrievable device which uses a highly controlled mechanism for delivery and release. Furthermore, the studies reported thus far have included relatively small numbers of patients. The aim of the present retrospective study is to expand on this reported experience, to summarize the advantages of this device, and to compare the trans-pulmonary and trans-aortic approach when placing the coil.

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Characteristics of patients and methodology

We attempted a total of 47 occlusions of patent arterial ducts using the DuctOcclud device of the pfm company between the years 2000 and 2001. Of the procedures, 45 were primary closures of a native patent arterial duct, and 2 procedures were performed for residual patency following a primary procedure.

There were 27 females and 20 males. The mean age was 4.6 years, while the median age was 2.85 years. The youngest of the patients was aged 9 months, and weighed 7 kg. The ages ranged from 9 months to 20 years.

The anatomical characteristics of the duct among the study population are shown in Figure 1. Two patients (4%) demonstrated a short and broad duct. It was long and tubular in 9 patients (19%), short and conical in 13 patients (28%), asymmetrical in 16 patients (34%), and symmetrical in the remaining 6 patients (13%). No patients demonstrated the window variant. All ducts were of small-to-moderate

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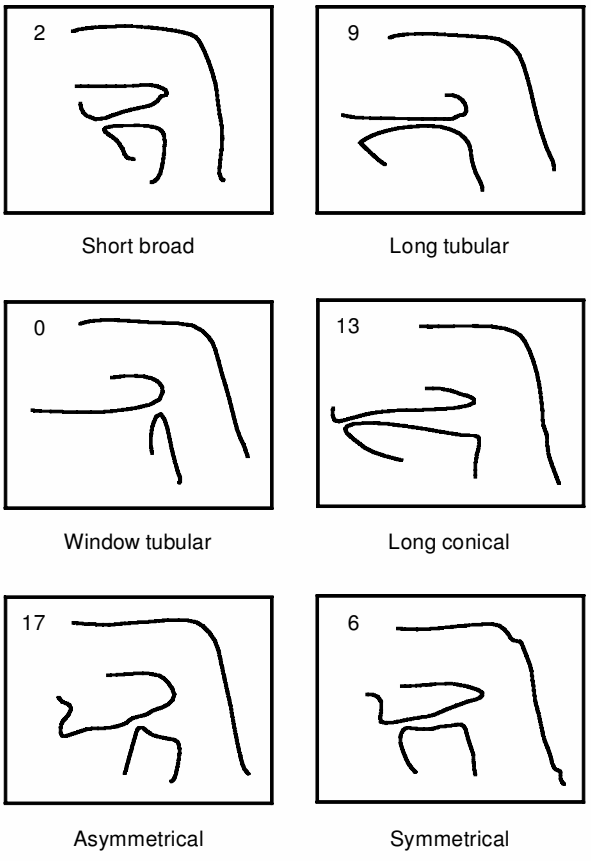

Figure 1.
Ductal morphology among the population. The number appearing in the upper left hand corner of each diagram depicts the number of patients having that morphology.

size, measuring 3.5 mm or less in diameter, and being found in the absence of heart failure or significant shunting, except for 2 ducts that measured from 4 to 5 mm in diameter. These occurred in the 2 youngest patients. All patients were asymptomatic clinically, with no signs or symptoms of overt heart failure. There was no marked left ventricular enlargement in any of the patients, albeit that, in the two youngest patients, there was slight left ventricular enlargement with normal left ventricular function. All electrocardiographic recordings were within normal limits, demonstrating normal sinus rhythm, and there were no signs of left ventricular overload or hypertrophy. All patients exhibited normal pulmonary arterial pressures.

Of the 47 procedures undertaken, 19 were performed using the standard, non-reinforced coil, 22 using the reinforced coil, and 6 using the Plug coil, in which the mid-coil windings are configured to exert a forward motion of the consecutive windings towards the ductal lumen adjacent to the pulmonary arteries.

A trans-pulmonary approach to deliver the device was used in 6 cases (13%, Fig. 2), and a trans-aortic approach in 41 cases (87%, Fig. 3).

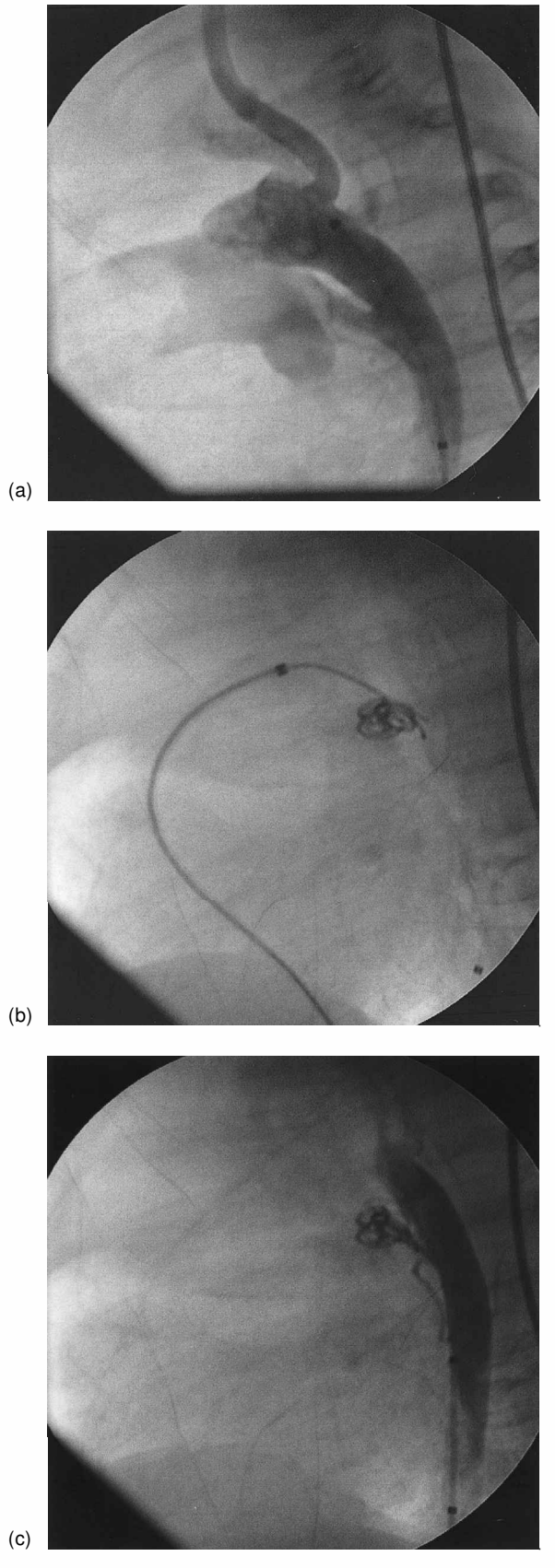

Figure 2.
Trans-pulmonary approach to placement of the DuctOcclud coil: (a) before; (b) during; (c) after placement of coil.

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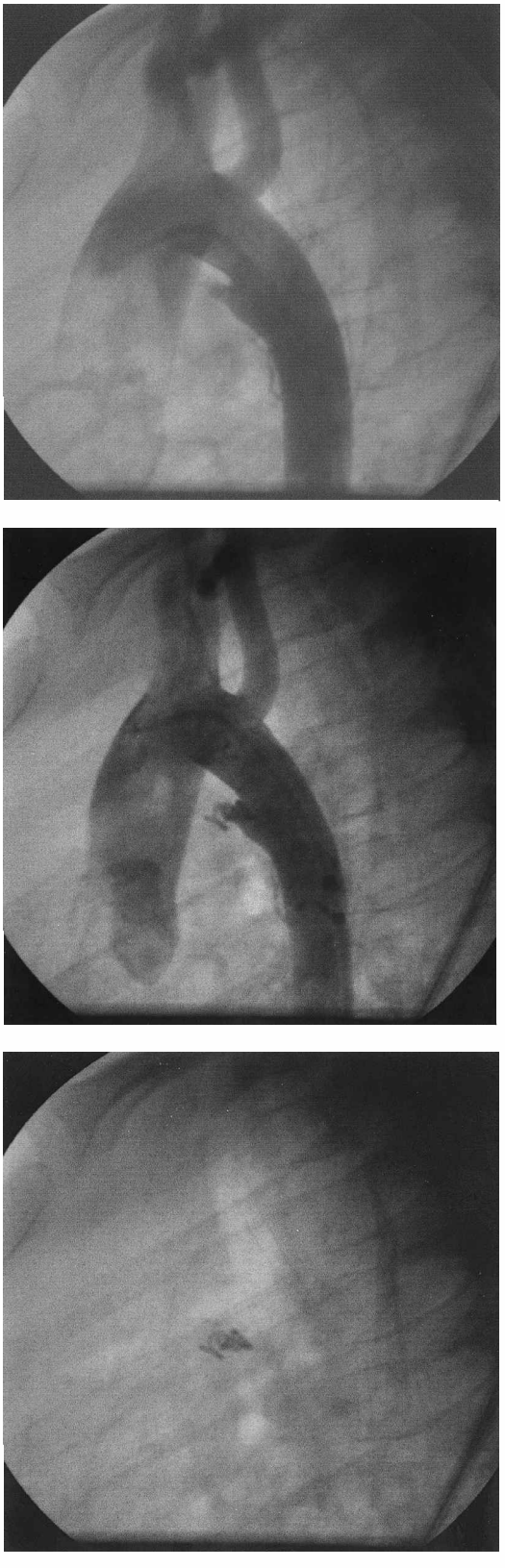

Figure 3.
Trans-aortic approach to placement of the DuctOcclud coil: (a) aortogram in left lateral projection demonstrating ampoule and body of duct; (b) coil well situated within duct ampoule with 1.5 windings in the pulmonary artery; (c) final position.

Technique of catheterization

All procedures were carried out under deep sedation using propofol or midazolam administered by an anesthesiologist. Tracheal intubation was not required in any of the patients to secure an adequate airway. After preparation of the thigh and inguinal region bilaterally, a 5French sheath was introduced to the femoral artery, through which an angiographic catheter was introduced to the ascending aorta. In children in whom the aortic approach was used, no other access was required. In children where a pulmonary approach was used, a second 5French sheath and catheter were introduced into the pulmonary trunk by way of the femoral vein. An aortogram was then performed, and the characteristics and size of the duct measured accurately using calibration markers on the angiographic catheter. The appropriate coil was then selected from a range of available coils and delivered by means of a delivery catheter of either 4 or 5 French calibre. After ascertaining optimal positioning of the coil by radiography, the coil was released, and closure confirmed by angiography of the aortic arch. If the optimal position is not confirmed, the coil may be repeatedly maneuvered prior to release, until a satisfactory position is achieved. The judgment of adequacy of the position of the coil is obtained using the previously acquired aortogram, and seeking to achieve the same projection for delivery of the coil. This may be done either by replay of the angiogram, or by splitting the screen, in which half of the screen stores a frame of a previous aortogram and the other half serves for radiography and deployment of the coil. This is necessary in order to avoid catheterization of the other femoral artery so as to achieve aortography prior to release of the coil. In the trans-pulmonary approach, while the coil is delivered through the pulmonary trunk, an aortogram is performed to evaluate the position of the coil.

Patients are discharged the day following the procedure after routine observation in the paediatric ward, and after examination and echo-doppler cardiography on the day of discharge. A follow-up visit, including examination and echo-doppler cardiography is then performed 10 days after the procedure, and then at 6 weeks, 3 months and 6 months.

Statistics

The basis for analysis of the data is descriptive statistics. Fluoroscopic times for the trans-aortic vs. the trans-pulmonary approach were compared using Student's t-test.

Results

Of the 47 procedures, 45 (96%) were successful at the first attempt. The remaining 2 patients demonstrated

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residual shunts, and were treated successfully at the second attempt, giving an overall rate of success of 100%. The technical characteristics of the coil allowed for its repeated maneuvering during the phase of placement, until optimal position was obtained prior to release as described previously.

Fluoroscopic time was 10.8 ± 8.6 min (mean ± S.D.), with a range from 2.5 to 34.1 min for the group as a whole. Fluoroscopic time for patients who underwent a trans-aortic approach was significantly shorter than for those who underwent a trans-pulmonic approach (8.2 ± 6.4 min vs. 20.7 ± 11 min respectively, $p < 0.02$).

Successful closure was determined by lack of ductal flow judged by intra-procedural injection of contrast material, and by colour echo-doppler on follow-up echocardiography 1 and 10 days after the procedure.

No short- or long-term complications of the procedure were noted in any of the patients. There was no incidence of embolization or late migration of the coil, hemolysis, stenosis of the branches of the pulmonary trunk, or obstruction of the aorta.

Discussion

Patency of the arterial duct predisposes patients to heart failure and infective endocarditis. The treatment is to obliterate the patent duct. Traditionally, this has been achieved via open-chest surgery by ligation and or transection of the duct. This procedure is highly successful, but exposes the patient to potential complications of surgery and anesthesia.[2] The use of detachable devices, including coils, delivered by endovascular catheterization has now been shown to be effective in obliterating the lumen of the patent duct,[3] and has revolutionized the treatment of this relatively common condition.[4] These developments have reduced the need for surgery, and thus lowered the morbidity and length of hospital stay associated with surgery.[5] Although the ratio of pulmonary to systemic flow cannot reliably be measured during catheterization of the duct because of preferential ductal flow to the left pulmonary artery, this measure can be closely approximated using echocardiographic doppler methods, together with the clinical and echocardiographic measurements of the left heart chambers.[6,7] Moreover, catheter closure of a patent duct using a catheter holds other advantages as compared to surgical closure. These include the ability to measure pressures during catheterization, the ability to evaluate pulmonary pressure while transversing the duct, and the ability to define ductal anatomy at time of catheterization.

The DuctOcclud implant device is a relatively new retrievable device for trans-catheter closure of the patent duct.[8,9] The device is delivered by accurate control of a grip handle, with a mechanism facilitating precise release of the coil. The results of our series demonstrate a 96% rate of first-attempt success in closure, and complete success after 2 attempts, with no complications. These results compare to the 91% success achieved in a multi-centric study reported from Japan.[10] These high rates of success may stem from the fact that, in contrast to other types of devices used to close patent arterial ducts, each DuctOcclud device is chosen from a large range of available coils, so as to fit precisely the dimensions and morphology of each specific duct. Experience with other devices has shown that the patent lumen should be totally obliterated during catheterization, leaving no residual shunt, often necessitating placement of multiple coils.[11–13] Unlike other devices, the DuctOcclud does not necessitate complete obliteration of the shunt immediately following placement of the device, or placement of multiple coils. Rather, small residual shunts are usually closed by natural coagulation and remodeling of the thrombus within hours to months following placement and endotheliazation of the device in the following weeks.[14] This endotheliazation reduces the risk of bacterial endocarditis and thromboembolism.[14] Primary residual shunting, or recanalization of previously occluded shunts, may occur,[15] although other studies report a high rate of closure in medium to long-term follow-up.[16,17] We encountered two cases of residual shunts among our population. In one of these, the shunt was discovered immediately after the procedure. It did not subsequently close, making a primary residual shunt the likely cause. In the second patient, the shunt was discovered at 3 months follow-up. This may have been due either to recannalization of the coil, or to discovery of a small, pre-existing, primary residual shunt. These patients, together with the aforementioned studies, warrant continued follow-up in all patients to monitor for this possibility.

Fluoroscopic time in our series was comparable to that reported in other series,[18,19] with a lower adverse effect rate, lending further credence to the value of the DuctOcclud device. Fluoroscopic time using the trans-aortic approach was half that of the trans-pulmonary approach, reflecting the shorter duration of the procedure with this approach.

The advantages of a retrievable system, mainly that it allows optimal positioning of the coil prior to release, has been demonstrated previously with other systems.[20] Our results are compatible with these prior conclusions, and confirm the advantages of a retrievable system. The highly controlled release, also facilitating optimal placement, might be another factor in improving results and decreasing the incidence of embolization, as shown for other controlled release and detachable devices.[21,22]

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Directions for delivery of the coil provided by the manufacturer stipulate a trans-pulmonary approach. Although we strictly adhered to these recommendations in the first period, experience showed us that, in a large proportion of patients, a trans-aortic approach was preferable. A small-to-moderate shunt, coupled with conal or tubular anatomy, normal pulmonary pressure and age beyond infancy, defined these patients. The use of a trans-aortic approach is important for a number of reasons. This approach necessitates only arterial catheterization, obviating the need for venous catheterization. Also, there is no need to transverse the heart, greatly reducing the length of the procedure and fluoroscopic time, reduced by more than half in our series. In these patients, the coil is situated almost entirely within the aortic ampoule of the duct, with only one or two windings of the coil situated within the pulmonary artery, thus greatly reducing the risk of aortic obstruction. We believe that these factors contribute to the extremely low adverse effects of the procedure. This approach is appropriate for patients with ducts of small-to-moderate size, and would thus benefit most patients with ductal patency. The trans-aortic approach has been described successfully for other types of coil.[19,23] The low adverse rate, and high effectiveness of the trans-aortic approach used in our population, confirm the validity of this approach for the DuctOcclud coil. We do, however, urge that a coil designed specifically for this approach be developed and implemented.

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