Cardiol Young 2005; 15: 279–285

ISSN 1047-9511

Original Article

The efficacy and safety of the Amplatzer ductal occluder in young children and infants

Jameel Al-Ata, Amin M. Arfi, Arif Hussain, Amjad A. Kouatli, M. Omar Jalal

Section of Pediatric Cardiology, Department of Cardiovascular Diseases, King Faisal Specialist Hospital & Research Center, Jeddah, Kingdom of Saudi Arabia

Abstract *Background:* We have used the Amplatzer ductal occluder for transcatheter closure of large persistently patent arterial ducts, and used our experience to assess the safety and efficacy of the device in young children and infants. *Methods and patients:* We used the Amplatzer ductal occluder prospectively in 43 patients with large patent arterial ducts, reviewing our experience to identify any problems or complications. *Results:* The procedure proved successful in 42 of the patients. We achieved complete occlusion of the duct in 33 (78.5 per cent) of the patients on the day of insertion. In 6 additional patients, complete occlusion occurred 1 week to 6 months after the procedure. Trivial leaks persisted in 2 patients, while one had a significant residual leak. Problems were encountered in 7 patients. The procedure failed in one, a device was wasted in 2, pulled through in 3, while we experienced kinking of the long Mullins sheath, being unable to retrieve the device, in one patient. Minor complications occurred in 6 patients, finding flow at a peak velocity of 2.2 metres per second in the descending aorta in 2 patients, and at 2.5 metres per second in 2 further patients, and flow at 2.5 metres per second in the pulmonary arteries of two patients. One patient experienced a major complication due to excessive bleeding. Out of the 14 patients suffering adverse events, 13 weighed less than 10 kilograms. This rate of problems and complication in these patients weighing less than 10 kilograms was significantly higher than in the patients weighing more than 10 kilograms. *Conclusion:* Transcatheter occlusion of moderate to large patent arterial ducts with the Amplatzer ductal occluder device is safe and effective, with a high rate of complete occlusion. Problems and minor complications may be encountered in children weighing less than 10 kilograms. If the device is to be deployed completely in the ductal ampulla, and to avoid descending aortic obstruction, the size of the retention flanges of the occluder should not exceed the largest diameter of the patent arterial duct.

Keywords: Patent arterial duct; transcatheter occlusion; interventional catheterisation

TRANSCATHETER OCCLUSION OF SMALL TO moderate persistently patent arterial ducts using coils is now accepted as the standard treatment.[1,2] It is also feasible to close large ducts by using multiple coils, but various problems have been identified with this technique.[3,4] For this reason, surgical ligation has remained the choice in such cases. Recently, however, the Amplatzer ductal occluder has been introduced as an alternative to surgical ligation for treatment of patients with large persistently patent arterial ducts.[5,6] There are few reports, however, describing the use of this device in young patients, or those with low body weight. In such patients, the device is still not recommended as the treatment of choice.[7,8] In this report, we describe our experience using the Amplatzer ductal occluder to close large arterial ducts in a relatively young cohort of patients, emphasizing the problems we encountered while using the device.

Correspondence to: Dr Amin Muhammed Arfi, King Faisal Specialist Hospital & Research Center, MBC J-16, PB # 40047, Jeddah, 21499, Kingdom of Saudi Arabia. Tel: +966 2 667 7777 ext 2511; Fax: +966 2 663 9581; E-mail: ped_cardiologist@doctor.com

Accepted for publication 6 December 2004

Methods and patients

Population of patients

We included in our study all 43 patients, 29 females and 14 males, in whom we attempted transcatheter

closure of the persistently patent arterial duct using the Amplatzer ductal occluder device between July 2001 and October 2003.

Criterions for inclusion

We included all patients seen with large, isolated, patent arterial ducts having a narrowest diameter of more than 3 millimetres as determined echocardiographically, and in whom we had expected a single coil not to be effective in achieving occlusion.

Criterions for exclusion

We excluded all patients who had multiple cardiac anomalies, along with those who had isolated but small ducts in whom occlusion using coils proved effective, and those with any other cardiac lesion requiring cardiac surgery.

Evaluation

Before they were taken to the cardiac catheterization laboratory, all the patients underwent a complete cardiac evaluation, including history, comprehensive physical examination, 12 lead electrocardiogram, chest X-ray and detailed echocardiography.

Echocardiography

Echocardiographic analysis was performed by using Hewlett Packard Sono 5500 system. Detailed cardiac analysis was done in multiple views according to the recommendations of the American Society of Echocardiography. The narrowest diameter of the arterial duct was measured, using electronic calipers, in the cut visualizing the duct. Echocardiography was repeated the same day of the procedure before the discharge to assess any residual shunting. Follow-up echocardiograms were also performed in all patients between one week and 6 months after the procedure, first to assess for any residual shunting, and second, to measure the velocity of flows in the pulmonary arteries and the descending aorta.

Cardiac catheterisation

All the patients were sedated with intravenous Ketamine and Medazolam after written consent had been obtained from the parents. None of the patients received general anesthesia. Intravenous heparin at 100 units per kilogram was administered to all patients after obtaining vascular access. Haemodynamic parameters were measured in the right and left heart. Angiograms were performed in the proximal descending aorta in straight anteroposterior, lateral, and other projections as dictated by the situation.

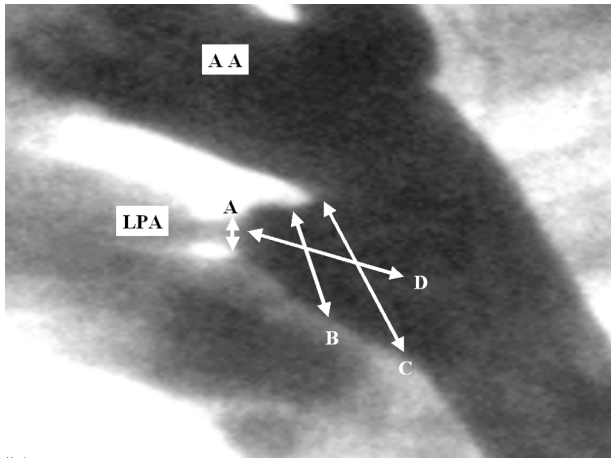

Figure 1.
Aortogram in the lateral projection, showing the different measurements we took to categorise the patent arterial duct. A is the narrowest diameter, B the diameter at the mid-ampulla, C is the diameter at the aortic ampulla, and D the total length of the duct. AA: aortic arch; LPA: left pulmonary artery.

These were reviewed to determine the morphology of the duct, which was classified as suggested by Krichenko et al.,[9] and to measure its size. We measured the narrowest diameter, the diameter at the middle, the diameter at the aortic end, and the total length of the ductal ampula, using for this purpose the software preinstalled in the Cathcore system by Siemens (Fig. 1). The diameter of the catheter was used as a reference point so as to correct for magnification. The duct was occluded antegradely according to standard procedures.[8,10] Cefuroxime or Cephazoline at 30 milligrams per kilogram was administered intravenously in all patients just before the device was deployed, with two oral doses also prescribed for use at home at eight hour intervals after discharge.

Selection of the device

Various authors[8,11] have recommended use of an occluder having the smaller diameter of the two dimensions given by the manufacturer 1 to 2 millimetres larger than the narrowest diameter of the arterial duct. We tried to follow the instructions of the manufacturer. It worked well for the first patient, but we faced difficulty in our second patient due to unexpected mismatch between the retention flanges of the device and the diameter at the aortic end of the ductal ampula, resulting in obvious protrusion of the device in the descending aorta, but without significant obstruction to flow. Subsequently, therefore, we used all of the measurements of the arterial duct when selecting the size of the occluder so as to achieve effective closure without causing any obstruction in the pulmonary arteries or in the descending aorta.

https://doi.org/10.1017/S1047951105000570 Published online by Cambridge University Press

Complications and problems

We classified complications as major or minor based on their severity and the perceived threat to life. A procedure-related complication was considered to have occurred if one or more of the following had happened:

Major complications:

- Procedure related mortality.
- Embolization either into the pulmonary artery or into the aorta.
- Loss of 5 per cent or more of the estimated blood volume.
- Protrusion of the device into the aorta or the pulmonary arteries causing acceleration of flow with a peak Doppler velocity of more than 2.5 metres per second.

Minor complications:

- Protrusion of the device into the descending aorta or into the pulmonary arteries causing acceleration of flow with a peak Doppler velocity between 2 and 2.5 metres per second.
- Temporary loss of femoral pulse on the side of vascular access.
- Loss of blood less than 5 per cent of estimated blood volume.

Technical problems:

We considered the following as procedurally related problems:

- Inability to position the device in the ductal ampula because of a mismatch in size
- Any difficulty related to loading, deployment or retrieval of the device.
- Malfunction of the Amplatzer device itself, or any component of the delivery system.

Statistical methods

The data and the results were expressed as mean plus or minus standard deviations, along with the range. The narrowest diameter of the arterial duct measured by echocardiography was compared with that measured on angiography using the paired *t*-test. The narrowest diameter measured by echocardiography in males and females was compared using Student's *t*-test.

The rates of complications in patients weighing more or less than 10 kilograms were compared using the *chi-square* test.

Results

Table 1 shows the demographic characteristics of our patients.

Table 1. Demographic data of our 43 patients.

Age (years)	3.79 ± 3.82 (0.45–13)
Sex	29 females, 14 males
Height (centimetres)	83.6 ± 21.1 (59–154)
Weight (kilograms)	11.9 ± 8.91 (4.5–44)

Table 2. Haemodynamic data of our patients.

Systolic pulmonary arterial pressure (millimetres of mercury)	40 ± 17.8 (17–87)
Systolic aortic pressure (millimetres of mercury)	88 ± 21.9 (59–115)
Ratio of pulmonary to systemic flows	2.43 ± 1.6 (1–7.6)
Index of pulmonary arteriolar resistance (Wood units)	3.29 ± 1.91 (0.39–6.5)

Table 3. Angiographic data of our patients.

Time required for fluoroscopy (minutes)	16.9 ± 7.8 (5.6–36.7)
Overall procedural time (minutes)	102 ± 31.7 (46–169)
Contrast used (milligrams per kilogram)	5.81 ± 4.1 (1.6–17.9)
Narrowest diameter of duct (millimetres)	5.18 ± 1.9 (3.4–11.1)
Largest diameter at the aortic ampulla (millimetres)	13.6 ± 4.9 (8–21)
Diameter at the mid-ampulla (millimetres)	10.2 ± 3.1 (5.9–15)
Total length of the duct (millimetres)	12.9 ± 5.1 (6–21.8)

Echocardiographic findings

The narrowest diameter of the duct as measured on echocardiography was 4.1 plus or minus 1.6 millimetres, with a range from 3.0 to 7.9 millimetres. The systolic pressure gradient across the arterial duct was 45 plus or minus 23.56 millimetres of mercury, with a range from 16 to 78 millimetres of mercury. All of the patients had peak velocities of flow of less than 2 metres per second in the pulmonary arteries and in the descending aorta.

Haemodynamic and angiographic data

Invasive haemodynamic and angiographic data is presented in Tables 2 and 3.

The narrowest diameter of the arterial duct as measured angiographically was larger than the diameter as estimated using echocardiography, albeit that the difference did not reach statistical significance. The narrowest diameter measured by echocardiography was larger in males, at 5.17 plus or minus 2.04, with a range from 3 to 8.5, than in the females, where the mean was 4.51 plus or minus 1.37, with a range from 3 to 8.5.

Deployment of the device

The procedure proved successful in 42 patients (97.5 per cent). We used a device of size 6/4 in 21 of

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the patients (50 per cent), using the 8/6 device in 10 (24 per cent), the 10/8 device in 7 (16.5 per cent), and the 12/10 device in 4 (9.5 per cent) of the patients.

Rate of occlusion

Immediate occlusion, confirmed angiographically, was achieved in 25 (60 per cent) patients. In another 8 (19 per cent), complete occlusion occurred some hours after the procedure, as confirmed by echocardiography. In 33 (79 per cent) of the patients, therefore, complete occlusion was achieved on the day of the procedure. At a further follow-up, of between one week and 6 months, complete occlusion had occurred in 6 more patients. At that time, 2 patients had trivial residual shunting, while one had a significant residual leak.

Problems

Problems were encountered on 7 (16 per cent) occasions. The procedure failed in one patient. The device was wasted on 2 occasions because of undersizing of the duct, bigger devices being deployed successfully on both occasions. Pull-through of the device occurred on 3 occasions, but the same devices were successfully re-deployed subsequently. Kinking of the long Mullins sheath, with inability to retrieve the device, occurred in one patient. There was no loss of femoral pulse. All but one of the patients in whom the problems were encountered weighed less than 10 kilograms.

Complications

Minor complications were observed in 6 (14 per cent) patients. The device was seen protruding into the descending aorta in 4 patients, producing abnormal flow at a peak velocity of 2.2 metres per second in 2 of these, and at 2.5 metres per second in the other two. The device was seen to protrude into the left pulmonary artery in 2 further patients, creating flows at peak velocity of 2.5 metres per second. One patient suffered bleeding in excess of 5 per cent of the estimated blood volume. He required transfusion, but there was no haematoma. This happened in the early phase of our experience, when we did not use the back-bleed device to control bleeding through the long Mullins sheath. Subsequently, we used this device and did not then encounter such a complication. All of these patients weighed less than 10 kilograms. There was no procedure related mortality or embolization of the device. The rate of problems or complications was significantly higher in patients weighing less than 10 kilograms when compared to the group with greater weight (chi square value equal to 10.281[b], p equal to 0.001).

Discussion

Since Masura et al.[6] first described the use of the Amplatzer ductal occluder for transcatheter treatment of patients with moderate-to-large patent arterial ducts, several further accounts have been provided.[5,12–16] Based on these reports, there is enough good evidence to support the efficacy and safety of the device in older children and adolescents. There are few reports, however, addressing its use in young patients.[7,11,17] It is difficult, therefore, to recommend the device as the treatment of choice in this population. As almost three-fifths of our patients weighed less than 10 kilograms, we sought to examine the problems and complications in this group of patients when compared to the older patients.

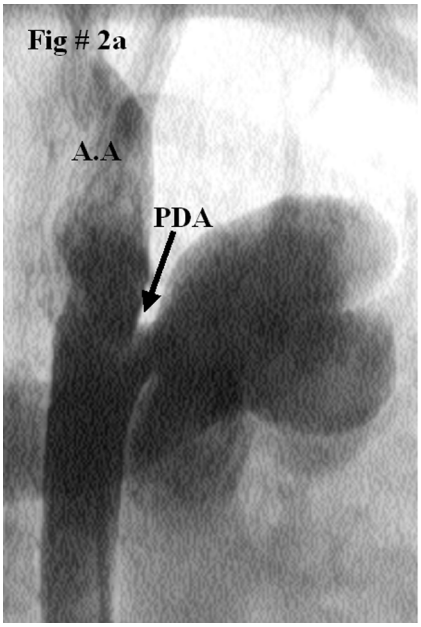
A new device is always associated with different, and sometimes unexpected, problems and complications. Some of these are recognized early, while others are noticed with the passage of time as the device gets used in different categories of patients. Many devices used to close the arterial duct share problems and complications, such as the potential risk of embolization, the danger of causing obstruction in the left pulmonary artery or descending aorta, and so on. Other problems are more specific to a particular device. Awareness of these difficulties ultimately helps in reducing and overcoming the risks, problems, and complications related to the procedure.

Failure of the procedure

Failure of the procedure has been well documented.[5–7,14,16] In our current experience, we failed once, the patient being two and a half years old and weighing 8 kilograms. The arterial duct had an abnormal take off, orientation, and shape. It originated from the left lateral side of the aorta, instead of arising in the expected anterior position (Fig. 2). Repeated angiograms in different projections failed clearly to delineate its boundaries, making it very difficult accurately to measure its size. Using the best images, we measured the narrowest and widest diameters, and its total length, at 5.5, 8.5, and 9.5 millimetres, respectively. On this basis, we selected the 10/8 device, but once it was positioned, the retention flanges were noted to be too large, and protruded into the descending aorta (Fig. 3). Repeat of the angiogram showed significant residual shunting, so we retrieved the device and referred the patient for surgical ligation.

Duct not well seen

It is interesting to note that, in almost one-quarter of our patients, we could not easily determine the anatomy of the arterial duct by routine angiography profiled in antero-posterior and left-lateral projections, either because of overlapping of the shadow



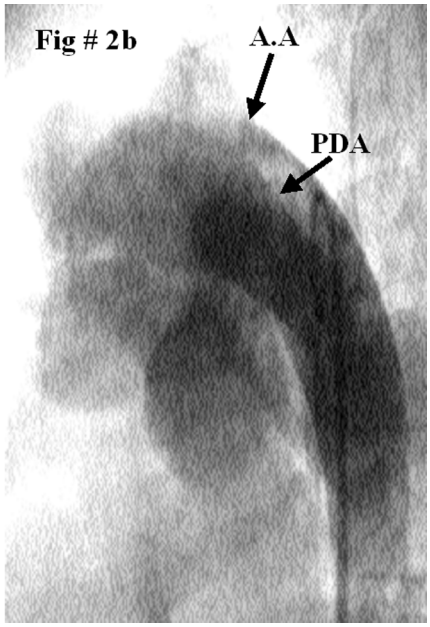
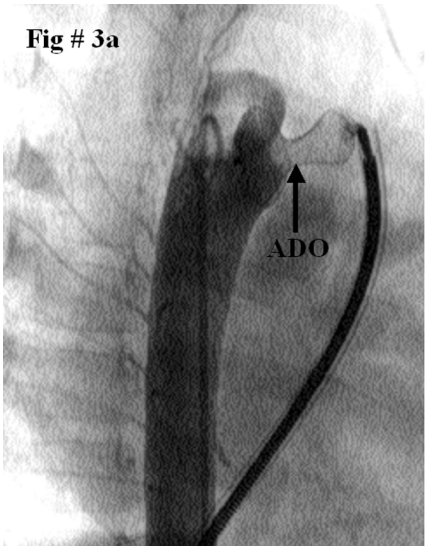


Figure 2.
*Aortograms taken in the antero-posterior (**a**) and lateral (**b**) projections reveal an abnormal orientation of the arterial duct. As seen in the antero-posterior projection (**a**), the duct arises from the lateral aspect of the arch, while in the lateral projection (**b**), its shadow is hidden behind the aortic arch. Note the dilated pulmonary artery. A.A: aortic arch; PDA: patent arterial duct.*



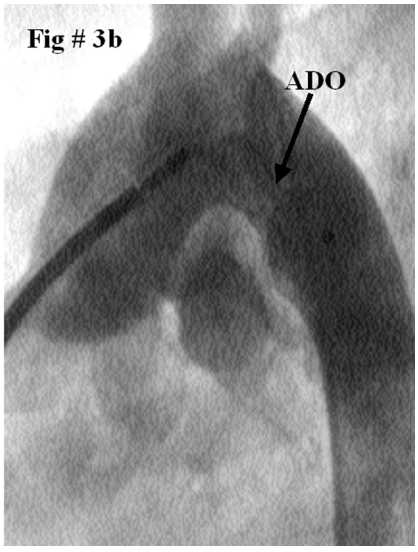


Figure 3.
*An aortogram is shown taken immediately after positioning of the occluder, and is seen in antero-posterior (**a**) and lateral (**b**) projections. As seen in the antero-posterior projection (**a**), the device protrudes into the arch, while in the lateral projection (**b**), the duct is hidden behind the shadow of the aortic arch. Note the significant residual shunting. ADO: Amplatzer ductal occluder.*

cast by the pulmonary artery because of the large size of the duct, or because of abnormal ductal orientation. Because of this, we required relatively longer times for both fluoroscopy and the overall procedure, and needed to use high volumes of contrast. The time used also contributed to the abandonment of the procedure in our failed patient mentioned above, and wastage of the device in another two because of undersizing the duct. In both of the latter patients, another larger device was successfully deployed. In many such cases, either the right anterior oblique or left anterior oblique projection, with or without cranial angulation, was required better to delineate the anatomy of the duct. Based on our limited experience, we believe that, when the duct is large, its anatomy can still be clearly delineated in most instances by reviewing together all of the angiograms done in multiple views. Thanopoulos et al.,[18] however, have suggested that, in these circumstances, sizing with a balloon, or the use of balloon occlusion angiography, better delineates the anatomy and size of the arterial duct.

Selection of the device

Poor angiographic delineation of the large patent arterial duct is not specific to the device used for closure, but rather relates to the size and orientation of the duct itself. This problem, nonetheless, does complicate the selection of the most appropriate device. As the Amplatzer ductal occluder is almost the only device available for closure of most large arterial

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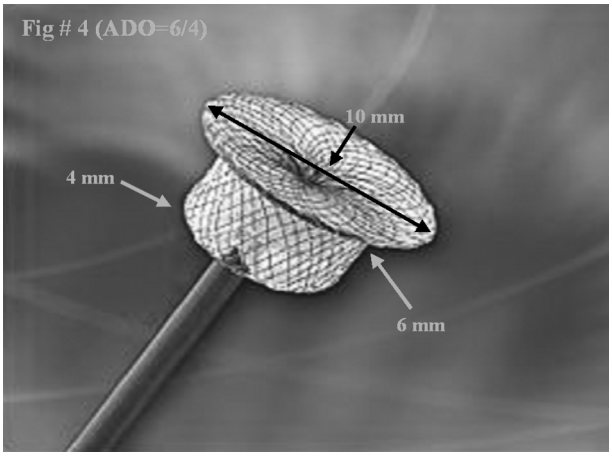

Figure 4.
Schematic diagram of Amplatzer ductal occluder of size 6/4. The aortic end has a diameter of 6 millimetres, and the pulmonary end of 4 millimetres, but the overall diameter of the retention flanges is 10 millimetres. Our experience suggests that note needs to be taken of the additional dimensions of the flanges over the number indicating the diameter of the aortic end of the device. ADO: Amplatzer ductal occluder.

ducts, irrespective of their anatomy, it is pertinent to consider in greater detail the geometry and dimensions of the device. The Amplatzer occluder has a retention flange and a cylindrical portion. It is supplied in seven different sizes, with each size having two numbers, expressing diameters in millimetres. The first number describes the diameter at the larger aortic end, while the second number accounts for the diameter at the smaller pulmonary end of the cylindrical portion of the device. The retention flanges extend by either 2 millimetres, for devices to the size of 8/6, or 3 millimetres for those larger than 8/6, beyond the aortic end of the cylindrical portion. The diameter of the retention flanges, therefore, is 4 to 6 millimetres larger than the numerical used for description of the size of the device. The length of the device also varies with its size, being from 5 to 8 millimetres (Fig. 4).

The criterions for selection recommended by the manufacturer do not take into account the length and the largest diameter at the aortic end of the duct. The assumption that the aortic end of the device will always fit the duct, without causing any obstruction in the descending aorta, does not appear to hold true in all instances. In case of a tubular arterial duct, if the device is selected based solely upon the criterion of the narrowest diameter of the duct, then the retention flanges of the device are prone to protrude into the aorta, as these are larger than the larger number given on the package of the device. We have also found that the aortic end of the device, when compressed, adopts a more convex shape, and that this configuration increases the risk of causing aortic obstruction. The recommendation made by the manufacturer that the retention flanges of the device be positioned in the descending aorta is valid only if the device is perfectly positioned. In the clinical situation, these flanges cannot always be centrally positioned. We found that the upper flange frequently protrudes, giving the potential for obstruction in the descending aorta. When selecting the most appropriate device, therefore, we have always ensured that the larger dimensions of the retention flanges fit snugly into the ductal ampulla, without causing aortic obstruction. Hence, we recommend that, in order to minimize the potential problems, and especially in young patients, all of the dimensions of the arterial duct should be taken into consideration while selecting the most appropriately sized device. When choosing the most appropriate size, we found that the best correlations were provided by the diameter of the aortic end of the device and the largest diameter at the aortic end of the duct. In our opinion, the diameter of the aortic end of the device should be about 1 to 2 millimetres smaller than the largest diameter of the duct. Using these guidelines, we were able, in most cases, to achieve complete occlusion of the duct without causing aortic obstruction, as well as minimizing the risk of embolization of the device. This issue, nonetheless, remains contentious, and is worthy of further discussion. The situation will become clearer as the long-term outcomes are analysed over the next five to ten years.

Problems and complications

Many might think that complications occurring in one-sixth of our procedures are excessive, but all but one of the complications we encountered was minor, and our cohort of patients was relatively younger. Indeed, all but one of the patients in whom complications and problems occurred weighed less than 10 kilograms. This suggests that, although the Amplatzer ductal occluder is otherwise very safe and effective, potential problems can still be encountered in younger children. Faella et al.[10] reported complications in a small number of their cohort of 316 patients, specifically 6 moderate and 8 minor complications, but one death. Bilkis et al.[7] reported aortic obstruction in one infant, and three instances of embolization of the device, out of a total of 209 patients. It seems, therefore, that the shape of the device has the potential to cause problems in patients weighing less than 10 kilograms.

Delivery system

Another difficulty that we encountered, but not classified as a problem, was the tight fitting of the

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loading device, and the long sheath of the proposed delivery system, for the specific size of the device. On different occasions, we encountered difficulties in advancing the device within the sheath. This was particularly the case for devices of size 10/8 and above. Loading and pushing the device in the tightly fitting delivery system results in distortion of its shape, and damages the delivery system, thus compromising its efficacy. This, we believe, was the reason we were left with significant residual shunting in one of our patients, and why the device kinked in the long sheath in another, making it difficult for us to retrieve the device. As far as we are aware, this problem has not been identified or reported by others. In fact, Bilkis et al.[7] reported that a bigger device could be retrieved into the sheath.

Rate of complete occlusion

The rate of instant complete occlusion, and the proportion of cases with complete occlusion at early follow-up, corresponds well with findings for these parameters reported by others,[5,7,16] while some have achieved higher rates of early occlusion.[6,8,14] We believe that evidence of a small residual shunt is acceptable in the catheterization laboratory, and that provided the position is stable, the device can still be released, since the majority of small residual shunts will close with the passage of time.

Conclusions

Our experience shows that, in most patients, the closure of moderate-to-large patent arterial ducts using an Amplatzer ductal occluder is generally safe and effective, and is a valid alternate to surgical ligation. When account is taken of the largest diameter of the duct, and particularly the added dimensions of the retention flanges of the device, embolization of the device or obstruction of the aorta can be minimized, particularly in young children. In such young patients, nonetheless, the variable geometry of the duct might still create occasional problems. Further studies of these issues are needed it will be possible to make definitive recommendations.

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