Transcatheter closure of persistent ductus arteriosus in infants using the Amplatzer duct occluder

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Abstract

Aim—To evaluate whether transcatheter closure with the Amplatzer duct occluder offers an alternative to surgical treatment in infants with a persistent ductus arteriosus.

Methods—12 patients under 1 year of age (age 1–11 months, body weight 2.6–8.7 kg) with clinical and echocardiographic findings of a significant duct were considered for transcatheter closure with the Amplatzer occluder. The device is made of a Nitinol and polyester fabric mesh and provides occlusion by stenting the duct. Measured angiographically, the narrowest diameter of the ducts ranged from 1.5–5 mm; in six patients pulmonary hypertension was also present.

Results—The devices were implanted and complete duct occlusion was demonstrated during follow up in 10 patients. Procedure related difficulties occurred in nine of the 12 cases and led to relatively long procedure and fluoroscopy times (procedure time 50–180 minutes, median 80 minutes; fluoroscopy time 4.9–49 minutes, median 16 minutes). In two infants transcatheter closure could not be achieved and surgical duct ligation had to be carried out.

Conclusions—In small infants with a persistent ductus arteriosus the Amplatzer duct occluder offers an alternative to surgical treatment, but further improvement of the implantation system is necessary before the procedure can be recommended as the treatment of choice.

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Keywords: persistent ductus arteriosus; transcatheter closure; infants; Amplatzer duct occluder

During the past decade transcatheter closure has become an established form of treatment for the majority of patients with persistent ductus arteriosus. Beginning with the initial experience of the Porstman plug in the 1960s,¹ several techniques and devices for non-surgical duct closure—for example, the Rashkind PDA umbrella² and coil occlusion devices—were developed in the late '80s and '90s. Soon after a new method had been tested in human trials, the drawbacks identified led to modifications and developments that made deployment easier or avoided residual leaks. The joint disadvantages of a large introduction system and a significant rate of residual leakage with the Rashkind PDA umbrella^{3–4} were overcome by coil occlusion techniques^{5–7} and by the modification of the plug technique that is represented by the Amplatzer duct occluder.^{8–10}

Despite technical improvements over the years, interventional closure of large ducts in infants remains a challenge. Because interventional closure of a moderate to large sized duct using multiple coils is sometimes technically demanding¹¹ and is accompanied by the risk of embolisation, residual shunting, and left pulmonary artery stenosis,¹² our aim in this study was to evaluate the use of the Amplatzer duct occluder with special reference to infants. The Amplatzer duct occluder was chosen because of its small introduction system (5–7 French sheath) and the theoretical advantage over coil occlusion techniques for patients with a persistent duct and pulmonary hypertension.

Methods

PATIENTS

Between August 1997 and May 2000, we considered transcatheter duct closure with the Amplatzer duct occluder in 12 patients under 1 year of age presenting with a persistent ductus arteriosus. Their age ranged from three weeks to 11 months (median 4.7 months). Body weight ranged from 2.6–8.7 kg (median 4.4 kg).

All the patients had clinical and echocardiographic findings of a significant ductus arteriosus with left atrial and ventricular volume overload, which was the indication for early closure in this group. In six of the 12 patients a large duct or an additional ventricular septal defect (in two patients) led to pulmonary hypertension; one patient had an additional secundum atrial septal defect and a small ventricular septal defect.

PROCEDURES

The device

The Amplatzer duct occluder (AGA Medical Corporation, Golden Valley, Minnesota, USA) is a 7 mm long, self expandable, cone shaped device made from a 0.004 inch (0.1 mm) thick Nitinol wire mesh and recommended for non-surgical duct closure independent of the shape and size of the duct. The Amplatzer duct occluder stretches and stents the duct, while polyester fibres sewn into the device promote thrombosis and complete duct occlusion. Secure positioning in the aortic ampulla of the duct is guaranteed by a retention skirt which is 4 mm larger than the device's cone diameter.

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Figure 1 Lateral aortogram showing the persistent ductus arteriosus (PDA diameter 2.8 mm) in a 4 month old girl, body weight 4.3 kg, Qp/Qs > 3, and with pulmonary hypertension.

Figure 2 Fixation of the Amplatzer duct occluder retention disc within the aortic ampulla.

Figure 3 Final angiogram after releasing the Amplatzer duct occluder (cone diameter 6 mm).

Figure 4 Kinking of the 6 French long sheath during advancing the delivery cable and device.

Figure 5 Snaring of the long sheath from the systemic arterial side using an Amplatzer goose neck snare.

Figure 6 Another illustration of snaring of the long sheath from the systemic arterial side using an Amplatzer goose neck snare.

For transvenous implantation of the duct occluder, a loader, a delivery cable, and a 5–7 French long sheath are used, as provided by the manufacturer.

Catheterisation

After introducing a 4 French sheath into the femoral artery and a 6 French sheath into the femoral vein, heparin was given (100 units/kg body weight). All patients underwent right and left heart catheterisation, starting with an initial biplane aortogram to evaluate the size and shape of the duct (fig 1).

A 0.032 inch (0.8 mm) exchange wire is placed across the duct from the pulmonary artery using a 4 French multipurpose catheter. Over this wire a 6 or 7 French long sheath (AGA Medical Corp) is introduced from the femoral vein through the duct into the aorta. An Amplatzer device with a cone at least 2–3 mm larger than the narrowest diameter of the duct was chosen. After connecting the device to the delivery cable by a micro screw it is introduced into the long sheath and advanced to the tip of the sheath. Withdrawal of the long sheath with the delivery cable held in position deploys the retention disc of the occluder and

further withdrawal of the sheath and the delivery cable fixes it within the aortic ampulla (fig 2). The cone of the occluder is configured within the duct by freeing the device completely from the sheath. An aortogram was performed while the occluder was still connected to the delivery cable. If the position was satisfactory the device was released by unscrewing it from the delivery cable. An additional aortogram showed the final position of the occluder and any residual shunting (fig 3).

This procedure, which follows the manufacturer's recommendations, could be carried out without difficulty in the majority of patients older than one year, but we often encountered technical problems in patients under 1 year of age. In this group, kinking of the long sheath tended to occur at the angle of the right ventricular outflow tract and the pulmonary artery. This happened while the delivery cable and device were advanced (fig 4) and led to the device and the cable becoming stuck at the kink. To overcome this problem the long sheath was snared from the systemic arterial side using an Amplatzer "goose neck" snare. If this failed, the AGA long sheath was exchanged for a

larger 6, 7, or even 8 French Cook sheath (William Cook Europe, Bjaeverskov, Denmark). These sheaths appear to be more stable and allow the device to be advanced with greater smoothness owing to their larger diameter. Even then, the snare technique sometimes proved helpful in positioning the long sheath (figs 5 and 6).

All procedures were performed under local anaesthesia and heavy sedation. Routine examination before the cardiac catheterisation included ECG, chest *x* ray, and a transthoracic echocardiogram. Before discharge an ECG, a biplane chest *x* ray, and a transthoracic echocardiogram were performed. Follow up examinations including transthoracic echocardiography were scheduled at one, three, and 12 months after the duct occlusion procedure.

Results

The mean (SD) duct diameter, measured angiographically, was 2.9 (1.0) mm at the narrowest point (range 1.5–5 mm). According to Krichenko's angiographic classification,¹³ the ducts were of type A (*n* = 10) and type E (*n* = 2), and devices with a maximum cone diameter of 6 mm (*n* = 8), 8 mm (*n* = 3), and 10 mm (*n* = 1) were chosen to achieve occlusion. The procedure time varied between 50–180 minutes (median 80 minutes), with a fluoroscopy time of between 4.9–49 minutes (median 16 minutes). Technical problems in advancing the device through the long sheath occurred in nine of the 12 cases (75%), though we experienced this problem only in five of the 25 older patients (20%) in whom we have used the Amplatzer duct occluder at our institution. Moreover, in two of the 12 patients (weighing 2.6 and 4.4 kg) neither the standard procedure nor one of the modified approaches was successful and the procedure had to be abandoned.

Complete occlusion was shown on colour Doppler echocardiography 24 hours after device placement in all but one patient. In this patient, complete occlusion was shown 45 days later, at the first follow up examination. Complications related to the procedure, such as blood loss with the need for blood transfusion (one patient) or thrombosis of the femoral artery (one patient), only occurred in the under 1 year age group. At follow up (after 1–3.5 years), we have seen no late complications such as haemolysis, recanalisation, device migration, or device related obstruction of the pulmonary arteries or descending aorta.

Discussion

Despite the improvement of techniques for interventional closure of persistent ductus arteriosus over the years, transcatheter closure of large ducts in small children remains a challenge. Coil occlusion is only effective in small to moderate sized ducts, even when multiple coils are used. Embolisation and residual shunting are recognised complications of this technique.^{12–14} Because of the small size of the introduction system and the cone shaped plug design the Amplatzer duct occluder seemed to offer transvascular treatment even in a group of

12 small symptomatic infants with relatively large ducts. Although the manufacturer does not recommend the use of the Amplatzer duct occluder in patients with a body weight of less than 5 kg, we included seven patients under that weight (from 2.6–4.4 kg) in our treatment cohort. Our study shows that it is possible to use this device successfully in the infant age group, as duct closure was achieved in all but two symptomatic babies. However, we experienced some specific difficulties with the procedure in infants.

The critical point of the procedure is when the device, connected to the delivery cable, has to be advanced around the curve of the right ventricular outflow tract towards the pulmonary artery. In infants this curve is tight, being more or less a right angle. Additionally, we found that the long sheath provided by the manufacturer often became kinked and so may not be strong enough to negotiate this curve while maintaining its integrity. Furthermore, a larger sheath than recommended was often needed to ensure the smooth advance of the device. Exchanging the sheath for another or the use of a snare technique to stabilise the sheath helped to overcome this drawback, but prolonged the procedure and fluoroscopy times. In our institution these difficulties not only occurred in the majority of the infants (75%) but also in five (20%) of a cohort of older patients whose bodyweight was between 10–20 kg. Comparing the infants with the older patients, the mean procedure and fluoroscopy times were longer in the infants, but this did not reach significance (procedure time, *p* = 0.118; fluoroscopy time, *p* = 0.0577; Wilcoxon rank-sum test).

In an attempt to eliminate these technical problems in small patients, the manufacturer has improved the delivery cable by making it thinner and more flexible. Despite this modification the procedure in small patients is still complicated by frequent kinking of the long sheath while the device and cable are advanced. It is apparent that the folded metal mass of the device may cause jamming within the sheath at the curve of the right ventricular outflow tract, with consequent kinking of the sheath. This happened even when using a larger sheath than recommended, for instance 7 or 8 French, and even, on occasion, with the stiffer Cook long sheath. In these cases the snare technique proved to be useful as a last resort to accomplish successful placement of the device.

As mentioned above, however, the procedure was not successful in two small infants of 2.6 and 4 kg body weight and finally had to be abandoned because of excessive procedural and fluoroscopy time. In all the other cases we were successful in placing the occluder and there was subsequent complete occlusion with good results on follow up.

The recently published results of the international clinical trial with the Amplatzer duct occluder¹⁵ reported 15 procedure related complications in 316 patients who underwent attempted transcatheter closure of a ductus arteriosus. Complications included haemolysis, left pulmonary artery stenosis, device

protrusion into the aorta causing coarctation,¹⁶ device misplacement, and one death following device embolisation. Looking at the original data file, which was kindly provided by the AGA Medical Corp, it became clear that these complications were more common in younger patients (complication rate in the group of patients under one year of age, 8.2%; complication rate in older patients 3.8%). Another recently published paper reported a single centre experience with the Amplatzer duct occluder in 209 patients,¹⁷ among whom 27% were infants weighing ≤ 5 kg. Surprisingly, kinking of the delivery sheath occurred in only one infant to the extent that device delivery was impossible. In another infant mild aortic narrowing was caused by the retention disc of the device. These results of the clinical trials with the Amplatzer duct occluder support our impression that procedure related difficulties may sometimes lead to severe complications especially in small infants.

CONCLUSIONS

Occlusion of a persistent ductus arteriosus with the Amplatzer duct occluder is clearly a more difficult and time consuming procedure in younger and smaller patients, necessitating relatively long procedural and fluoroscopy times. Our experience in small infants supports the manufacturer's recommendation that the procedure should not be attempted in patients below 5 kg body weight. Thus the Amplatzer duct occluder cannot be generally recommended for this patient group until further improvements to the delivery technique are available.

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