

HEART

Editorial

Closure of the arterial duct: past, present, and future

Most patients with a patent arterial duct are symptom-free, and because the duct is small many would probably have a normal life expectancy without any treatment. The rationale for closure is, however, usually to prevent late complications, such as endarteritis, Eisenmenger's syndrome, and heart failure in middle age resulting from chronic left ventricular volume overload. The exceptions are the premature or term infants with a large duct.

After the first reports of the surgical closure of an arterial duct,^{1,2} Jones, in his presidential address to the American Society of Thoracic Surgeons in 1963,³ reported on a large number of patients undergoing surgical treatment. He emphasised that division of the duct was preferable to ligation. Subsequently, it has been shown that surgical treatment is safe and effective,⁴ but recanalisation may occur after ligation. To justify the new techniques used to occlude the arterial duct, they must be shown to be at least as safe and as effective as conventional surgery. The onus on all investigators is to perform controlled clinical trials with strict protocols so that results can be analysed and interpreted properly.

Transcatheter occlusion of the arterial duct is now a well established method of treatment,⁵ which is performed frequently, with conventional surgery often being reserved for a large duct in the infant with symptoms. Although successful in some hands, the exact role of the thoracoscopic approach to duct ligation is unclear. It has not gained universal acceptance, and can be considered obsolete because the other techniques are safer and easier to perform and teach.

Many different devices have been designed for transcatheter closure of the duct, but surprisingly few have been the subject of clinical trials. The pioneering work of Porstmann and Wierny was updated in 1991.⁶ Many patients have subsequently undergone duct closure with the Ivalon plug, but this has not achieved general acceptance because of the need for a very large arterial sheath, with the consequent risks of femoral artery trauma. It should now also be considered obsolete.

The Rashkind PDA occluder was the second notable breakthrough and is probably the most extensively investigated device.⁷ Despite several disadvantages, its use has become routine, safe, and easy. However, the high cost (4000 to 5000 US dollars),⁵ the limitation of two sizes of umbrella (12 mm and 17 mm), the need for a relatively large transvenous sheath (8 or 11 French respectively), a late incidence of residual ductal shunting of up to 15% to 20%,⁸ and the risk of stenosis at the origin of the left pulmonary artery when a 17 mm device is used in small infants led to the search for alternatives.⁹ The frequency of use of the Rashkind PDA occluder has declined, not only because of these disadvantages, but also because the device is no longer approved in the United States and because other techniques for transcatheter closure have now become available. It is difficult to understand the regulatory issues in the USA which have prevented development and refinement of this device. Thus the Rashkind umbrella is also becoming obsolete, but will probably continue to be used

occasionally. Variations of the Sideris buttoned device have also been used successfully to close the duct in patients of all ages.¹⁰ The occlusion rate is high, but it seems unlikely that this device will achieve universal acceptance in its present form.

It is clear from some recent studies and from numerous reports of transcatheter coil closure of the duct in this current issue of *Heart* that there is, as yet, no consensus on the ideal device and the indications for its use.¹¹⁻¹⁵

However, the most striking aspect of these latter reports, whatever coils or protocols are used, is the relatively high cumulative occlusion rate (up to 98%) and the low incidence of embolisation. Coils can be delivered via a 4 or 5 French end hole catheter by a transvenous or transarterial route. Safe and effective closure can be achieved in most cases with one coil, but for large ducts more than one may be required and then there is a small risk of causing stenosis at the origin of the left pulmonary artery. Two coils can be delivered in series or simultaneously in parallel via two delivery catheters, even in symptomatic infants with a large duct. Tometzki and colleagues,¹⁴ reporting their experience with detachable coils, used more than one in 75% of cases of native duct, an experience not shared by other groups who achieved a high closure rate with a single coil in most.¹²⁻¹³ The protocol described in some detail by Tometzki *et al* may therefore be flawed and viewed with some scepticism, although the overall outcome for their group of patients seems very good. An audit of our own experience at the Royal Brompton Hospital in a similar group of patients has shown a cumulative occlusion rate of 96% when a single Cook coil was used in 85% of infants and children.

Although single or multiple Gianturco embolisation coils are effective in occluding the small or medium sized duct,¹¹ they have not been adopted widely because of the relative lack of control of coil positioning and release. Nevertheless, the results described by Hijazi and Geggel¹¹ in this issue are impressive. The (Jackson) Cook detachable coil is a Gianturco coil modified to be retrievable into the delivery catheter and in theory and practice may be less subject to embolisation. Although the 5 mm and 8 mm coils are specifically used for closure of the duct, various other diameter coils are also available. Though Rosenthal *et al* chose coils according to the morphology of the duct,¹³ other groups imply this is not necessary for effective treatment.

The Duct-Occlud pfm coil is the subject of extensive and exemplary clinical trials in Europe. The results of the British multicentre trial reported by Tometzki *et al* indicate that this device has no particular practical advantages over the (Jackson) Cook detachable coil.¹⁵ Although the Duct-Occlud is being subjected to continuing modification and refinement and is still undergoing clinical trials, it likely to become obsolete because of the relatively high cost (up to 2000 US dollars) and arguably an unnecessarily elaborate method of delivery.

But what of the future? Uzun *et al* emphasised the

importance of cost.¹² In every country, reducing the cost of medical treatment is becoming a priority. In the so-called "third world" surgical treatment of the duct is much cheaper than closure with the Rashkind umbrella or Duct-Occlud coil. At last, however, Giantures coils and (Jackson) Cook detachable coils provide an inexpensive and safe alternative with a high cumulative occlusion rate. The Giaturco embolisation coil probably requires greater operator skill if complications are to be avoided and this factor may limit its wider use. In the short term, the Cook detachable coil offers an effective and easy method of duct occlusion in most cases and more than one can be used in larger ducts. It seems unlikely that there will be any late complications, although scrupulous follow up should continue. Although symptomatic premature infants who do not respond to medical treatment will still require surgery, transcatheter coil occlusion can be used in infants as small as 2 kg. A variety of shapes of the Duct-Occlud coil, however, may in theory offer advantages for some patients in the future, and the continuing development of this device is justifiable.

It is salutary that the best and least expensive device for transcatheter closure of the duct currently available is a stainless steel spring coil, containing fibres of Dacron wool: similar coils have been in clinical use for over 20 years. Even for the ductus, it seems that the future cannot escape the past.

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