Stenting the arterial duct

Patency of the arterial duct is usually unwanted. Clinical assessment and treatment of patients whose ducts have failed to close spontaneously have been reviewed recently in this journal.^{1 2} This article reviews the latest attempts to prevent rather than promote ductal closure.

In a small percentage of neonates the duct is vital to survival and urgent treatment is required to maintain ductal patency. Prostaglandin E is highly effective at preventing ductal closure in these patients as a short term measure.^{3 4} In some cases normal or near normal circulation can then be restored by surgery (for instance in coarctation of the aorta) or by interventional cardiac catheterisation (for instance in selected cases of pulmonary atresia with intact ventricular septum^{5 6}), but in complex heart disease only palliation may be possible. It has long been recognised that this latter group, most of whom have complex pulmonary atresia or hypoplasia of the left heart, could benefit considerably if ductal patency could be maintained reliably in the medium to long term without the need for neonatal surgical treatment. The potential value of long term duct patency is well illustrated by a report of survival into adult life with hypoplastic left heart syndrome when the duct had remained widely open without any surgical or medical interference.⁷

Attempts at preventing ductal closure by simple dilatation of the duct with a balloon,^{8 9} or with a heated balloon in animals,¹⁰ have proved disappointing and recently attention has been focused on preventing ductal closure by implantation of balloon expandable metal stents. Stents have been successfully used in the treatment of a variety of intravascular stenoses unresponsive to simple balloon dilatation in children with congenital heart disease.¹¹ Improvements in design and technology have allowed the manufacture of stents small enough to be implanted into the neonatal arterial duct.

In duct dependent pulmonary circulations not amenable to repair, aortopulmonary shunt surgery provides a reliable source of pulmonary blood flow with low surgical mortality. The duct may then be allowed to close without risk, and many babies will lead a near normal life while the shunt remains fully patent or until they outgrow the limited blood supply provided by it. Although aortopulmonary shunts may be fashioned with low risk, medium to long term maintenance of ductal patency without thoracotomy or scarring of the pulmonary arteries induced by surgery is a very attractive goal for neonates with pulmonary atresia or other complex congenital heart disease with inadequate pulmonary blood flow.

In patients with uncorrectable obstruction to systemic blood flow such as the hypoplastic left heart syndrome, palliative surgery is much less effective than in infants with duct dependent pulmonary blood flow. Use of the pulmonary trunk to reconstruct the ascending aorta (maintaining pulmonary blood supply with an aortopulmonary shunt) has met with a certain degree of success in some hands,¹² but experience of this operation has been generally less favourable in the UK and it has not been adopted widely here. Neonatal cardiac transplantation can provide effective palliation, but shortage of donors in the UK¹³ has meant that almost all patients die before an organ is available. In the very few babies whose parents opt for an attempt at palliative treatment, cardiac transplantation offers a reasonable chance of survival in the medium term if the circulation can be maintained until a donor organ becomes available.

Ductal stent implantation might offer one means of short term palliation for these babies.¹⁴

Animal studies

Studies in lambs have shown that balloon dilatation of the arterial duct may produce short term improvement in duct diameter and delayed ductal closure, but these effects are often relatively short lived.⁸ Further studies were carried out using balloons heated by laser or radiofrequency energy,¹⁰ in the hope that smooth muscle in the duct wall might be inactivated by heat. Unfortunately, the heat injury to the media and endothelium can result in irregular stenoses in the duct that would limit the technique's clinical application. Implanting a stent, however, into the arterial duct in lambs has been shown to be technically possible and straightforward and it is clear that long term patency may be achieved.^{8 15 16} Study of the duct wall has shown that in many cases the metal mesh of the stents becomes covered by a thin layer of neoendothelium within a matter of weeks.¹⁷ Narrowing of the vessel lumen due to endothelial proliferation, a well known complication after stent implantation in diseased peripheral arteries, has been observed in lambs, but this does not appear to be as prominent as in diseased peripheral vessels. Studies in lambs have confirmed that stents may be successfully enlarged late after implantation, to allow for growth of the patient, by introduction and inflation of a larger balloon.^{18 19}

Clinical studies

DUCT DEPENDENT PULMONARY CIRCULATION

The arterial duct is frequently longer, more tortuous, and more inaccessible in pulmonary atresia than it is in duct dependent systemic circulations.²⁰ Because of this, ductal stent implantation in pulmonary atresia is technically demanding and in most neonates the duct must be approached from the aorta, usually via an axillary arteriotomy. To date only small numbers of patients with very complex disease have been treated. Early clinical studies in Leeds²¹ and at Guy's Hospital have shown that neonatal ductal stenting is possible in these patients but inability to enter the duct, ductal spasm (potentially fatal) and incomplete stenting of the full length of the duct (requiring a repeat procedure) were some of the early difficulties encountered. The technical difficulties of introducing a relatively large and inflexible device into a tortuous vessel in a remote part of the neonatal circulation are considerable, but further experience and refinement of the technique along with improvement of stent design will, no doubt, reduce these difficulties. It seems likely that at some stage in the future ductal stenting will be a more widely available alternative to surgical palliation in neonates with complex cyanotic heart disease, although it will be many years before sufficient data becomes available to allow late complications of stent implantation and surgical treatment to be compared.

DUCT DEPENDENT SYSTEMIC CIRCULATION

Stent implantation is technically relatively straightforward in patients with duct dependent systemic circulation because the duct is usually fairly straight. The stent is mounted on a balloon catheter which is introduced through a long sheath passing from the femoral vein to the duct via the right atrium, the right ventricle, and the pulmonary trunk and the

stent is deployed by inflation of the balloon. Stenting can maintain duct patency in this group of patients¹⁴ but even if the duct is kept open, progressive heart failure due to unrestricted pulmonary blood flow will usually develop unless a donor is found within a month or so. The shortage of very young donors in the UK led to the trial of a combined medical and surgical approach of ductal stent implantation (to maintain duct patency), balloon atrial septostomy (or septectomy, to allow the left atrium to empty), and surgical banding of the pulmonary arteries (to control excessive pulmonary blood flow).²² Although this is a more complex procedure than stenting alone, two (28%) out of a series of seven infants survived until transplantation at 4 and 6 months of age. Persisting heart failure, mostly due to persistent high pulmonary blood flow, was the cause of death in the remaining cases.²³ These results seem depressing but none the less represent a considerable improvement upon survival until organ availability compared with treatment with prostaglandin E alone in the centres involved in the study. While surgical reconstruction of the ascending aorta using the pulmonary trunk has retained its proponents and there is some understandable antipathy to the introduction of new techniques with unknown associated risks,²⁴ ductal stenting and bilateral pulmonary artery banding may offer an alternative hope of short to medium term palliation and act as a bridge to cardiac transplantation for a condition with a notoriously appalling prognosis in the UK.

Conclusions

Although maintenance of ductal patency by stent implantation may well prove to be an attractive alternative to palliative surgery, the technique is still very much in its infancy and there is much to be learnt about the technique itself as well as its short and long term benefits and complications. Clinical trials of new techniques which hope to improve upon tried and tested traditional surgical treatment must be carefully controlled along with attention to the delicate marriage of ethics and innovation. It is likely and seems appropriate that this potentially promising new technique will be restricted to a few specialised centres until the longer term results of clinical trials are available.

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