Intracoronary stents

The enormous growth of intracoronary interventions has brought an assortment of devices to help deal with coronary atheroma. In most cases the clinical role of these devices has yet to be defined and reports of their benefits and complications are often confined to selected groups of patients. There is justifiable concern that the treatment may be worse than the disease and that over-enthusiastic interventional cardiologists are modern “sorcerer’s apprentices”.

In the November issue of the British Heart Journal Haude and colleagues reported their experience with the Palmaz-Schatz stent in 50 patients. The indications included restenosis after a previous successful angioplasty, a poor angiographic result at the time of balloon angioplasty, “bail out” of coronary artery dissection and occlusion during angioplasty, and the treatment of stenoses in coronary vein grafts. Early events including death, need for bypass surgery, or stent thrombosis occurred in 10 patients, and bleeding complications in nine. In 41 patients angiographic follow up four to six months later showed restenosis or reocclusion in 10 (24%). Restenosis or late occlusion or both were more common in patients who received multiple stents.

These high rates of early thrombosis and of haemorrhage are similar to those reported in other series of coronary stents and the overall restenosis rate is not much below that seen after conventional balloon angioplasty. Despite this there is continuing interest in coronary stents because conventional balloon angioplasty is limited by the 5% incidence of acute dissection and occlusion of the coronary artery and by the 30–40% incidence of angiographic restenosis. In theory both these problems might be reduced by intracoronary stents if further research and development lead to improvements in stent materials and design.

Stents for “bail out”

In acute coronary dissection, intracoronary stents seem to stabilise the dissected arterial segment, preventing occlusion of the lumen by intimal flaps and possibly reducing the propensity to thrombosis by holding intimal flaps over exposed subintima. Four studies have suggested that the need for emergency coronary bypass surgery is reduced when stents are used to treat acute occlusion of the coronary artery. There are few data, however, on the long-term follow up of patients “salvaged” in this way.

Preliminary results from Fajadet et al show a 33% restenosis rate nine months after emergency stenting for “bail out” of unstable lesions.

Definite conclusions about the value of stents for “bail out” are difficult because of the lack of long-term data and because in many cases stents cannot be used because of the difficulties with delivery into tortuous arteries or to distal sites. Other bail out strategies such as perfusion catheters may be equally successful and randomised comparison of stents with these other methods are needed to assess their proper role in the treatment of acute occlusion.

Stents to reduce secondary restenosis

It may be useful to distinguish restenosis occurring in patients who have not previously undergone angioplasty at that site, which may be termed “primary restenosis”, from restenosis occurring at a site that has already restenosed after a previous angioplasty (secondary restenosis). It was hoped that intracoronary stents would reduce the rate of restenosis in lesions that had previously restenosed, and initial results were encouraging. Subsequent experience with stents at the site of previous restenosis showed restenosis rates approaching those after conventional balloon angioplasty in this situation. When multiple stents have been placed in one coronary artery both restenosis and thrombotic occlusion are particularly common.

Stents to reduce primary restenosis

The results of coronary stenting de novo—that is as part of the initial procedure—are more promising, with restenosis rates of between 7% and 18%. However, the routine use of stents for all lesions would considerably increase the cost and complexity of coronary angioplasty. It would therefore be logical to use stenting at the first intervention for lesions with an especially high risk of restenosis, such as lesions in the proximal left anterior descending coronary artery. Restenosis is also common after angioplasty of coronary vein grafts and early results suggest that stenting might be appropriate as the initial treatment in this situation.

Stent to reduce distal embolisation

Another complication of balloon angioplasty to bulky vein graft lesions is distal embolisation of plaque debris in 2–3% of cases. Placement of an intracoronary stent simultaneously with the first dilatation might trap such material and reduce this problem: in one series of 57 stent placements in vein grafts there were no episodes of distal embolisation (Dr U Sigwart, personal communication) but as yet there is no definitive data on this point.

High success rates in stent placement

The rate of successful implantation of stents was 98% reported by Haude and colleagues and rates of 94%–100% have been reported by other groups. However, these success rates apply to patients who have been selected on the basis of their suitability for stenting, excluding those with small or tortuous vessels or both, and therefore may not apply to the general population of patients undergoing coronary angioplasty. In most cases predilatation with a conventional balloon may be necessary before a stent can be introduced into the lesion. Lower profile and more flexible designs of stent should increase the number of patients who can be treated by this technology.
Thrombosis and haemorrhage
In studies using early designs of stents thrombotic occlusion was frequent and the vigorous anticoagulant and antiplatelet treatment intended to prevent this in turn caused haemorrhagic complications. In the study of Haude et al \(^1\) using the Palmaz-Schatz stent patients received heparin and dextran infusions during the procedure, and thereafter aspirin, dipyridamole, and coumarin. Acute or subacute thrombosis of the stent occurred in eight of their 50 patients and bleeding complications in nine. Schatz, Palmaz, and colleagues reported subacute thrombosis of their stent in 15% of 39 patients in whom stenting was followed by aspirin and dipyridamole, and in only 0-6% of 174 patients given aspirin, dipyridamole, and warfarin.\(^7\) However, almost 10% of the 174 had serious haemorrhagic complications including two cases of tamponade, one of intracranial haemorrhage, four of gastrointestinal bleeds requiring transfusion, eight haematomas requiring surgery or transfusion or both, and two femoral pseudoaneurysms. Current data suggest that carefully controlled anticoagulant regimens are able to prevent stent thrombosis and are associated with lower rates of haemorrhagic complications.\(^3\)

Careful selection of lesions suitable for stenting may also reduce the risk of thrombosis and the need for vigorous anticoagulation. It is now appreciated that the risk of thrombosis depends on stent diameter: thrombosis occurred in 16% of patients with smaller diameter stents (expanded to 3·5 (0·5) mm) and only 3% of those with larger stents (expanded to 4·1 (0·8) mm).\(^3\) Thrombosis was also more common when multiple stents were placed in an artery,\(^3\)\(^7\) although multiple stents in different coronary arteries do not seem to cause additional problems. Current recommendations are that stents are placed only in vessels that are expected to attain a diameter of >3 mm after dilatation and that as few stents as possible are placed in any one coronary artery.

Stent materials and design
There has been much discussion concerning the materials and designs of stents. Inadvertent deployment may be a problem of self-expanding stents; balloon rupture sometimes occurs during deployment of balloon expanded stents. Most coronary stents are difficult to visualise in patients because of the small mass of radio-opaque material. This causes difficulties with accurate placement within the lesion, and may lead to confusion if the operator suspects that the stent has become detached and embolised; radio-opaque markers have now been added to some stent delivery systems. Increased axial flexibility of stents would improve the ability to deliver them to tortuous coronary arteries and might reduce the risk of damage to the arterial wall.\(^3\) Placement of stents distally or in tortuous arteries may also be aided by soft-tipped 5 French flexible sheaths (Teleguide (Schneider) and SDS (Johnson & Johnson)). The balloon and stent can be advanced into the coronary lesion within the sheath, over an angioplasty guide wire. The sheath is then withdrawn, leaving the stent and balloon within the lesion. This technique reduces the risks of inadvertent stent displacement and of coronary dissection during passage of the stent through the proximal coronary artery.

The material of the stent influences the mechanical properties and also the propensity to thrombosis and to endothelialisation. Positively charged metal such as stainless steel are thrombogenic unless highly polished,\(^3\) negatively charged metals are less thrombogenic but most are corrosive.\(^3\) Biodegradable materials may provide short support of the arterial segment without long term risks of thrombosis.\(^4\)\(^5\) but such stents are not yet available for clinical trials. Other possibilities include eluting stents that slowly release drugs to reduce thrombosis and restenosis,\(^4\)\(^5\) coated stents with surface-bonded anticoagulant factors,\(^43\) and seeded stents coated with cultured endothelial cells.\(^4\)\(^4\)\(^5\)

Unfortunately the cost of intracoronary stents may well limit their use; the only coronary stent currently available costs approximately £200, excluding the cost of the balloon. Formal cost-benefit analyses are needed that include comparison with standard balloon angioplasty, with other devices, and with coronary bypass surgery.

Opinion
At present, the use of intracoronary stents in the United Kingdom is limited to a few centres. In our opinion, stents should be available in all centres for bail out procedures for acute dissections which cause or threaten acute coronary occlusion and perhaps for other selected cases such as vein graft angioplasty. Recent clinical experience suggests that, with the Palmaz-Schatz stent at least, the acute risk of thrombosis can be controlled to an acceptable level without unacceptable risks of haemorrhage. Medium-term anticoagulant and long-term antiplatelet therapy are important to minimise thrombosis, and close follow up of patients is essential.

It seems likely that stents will prove useful adjuncts to conventional angioplasty: experience to date is not yet sufficient to formulate guidelines for clinical use. Multicentre studies of primary coronary stenting to reduce primary restenosis are in progress. Mechanical factors alone are unlikely to prevent restenosis—perhaps a combination of the mechanical advantages of stents with pharmacological intervention will solve this problem.

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Editorial


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