Fortnightly Review

New methods of making blocked coronary arteries patent again

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The use of percutaneous transluminal coronary angioplasty is limited by procedural complications and the serious drawback of restenosis, but some new techniques have been developed in an attempt to lower the complication rate for difficult lesions and reduce the rate of restenosis. These include devices to physically remove atheromatous plaque, such as the Simpson Coronary AtheroCath and the transluminal extraction catheter, as well as devices to ablate the plaque in situ, including the Rotablator and the excimer laser catheter. Although each device

Technical problems with balloon angioplasty

- Peripheral vascular disease may limit access of the guiding catheter to the coronary ostium
- Extreme angulation of the diseased vessel may cause difficulties in passing guidewire or balloon
- Guidewire may not be able to cross totally occluded vessels
- Balloon may not be able to follow guidewire through very severe stenoses (rare with modern balloons)
- Vessels with hard lesions may not dilate even at pressures likely to cause the balloon to rupture
- Elastic lesions may recoil as soon as balloon is deflated
- Bulky plaque is not removed
- Balloon inflation may cause an uncontrolled dissection and risk abrupt closure

FIG 1—Balloon angioplasty. With the guiding catheter in the ostium of the coronary artery, the fine guidewire is manipulated across the stenosis (1); the deflated balloon is advanced over the guidewire (2) and inflated once across the stenosis (3); the stenosis is reduced (4) by splitting and compressing the plaque

FIG 2—Angiogram of stenosis in left anterior descending coronary artery successfully relieved by balloon angioplasty. The balloon is filled with contrast and can be seen fully inflated during the angioplasty (middle panel)

may have advantages in certain types of lesion, few data on their use have been reported in properly controlled randomised trials. The data available so far do not suggest that these devices will be safer than balloon angioplasty or that they will reduce restenosis. However, using metallic stents to support coronary arteries after balloon angioplasty seems to reduce acute complications and to lower the rate of restenosis, and the use of stents is likely to increase.

In the United Kingdom almost 10 000 patients with coronary artery disease were treated with percutaneous transluminal coronary angioplasty in 1991, and the use of the procedure is increasing at 17% a year.¹ But balloon angioplasty has drawbacks, which divide into two main areas: the first is technical, related to the feasibility of carrying out the angioplasty and obtaining a satisfactory immediate result (fig 1); the second relates to the healing process, which may be exuberant enough to cause a restenosis.

Balloon angioplasty

The technical problems are predictable (box). None the less, increasing experience and improvements in the equipment now mean that in almost 90% of cases balloon angioplasty is a "primary" success (fig 2).¹⁻³ This is usually defined radiographically as a reduction in the stenosis to less than 50% without major complications. The balloons are enormously sophisticated—each one is handmade and costs about £500—but the split they create is uncontrolled and may continue into the "normal" vessel wall, causing an extensive

dissection. This is especially likely with eccentric, calcified, or angular lesions. Such dissections are the commonest cause of abrupt closure of the vessel after balloon angioplasty, which is seen in 3-5% of patients.⁴ This accounts for most of the serious complications of angioplasty, including myocardial infarction (1.5-3%), emergency coronary artery bypass grafting (2.5-4.5%), and death (0.5%).^{1,3}

In the first six months after operation exuberant healing causes restenosis in 25-50% of cases,⁵ and this remains the Achilles' heel of percutaneous transluminal coronary angioplasty. There are no reliable features that can be used to predict restenosis in an individual. A vast worldwide research effort has tried to find drugs to prevent it, but as yet all have proved useless.

The limitations of balloon angioplasty have encouraged the development of some ingenious new methods to unblock coronary arteries. This article describes some of these techniques and examines how they compare with balloon angioplasty.

New devices

Removing the plaque, rather than just cracking or splitting it, should result in fewer immediate complications and reduce the stimulus to restenosis. Several devices have been designed to cut and remove the atheroma (atherectomy) or to pulverise or denature it (ablation).

PLAQUE REMOVAL

Directional coronary atherectomy

In 1990 the first new device licensed by the Food and Drug Administration in the United States was the Simpson Coronary AtheroCath (Devices for Vascular Intervention, Redwood, CA). This device consists of a metal housing with a 10 mm long, canoe shaped window in one side, containing a cylindrical cutter capable of rotating at 2000 rpm (fig 3). The window

FIG 3—Detail of cutting end of Simpson Coronary AtheroCath. The rotating cylindrical cutter is seen inside the canoe shaped window; when advanced, the cutter "shaves" off a strip of plaque and pushes it firmly into the nose cone. The balloon attached behind is used to press the window against the plaque

allows the cutter to be directed towards bulky or eccentric plaque. The device is advanced over a guidewire across the stenosis, where a soft balloon attached to the back is expanded so that some of the plaque bulges into the housing. The cutter is then activated and advanced slowly, shaving off a strip of plaque and pushing it firmly into the collecting nose cone. Multiple passes may be made to cut away the plaque before the device must be withdrawn to empty the nose cone.

Pathological studies suggest that some of the benefit of this technique results from the effect of simply pushing the rigid AtheroCath through the lesion,⁶ while the deep cuts facilitate subsequent balloon dilatation. The device has the unique advantage that specimens of new and restenotic lesions may be obtained for analysis; this has proved valuable for research. Technical disadvantages are principally related to the large size and rigidity of the device, which necessitate a special large guiding catheter (10-11 French gauge, approximately 3.5-4 mm

diameter) in the artery and means that stenoses in small or tortuous vessels cannot be reached. It is of no use in crossing tight stenoses and has higher complications when the lesions are heavily calcified.

The results of a large randomised trial (CAVEAT) to assess directional atherectomy in comparison with balloon angioplasty have recently been published: they showed a rather high abrupt closure rate (7% v 3% with balloon angioplasty) and incidence of clinical myocardial infarction (6% v 3%), with an overall restenosis rate of 30-50%, which was no better than balloon angioplasty alone.⁷ Second and third generation devices are under development and may allow safer access to a wider range of lesions, but at present this technique seems to confer no advantage over balloons.

Transluminal extraction

The transluminal endarterectomy catheter (InterVentional Technologies, San Diego, CA) is another form of atherectomy catheter which cuts the atheroma and immediately extracts the fragments under vacuum aspiration. It is essentially a reinforced epoxy tube with a nose composed of cutting blades and open sides (fig 4). The device is passed over a special

FIG 4—Detail of cutting end of transluminal endarterectomy catheter. The nose cone is formed from two cutting blades and rotates at 750 rpm. Fragments of plaque are immediately aspirated through the body of the catheter into a collecting chamber (not shown)

guidewire which is stiffer than normal to provide support and which ends in a ball. The ball is a safety device to prevent embolisation in case of fracture of the cutting head. The central lumen extends the length of the tube, allowing infusion of a pressurised flushing solution and aspiration of the excised tissue. The principles of use are standard but again a large (10 French gauge) reinforced guiding catheter is necessary. In use, the cutting head rotates at 750 rpm and, as with directional atherectomy, multiple passes are necessary.

Compared with the data on directional atherectomy, there is a paucity of information about transluminal extraction, but the device seems to have certain advantages and disadvantages. One purported advantage is its ability to extract thrombus from the lumen of saphenous vein grafts or native arteries, a situation in which conventional balloon angioplasty carries a substantial risk of embolisation. As with directional atherectomy, tissue is removed, but the specimens extracted are too fragmented for histological analysis. The cutting head of the transluminal extraction catheter is rigid and limited in size by the guiding catheter, so subsequent balloon dilatation may be needed to obtain a satisfactory result, adding considerably to the cost.

There are as yet no published randomised controlled trials of transluminal extraction, but descriptive information on the device is provided by the transluminal extraction catheter registry.⁸ The device seems to be used most frequently to treat saphenous vein grafts and the primary success rate is around 82%; if the procedure is followed by a balloon angioplasty the success rate rises to nearer 90%. The incidence of major complications seems similar to that for balloons but there is a higher complication rate in eccentric lesions and the problem of embolisation of gummous

material in vein grafts still remains. Clinical follow up showed a restenosis rate of 38% for native lesions and 42% for vein grafts; the angiographic restenosis rate was greater than 50% and 60%, respectively.⁸ These figures are no better than those for balloon angioplasty.

PLAQUE ABLATION *Rotational ablation*

Percutaneous transluminal high speed coronary rotational ablation ("Rotablation") differs from atherectomy in that the plaque is not cut and extracted but is pulverised into particles sufficiently small (about 5 µm diameter) for them to pass into the capillary circulation, where they are scavenged by the reticulo-endothelial system.

The Rotablator (Heart Technology, Bellevue, WA) consists of an olive shaped abrasive burr studded with microcrystal diamond chips attached to a helical coil shaft capable of rotating at speeds up to 200 000 rpm (fig 5). The shaft is perfused through an outer sheath

FIG 5—The Rotablator rotates around a guidewire at speeds approaching 200 000 rpm and operates on the principle of "differential cutting": rigid inelastic or calcified plaque is pulverised while the healthy elastic wall is deflected away undamaged

with pressurised saline to cool and lubricate it. By using a 9 or 10 French gauge (3-3.5 mm diameter) guiding catheter, a long, rather unwieldy stainless steel guidewire is manipulated across the stenosis and the burr advanced to just before the lesion. The device is then activated (it sound like a dentist's drill) and advanced slowly in a "pecking" motion until the plaque is ablated. The technique uses the principle of differential cutting, like the saws used to remove plaster casts—rigid, calcific tissue is cut but there is minimal abrasion of the normal elastic wall. The device is usually demonstrated at sales meetings by being run over the surface of a fresh egg, pressed down by the operator's thumb: the eggshell has a neat channel drilled through it but the membrane inside the egg, and the thumb, are unharmed.

The small burr and flexible drive shaft of the Rotablator allow the device to navigate tortuous vessels as well as angulated, calcified lesions,⁹ but the device has some unique procedural problems. Transient atrioventricular block, sometimes needing a temporary pacing wire, is common; intense coronary spasm may be seen in one third of patients but is usually transient and responds to nitrates or gentle stretching with a balloon; more rarely, flow in the treated artery is very sluggish even though the vessel is patent. This "no reflow" phenomenon is accompanied by angina and electrocardiographic changes and is thought to be due to capillary sludging—recovery can take up to 15 minutes.

The Rotablator has recently been licensed by the Food and Drug Administration in the United States so we are likely to see an increase in the number of papers reporting its use. It is interesting to note in passing the legal quirk that allows a new device to be marketed

without randomised, controlled trials while drugs must go through years of careful evaluation before they are released on to the market. The currently available data come from the rotational atherectomy multicentre registry, which reports a high primary success rate (90-97%) even in small vessels or those with long, angulated, calcified, and previously undilatable lesions.^{10,11} Unlike in balloon angioplasty, the incidence of major complications (myocardial infarction, urgent surgery, and death) was not greater with the Rotablator in this high risk group than in patients with less complex lesions. Intravascular ultrasound images generally show a smooth, "polished" lumen with only minor damage to the media, although the intima is entirely denuded, but dissections may none the less be seen in 10-30% of cases. As with atherectomy devices, the size of the rigid burr is limited by the size of the guiding catheter and adjunctive balloon angioplasty is often needed, adding to the expense. Overall restenosis rates are around 30-50%, which is no better than with balloon angioplasty, but once again there are as yet no published randomised controlled trials.

Laser

Laser energy from various devices can ablate plaques directly or indirectly by several different mechanisms (box). Many of the devices are very new—fluorescence guided "smart" lasers, holmium "cold" lasers, or balloon centred argon lasers, for example—and there are scant preliminary reports on their use. Some, such as the "hot tip," which uses laser energy to heat a metal cap, have already largely fallen into disuse because of a high incidence of coronary thromboembolism and vasospasm, difficulty of use, and inability to ablate tortuous or calcified lesions. Two devices have been more extensively evaluated: excimer laser and laser balloon angioplasty.¹²

Modes of action of laser energy

Photothermal ablation:

- Tissue absorbs energy generating intense heat
- Seen with continuous wave laser

Photochemical ablation:

- Energy disrupts tissue chemical bonds
- Seen with pulsed wave lasers

Photoacoustic trauma:

- Uncontrolled formation of intracellular vapour disrupts cell membranes
- May damage adjacent tissue

The excimer laser, licensed in January 1992, is also known as the cold tip laser since it ablates through photochemical, non-thermal decomposition and reportedly produces no intraluminal charring on angiography (fig 6).¹³ Again no randomised studies are available. The most extensive information from the excimer laser coronary angioplasty registry of over 2000 patients¹⁴ and from other descriptive studies^{15,16} suggests that the primary success rates are 90-95%, with 60% of patients requiring adjunctive balloon dilatation, and complication rates of 3.5% myocardial infarction, 3.6% emergency coronary artery bypass grafting, and 1.2% perforation (half of these had serious consequences for the patient). Acute closure occurred in 5%, although one study reported a rate of 20%.¹⁵ Both the nature of the lesions attempted and the design of the lasers have changed during the period of these studies, which reduces their validity, but restenosis rates were 30-46% and complications during follow up, such as the need for coronary artery bypass surgery or repeat intervention, were no better than would be expected for conventional balloon angioplasty.

FIG 6—Excimer laser. Pulses of ultraviolet light ablate tissue in direct contact with the tip by breaking down chemical bonds: photochemical ablation

FIG 7—The Palmaz-Schatz stent is made of stainless steel. It is placed across the stenosis mounted on a deflated balloon (top) and expanded by balloon inflation, embedding itself in the vessel wall (bottom). The balloon can then be deflated and withdrawn, leaving the stent in situ

With the laser balloon angioplasty device the balloon itself becomes heated by laser energy transmitted through a fiberoptic system to a heating element within the balloon. Although the technical success rate is around 95% and the rate of immediate complications seems to be low, the restenosis rate is unacceptably high at 50-80%, probably owing to the extensive tissue damage produced.¹⁷ The device is now used only after conventional balloon angioplasty to reduce a residual stenosis or to tack back a dissection flap and help avoid abrupt closure. However, even this limited role has been usurped by another category of new devices: stents.

Stenting

Coronary stents are metallic mesh tubes which may be placed in a collapsed state within a stenosis and then expanded, embedding themselves into the vessel wall to hold the artery widely open. Of the devices currently available, most are expanded by balloon but some are self expanding once released from a restraining sheath. The ones most commonly used in the United Kingdom are the Palmaz-Schatz (Johnson and Johnson, Maidenhead, Berkshire) and the Wiktor (Medtronic, Watford, Hertfordshire) (figs 7, 8).

Although they were initially developed in an attempt to reduce restenosis, all stents have proved to be extremely useful in treating important dissections which are causing, or threaten to cause, abrupt vessel closure. They do not require special guiding catheters and are usually placed through the catheters routinely used for balloon angioplasty. It can be difficult to advance the stents to the site of the dissection if the vessel is very tortuous or diseased, and occasionally it is difficult to visualise exactly where they are to be placed, but implantation is successful in 95% of cases^{18,19} and they give very attractive radiographic images of a smooth, widely patent artery (fig 9).

Unfortunately, these advantages are counterbalanced by some disadvantages. The most important of these is the tendency to clotting up to 14 days or more after implantation (with a peak incidence at three

FIG 8—The Wiktor stent is a flexible mesh of tantalum wire which is densely radio-opaque. Shown here in its expanded state, it is delivered mounted on a balloon over a guidewire and expanded in situ by balloon inflation

FIG 9—Tissue cross section of an expanded stent. Cut ends of struts are seen as dark spots embedded in the wall of the vessel, sealing down a dissection (arrow)

to four days) which currently necessitates the use of an extremely aggressive anticoagulation regimen including aspirin, low molecular weight dextran, high dose heparin, dipyridamole, and warfarin—all given together initially. This has reduced the risk of subacute thrombosis to around 9%,^{18,19} but accounts for most of the considerable complications. Local haematoma at the site of the femoral puncture is common and may require blood transfusion or surgery; pseudoaneurysm formation and abdominal and intracranial bleeding also occur. Further, anticoagulation control takes a considerable amount of nursing and medical time, and patients remain in hospital for up to eight days. Recently, there are reports that larger stents which are carefully and fully expanded have a lower risk of thrombosis and allow a much more acceptable anticoagulation regimen to be used. This remains to be confirmed.

Several trials are examining the use of stents. Preliminary reports of one major European trial—the Benestent trial—suggest that stents may substantially reduce the restenosis rate (from 33% to 20% compared with conventional balloon angioplasty) when implanted electively into new lesions, although the restenosis rate is less attractive when they are used in an emergency or in restenotic lesions. Despite the anticoagulation regimen, the complication rate also seemed to be acceptable. A similar reduction in restenosis—from 43% to 29%—has recently been reported from another multinational study called the stent restenosis study (STRESS). Bleeding complications were 10% with stents compared with 5% with balloon angioplasty.

We must await publication of the full results of these ongoing trials, but of all the new techniques coronary stenting comes closest to fulfilling the original aims of a lower immediate complication rate and a reduction in restenosis. The use of these devices is likely to increase.

Future developments

The hunt for a simple pharmacological method to prevent restenosis continues but with diminishing hope as each agent tested fails to work in humans. This, coupled with the impulse of cardiologists to push back the frontiers of intervention and the drive of manufacturers who see a considerable market, provides the impetus to continue development of newer, cleverer mechanical devices. However, the sparse data already available do not suggest that these devices will have much of an advantage over conventional balloon angioplasty or be cost effective (box). The one exception may be stents: those currently available certainly have a role in reducing the requirement for emergency surgery and possibly in reducing restenosis, and future refinements—which include heparin coated, endothelial cell coated, and biodegradable stents—may help to reduce their complications and make them more user friendly. Meanwhile the use of balloon angioplasty is entering the mature “third phase”: careful use in appropriate circumstances produces beneficial results which no new method at present looks likely to supersede.

All illustrations are courtesy of Advanced Cardiovascular Systems Inc, Basingstoke.

Comparison of new devices and balloon angioplasty

Criterion	Directional coronary atherectomy	Transluminal extraction catheter	Rotablator	Laser	Stents
Easier or cheaper?	No	No	No	No	No
Use if guidewire fails to cross?	No	No	No	No	No
Use if balloon fails to cross?*	No	Yes	Yes	Yes	No
Able to dilate lesions where balloon fails?*	Yes	Yes	Yes	Yes	No
Fewer immediate complications?	No	No	No	No	Yes
Lower restenosis?	No	No	No	No	Yes

*Failure is rare with modern balloons.

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Care of dying patients in hospital

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Abstract

Objective—To study the process of care of dying patients in general hospitals.

Design—Non-participant observer (MM) carried out regular periods of continuous comprehensive observation in wards where there were dying patients, recording the quantity and quality of care given. Observations were made in 1983.

Setting—13 wards (six surgical, six medical, and one specialist unit) in four large teaching hospitals (bed capacity 504-796) in west of Scotland.

Subjects—50 dying patients (29 female, 21 male) with mean age of 66 (range 40-89); 29 were dying from cancer and 21 from non-malignant disease.

Results—Final period of hospitalisation ranged from 6 hours to 24 weeks. More than half of all patients retained consciousness until shortly before death. Basic interventions to maintain patients' comfort were often not provided: oral hygiene was often poor, thirst remained unquenched, and little assistance was given to encourage eating. Contact between nurses and the dying patients was minimal; distancing and isolation of patients by most medical and nursing staff were evident; this isolation increased as death approached.

Conclusions—Care of many of the dying patients observed in these hospitals was poor. We need to identify and implement practical steps to facilitate high quality care of the dying. Much can be learned from the hospice movement, but such knowledge and skills must be replicated in all settings.

Introduction

Though most terminally ill patients indicate a preference to die at home,¹⁻⁴ national statistics show that in the past two decades more than 60% of all deaths occurred in an institution.⁵ Most of these deaths were in general hospitals.^{5,6}

Several retrospective studies have attempted to assess the level of satisfaction with care in hospital during the final stage of life by means of the recollections of relatives or close associates.⁷⁻¹³ The findings indicate that, despite general satisfaction with the medical treatment, there is evidence of deficiencies in the service, including inadequate control of symptoms

and failure to meet the physical, social, and emotional needs of the patients. More recent surveys have highlighted the distress experienced by patients and their families.¹⁴⁻¹⁶

Few studies have reported systematically collected data on the process of care in hospitals.^{17,18} This descriptive, exploratory study goes some way to redress this. The aims were to describe the nursing care of patients during the final six days in hospital and to identify factors that might influence that care.

Methods

The study was conducted in four large teaching hospitals (bed capacity 504-796) in the west of Scotland, the data being collected during 1983. It was not prepared for publication earlier because of the untimely death of both academic supervisors and the appointment of the first author to a post in the Far East. Permission for access was given by the area health board and by the senior medical and nursing committee of each hospital. Investigations were carried out in 13 wards—six surgical, six medical, and one specialist unit.

Initially, interactions were monitored between 23 dying patients and 190 nurses (48 qualified and 142 unqualified). Notes were made of which nurses attended each patient, the care given, and the length of the interaction. Secondly, 91 ward rounds were attended; the content and length of the consultation between 14 consultants and a further 27 dying patients were noted. Communications between the consultants and 22 senior nurses concerning the dying patients were also noted, ward report sessions were attended, and nursing reports and clinical records were read.

The senior nursing officers in each hospital identified wards in which the criteria for the study were met (that is, an acute general ward where there were patients with varied nursing needs including a patient who was expected to die within six days). All nursing staff were informed that interactions between nurses and the dying patient were being monitored. An approach was made to the consultants for permission to attend the ward rounds, the reason given being to elicit factors that might influence nurses during their care of

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