Coronary angioplasty in the United Kingdom

Report of a working party of the British Cardiac Society

1 Introduction

1.1 BACKGROUND

Percutaneous transluminal coronary angioplasty (PTCA) was first performed by the late Dr Andreas Grünzig in 1977 and patients have been treated in Britain for over ten years. Successful PTCA restores blood flow to ischaemic heart muscle by temporary inflation of a balloon within a diseased segment of a coronary artery. After removal of the balloon the previously stenosed segment is left wide open but with a very disrupted surface. Subsequent healing can lead to establishment of a normal lumen but in a substantial minority a stenosis recurs usually within the first six months. The procedure is carried out under local anaesthesia. It is usually performed in a cardiothoracic centre and requires a skilled team and high quality catheter laboratory. Major advantages are the very short hospital stay (typically two to three days), the patient’s ability to return to full activities immediately without prolonged convalescence, and the possibility of repeat procedures for future disease.

1.2 PURPOSE OF THIS REPORT

The aims of this report are to:

(i) Assess the need for PTCA in the United Kingdom.
(ii) Identify the facilities available.
(iii) Estimate the increase in demand.
(iv) Review the relation between cardiac bypass surgery and PTCA.
(v) Consider the implications for costs and training.

2 Indications for PTCA

Revascularisation on symptomatic or prognostic grounds should be indicated before PTCA is considered—as it is before coronary artery bypass grafting (CABG) is considered. The population of patients that can be treated by angioplasty overlaps partially, but not completely, with those who are suitable for CABG. Continuing changes in apparatus and skills are leading to rapid expansion of indications for PTCA. Even in 1987 over 50% of patients treated by PTCA in many centres in the United States had multivessel disease and this trend has been followed in the United Kingdom. The main patient groups in which PTCA should be considered are discussed below. These groups are not mutually exclusive. The procedure can be carried out in elderly patients (over the age of 80), though the risks are higher.

2.1 PATIENTS WITH STABLE ANGINA

PTCA may be the appropriate treatment when stenoses in one or more coronary arteries are discrete, short, proximal enough to be reached by the balloon catheter, and preferably not in the immediate vicinity of acute bends or large side branches. Bifurcation stenoses can be dealt with by two wire “kissing balloons” or by double fixed wire techniques. Total or subtotal occlusions may also be re-opened by PTCA in many cases. Favouable factors include the presence of a proximal stump in which to engage the balloon, a relatively short duration of occlusion (three months or less), and good visualisation of the distal vessel from retrograde filling. New technology for obliteration of occluded arteries is being introduced with increasing frequency.

2.2 PATIENTS WITH UNSTABLE ANGINA

Most reported series include a high proportion of patients with unstable angina and similar success rates are achieved as when angina is stable. The acute situation was usually controlled with bed rest and nitrates before the PTCA was performed. Emergency PTCA is available as a method to reverse continuing deterioration when medical treatment fails to produce improvement, but the risks are somewhat higher than when the patient’s condition is stabilised.

2.3 PATIENTS DURING MYOCARDIAL INFARCTION

Attempts have been made to reverse myocardial infarction by emergency PTCA of an occluded coronary artery. Although some success has been reported the technique is only applicable where patients can be transferred to a catheterisation laboratory at a very early stage. At the present time in the United Kingdom this restricts the approach to patients who develop infarction while in hospital or who can be transferred urgently from the immediate surroundings. It also requires that a catheterisation laboratory and an angioplasty team are available immediately. With the advent of thrombolysis as the immediate treatment for myocardial infarction the indications for emergency PTCA have diminished.

2.4 PATIENTS WITH PREVIOUS BYPASS GRAFTS

Many patients whose CABG operations were performed some years ago are again developing angina, either from graft stenosis or from progression of the native disease. Repeat CABG is often unnecessary because many
such patients can be treated by angioplasty, though high rates of restenosis have been reported particularly in late graft failure.\textsuperscript{10} In several centres in the United States 20–25\% of angioplasty patients have undergone previous bypass graft surgery. The proportion in the United Kingdom is lower than this but is steadily increasing.

In addition to dilatation of stenoses in the body of the bypass graft, lesions at the attachment of the graft to the aorta or to the insertion into the distal vessel may be dilated. Additional use can be made of the graft as a conduit by which a balloon can be passed to the distal native vessel for the treatment of otherwise unapproachable lesions.\textsuperscript{11}

2.5 Patients in whom CABG is inappropriate
A small group of patients with severe angina may be considered for angioplasty even though a bypass graft operation is not advisable. The group includes patients in whom the prognosis is poor because of other diseases, such as malignancy, renal failure etc, and those whose operative risk is judged unacceptably high because of concomitant lung disease, previous strokes, or extremely poor left ventricular function. In such patients a palliative "salvage angioplasty" may produce relief from angina for the remaining lifetime of the patient.\textsuperscript{12}

3 Present results of PTCA
3.1 Immediate results
In experienced hands the initial procedure has a success rate in excess of 90\% for dilatation of a single stenosis, 75\%–80\% for re-opening a near total stenosis, and 50\%–70\% for disobliteration of a chronic total occlusion. Usually it fails because the lesion cannot be crossed with the guidewire or the balloon. Complications include precipitation of myocardial infarction, major coronary artery dissection, and abrupt closure of the artery requiring immediate bypass surgery. Mortality varies with myocardial function and complexity of the procedure but should be much less than 1\%.

The need for immediate bypass surgery is considered later in this report.

3.2 Short term results
The most important factor is the recurrence rate which varies in different reports from 20\% to almost 50\%. Currently recurrence of angina within one month is regarded as being due to inadequate dilatation while return of angina between one and six months is likely to be due to recurrence of the stenosis during the healing phase. Both groups form a population requiring further assessment. About half will be treated with further angioplasty with a high degree of success. This procedure can be repeated several times.\textsuperscript{13}

The likelihood of restenosis differs between vessels, being highest in the left anterior descending coronary artery and lowest in the circumflex coronary artery.\textsuperscript{14} It is higher:
(i) when the dilated lesion was near the origin of a artery than when it was distal,
(ii) when a totally occluded artery has been reopened,
(iii) in a graft than in a native vessel.

It is not established that the incidence of restenosis is reduced by the use of new techniques such as atherectomy or stenting.

When angina develops more than one year after the procedure it is usually caused by progression of the native disease and in this respect PTCA patients do not differ from those undergoing CABG.

3.3 Long term results
Follow up on large numbers of patients is available for relatively few years but some patients in the United Kingdom remain free from symptoms 10 years after angioplasty. Over 80\% of patients who have angioplasty are free from pain five years later.\textsuperscript{15}

4 Activity levels in the United Kingdom
4.1 Source of data
For a follow up study of past number of patients treated by PTCA as an initial procedure were requested from all known angioplasty centres in the United Kingdom, including private hospitals. A postal questionnaire was addressed to all cardiologists and radiologists in each unit known to be performing procedures and the returns were compared. Where no information was received a telephone follow up was instituted.

Direct inquiries were also made to the nursing sister in charge of the procedure room, usually the catheterisation laboratory. We are grateful for the effort expended by these nurses in counting back through the record books to supply figures of the number of coronary angioplasties performed each year.

We asked the information office at each district health authority in the United Kingdom for information on the number of PTCA procedures, and particularly the number of new patients, being dealt with within their district year by year.

Commercial agents and distributors of angioplasty equipment were a further source of information. All of them collect marketing information and make in house estimates of the number of procedures carried out yearly. Each distributor we approached provided their confidential estimates.

A final check was made to validate the figures by telephoning all centres one year after the information had initially been provided. The results of this inquiry were then compared with the original report and a further check made if they were appreciably different.

It is apparent that in the early years very few records were kept apart from the nursing procedure register, and these appear to be the most accurate source of data throughout. They are supported strongly by the estimates of commercial distributors. Figures from PTCA centres usually claimed higher numbers than could be supported from the procedure register.
Coronary angioplasty in the United Kingdom

particularly in early years. Information from district health authorities was sometimes extremely detailed and correlated well with other sources. However, this was frequently not the case, and many health authorities have no information on the PTCA activity within their district. More accurate figures should be available in the future after the initiation of the British Cardiovascular Intervention Society in establishing an annual survey. 16

The PTCA figures in the present report are primarily based upon the number of cases recorded in the procedure books in each centre.

4.2 AVAILABILITY
PTCA is potentially available at all cardiothoracic centres where surgical standby can be provided and is carried out in a few additional centres. The need for operator training, redistribution of catheter room schedules, and inappropriate funding prevented the procedure being introduced in some areas until recently. In 1985 angioplasty was available at 15 sites in the United Kingdom although often in small numbers and for uncomplicated lesions only. By 1987 all cardiothoracic centres were able to offer the procedure, at least to a limited extent. In 1989 PTCA was performed at 43 NHS and seven private hospitals in the United Kingdom. Table 1 shows the total numbers of patients treated each year by PTCA over this period.

4.3 REGIONAL DISTRIBUTION
The availability of PTCA is unevenly distributed across the country with over half the procedures being carried out in the London area. Table 2 shows the increase in activity in individual regions.

Table 1     Total number of patients treated each year from 1985 to 1989

<table>
<thead>
<tr>
<th>Year</th>
<th>Total</th>
<th>N/million</th>
</tr>
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<tbody>
<tr>
<td>1985</td>
<td>1640</td>
<td>29</td>
</tr>
<tr>
<td>1986</td>
<td>2780</td>
<td>49</td>
</tr>
<tr>
<td>1987</td>
<td>4150</td>
<td>74</td>
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<tr>
<td>1988</td>
<td>5750</td>
<td>101</td>
</tr>
<tr>
<td>1989</td>
<td>6600</td>
<td>120</td>
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</table>

Table 2     Increase in activity in individual regions (1985-7)

<table>
<thead>
<tr>
<th>Regional Health Authority</th>
<th>New cases/million</th>
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<tr>
<td></td>
<td>1985</td>
</tr>
<tr>
<td>East Anglia</td>
<td>3</td>
</tr>
<tr>
<td>Mersey</td>
<td>3</td>
</tr>
<tr>
<td>North East Thames</td>
<td>90</td>
</tr>
<tr>
<td>Northern</td>
<td>9</td>
</tr>
<tr>
<td>Northern Ireland</td>
<td>86</td>
</tr>
<tr>
<td>North Western</td>
<td>26</td>
</tr>
<tr>
<td>North West Thames</td>
<td>30</td>
</tr>
<tr>
<td>Oxford</td>
<td>9</td>
</tr>
<tr>
<td>South East Thames</td>
<td>88</td>
</tr>
<tr>
<td>South Western</td>
<td>8</td>
</tr>
<tr>
<td>South West Thames</td>
<td>9</td>
</tr>
<tr>
<td>Scotland</td>
<td>8</td>
</tr>
<tr>
<td>Trent</td>
<td>33</td>
</tr>
<tr>
<td>Wales</td>
<td>13</td>
</tr>
<tr>
<td>Wessex</td>
<td>7</td>
</tr>
<tr>
<td>West Midlands</td>
<td>11</td>
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<tr>
<td>Yorkshire</td>
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Table 3     Comparison with other countries

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>Australia</td>
<td>84</td>
<td>128</td>
<td>164</td>
<td>188</td>
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<tr>
<td>Austria</td>
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<td>Germany</td>
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<tr>
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<td>324</td>
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<tr>
<td>Switzerland</td>
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<td>123</td>
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<tr>
<td>United Kingdom</td>
<td>29</td>
<td>52</td>
<td>74</td>
<td>120</td>
</tr>
<tr>
<td>USA</td>
<td>452</td>
<td>668</td>
<td>742</td>
<td>1004</td>
</tr>
</tbody>
</table>

5 Comparison with other countries
Revascularisation by PTCA is increasing rapidly in all developed countries. Reports from various national bodies, publications, and local surveys are combined in table 3.

In the United Kingdom the availability of PTCA has increased fourfold since 1985. In 1988 approximately 100 procedures per million population were performed. This is still appreciably less than half the level in France, Germany, or Switzerland and is well below one third of the level in the Benelux countries. In the United States ten times as many patients per million population were treated by angioplasty as in the United Kingdom.

An investigation of PTCA availability in Europe was carried out by Van den Brand with surveys in 1986 and 1988. The number of procedures was shown to be related to the number of catheterisation laboratories in each country but not to the number of cardiologists, to the overall incidence of ischaemic heart disease, or to the gross domestic product per head.

6 Relation between PTCA and CABG
6.1 RATIO OF REVASCULARISATION PROCEDURES
In the United States the number of patients revascularised by PTCA and by CABG became approximately equal during 1988. During 1989 the numbers treated by PTCA (290 000) exceeded those having surgical bypass (250 000). This crossover point has not been reached in most other countries, but the trend is similar. Although the percentage of patients revascularised by PTCA approaches that of the United States the total procedures per million are far less. In the United Kingdom revascularisation is carried out at about one quarter the rate per million population compared with the United States, and at about half the rate per million in West Germany. Table 4

Table 4     Revascularisation performed by PTCA (1988/89)

<table>
<thead>
<tr>
<th>Country</th>
<th>% of total</th>
</tr>
</thead>
<tbody>
<tr>
<td>France</td>
<td>50</td>
</tr>
<tr>
<td>USA</td>
<td>50</td>
</tr>
<tr>
<td>West Germany</td>
<td>44</td>
</tr>
<tr>
<td>Holland</td>
<td>40</td>
</tr>
<tr>
<td>Switzerland</td>
<td>40</td>
</tr>
<tr>
<td>Spain</td>
<td>40</td>
</tr>
<tr>
<td>United Kingdom</td>
<td>30</td>
</tr>
<tr>
<td>Australia</td>
<td>25</td>
</tr>
</tbody>
</table>
shows the percentage of revascularisation procedures by PTCA in other countries.

It must be remembered that surgical procedures were almost entirely multivessel, while many of the PTCA dilatations were for single vessel disease. Multivessel PTCA is increasing rapidly and the preponderance of single vessel disease in angioplasty series is largely historical. Most high volume PTCA centres in Europe and America now carry out multivessel dilatation in most patients.

6.2 SURGICAL STANDBY
It is general practice for PTCA to be performed only when the patient can be transferred rapidly to theatre for bypass grafting in the event of abrupt closure of the artery. Some years ago urgent surgery was required after approximately 6% of procedures but the incidence has fallen to less than 2%. The original aim of providing a surgeon, anaesthetist, nursing staff, and pump technician standing by with an empty theatre during every angioplasty would be a great waste of resources, and experience no longer supports this concept.

Present policy in most centres, both abroad and in the United Kingdom, is that the patient’s condition is stabilised as far as possible in the catheter room and the patient is transferred when necessary on a semi-urgent basis. This requires the surgical team to be available but not occupied.

In most United Kingdom centres the operating theatre and the catheterisation laboratories are not immediately adjacent and there is a considerable interval between the catheter room decision that surgery is necessary and the patient going on bypass. Our information indicates that in the United Kingdom this is usually between 45 minutes and three hours. Rather surprisingly, similar figures are reported from other countries including large centres in the United States. This interval is too long to prevent muscle damage in the event of total myocardial ischaemia from vessel occlusion but the presence of collateral circulation frequently allows surgical revascularisation with no significant damage. Acute supportive measures include distal perfusion through special catheters, re-opening of thrombosed sites, and “tacking back” of dissected flaps.

Other methods such as coronary sinus retroperfusion or intra-aortic balloon pumping are under investigation but not yet established as appropriate for this indication, because little reperfusion of the ischaemic heart is achieved.

As expected, overall results in patients in whom urgent grafting has followed complicated PTCA are less satisfactory than in purely elective procedures, though the differences are not great.

6.3 ABSENCE OF SURGICAL BACKUP FOR PTCA
In many countries PTCA is carried out in patients judged to be low risk without surgical backup being available on site. Such arrangements usually involve transfer of the patient by ambulance to the surgical centre in the event of a complication and this has been shown in some instances to be successful. An average time to reperfusion of 151 minutes after occlusion was achieved in Melbourne, where the nearest surgical backup was 2 km away.14 Reports from Dublin (B Maurer, 1990, personal communication) and Belfast15 show identical results after PTCA complications in hospitals without surgery on site compared to those with surgery. The major delays occurred in organising bypass, not in transfer of the patient from the catheter room to the operating theatre. A possible parallel exists with the early days of coronary angiography in the United Kingdom. In 1973 the Cardiology Committee of the Royal College of Physicians considered the risks of angiography, and an editorial published in the British Heart Journal in 1975 included the recommendation that surgical standby should always be immediately available.20 This proved too onerous a restriction and was largely ignored in the United Kingdom, as in all other countries. Coronary arteriography has become widely available to the United Kingdom population through hospitals without cardiac surgery. The risks of this philosophy have recently been re-emphasised in a report from St George’s Hospital.21 It is universally appreciated that these risks exist, but they are held to be so small that patients should not be denied the benefits of the procedure, even without surgical cover. It is our perception that similar development is now occurring in the field of PTCA. As an example we note that over 50% of PTCA procedures carried out in West Germany during 1988 were in hospitals without surgery on site (P Lichlen, personal communication).

The view taken by both the Joint United States/European Task Force on Coronary Angioplasty and the American College of Cardiology/American Heart Association Task Force Report on PTCA is that immediate surgical backup should always be available on site.2223 This position has not been universally endorsed, either in the United States or in Europe, and appears untenable in the light of present practice. If transfer to another site can be achieved fast enough for surgery to start with no more delay than on the primary site we regard this as a satisfactory alternative.

6.4 EFFICACY OF SURGICAL BACKUP
The results of urgent surgery after a complication during PTCA vary widely. Patients who can be transferred in a stable haemodynamic condition can be expected to have an excellent outcome, often with no evidence of muscle damage. On the other hand, patients in shock, possibly being maintained with external chest compression from the catheter room to the operating theatre, have a very bad prognosis. We have been unable to find convincing evidence that surgical attempts at immediate revascularisation influence the prognosis. Most published reports are descriptive, not analytical, and there are examples of patients in shock making complete recovery while others suffer significant infarction despite early grafting of a single vessel. It is extremely unlikely that any randomised trial could now be carried out.
6.5 RECOMMENDATIONS FOR SURGICAL STANDBY

It is our view that in carefully selected patients it is ethical to attempt PTCA in the absence of immediate surgical standby. This is in effect the present situation in many hospitals where logistic, staffing, or administrative problems delay the establishment of cardiac bypass. We recommend that this course is followed only when a fully trained PTCA operator has assessed the patient as low risk, and the patient belongs to one of the three following subgroups:

(i) **Previous cardiac surgery**—The presence of adhesions and distorted anatomy make surgical access to the heart slow. Previous grafts, including the internal mammary artery, may be adherent to the back of the sternum with resulting disruption of the graft if hasty access is attempted. It is impossible to offer such patients immediate surgical revascularisation although elective procedures are still available.

(ii) **Patients with extremely bad left ventricular function** may face an overwhelming surgical risk.

(iii) **Patients with concomitant illness** such as renal failure or obstructive airways disease which makes the risk of even elective surgery very high. We do not think these patients should be denied surgical standby but they should be aware that the risks of operation after a PTCA complication will be higher than normal.

6.6 CROSSOVER PTCA TO CABG

There are several reasons why patients initially treated with PTCA may subsequently be referred for CABG. The most obvious group is where PTCA has failed. Another group is where restenosis has occurred one or more times and further PTCA is judged inappropriate by the physician or the patient. There is also a large group of patients with multivessel disease where full revascularisation is not achieved by PTCA and only the “culprit” vessel can be dilated. Published results on this procedure sometimes indicate that excellent relief from symptoms, without increased morbidity or mortality, can be achieved for several years. This approach offers the possibility of postponing a major operation. Repeated PTCA may be appropriate even when symptoms deteriorate: so CABG can be avoided altogether even though total revascularisation is never achieved.

Progression of native disease will produce new lesions in many of the patients treated with PTCA and some of these will be appropriately treated with bypass grafting instead of further PTCA. Present trends indicate that the crossover rate of PTCA to CABG is approximately 20% over a five year period from the first intervention. Because coronary artery disease is a progressive disorder, often spanning many years, progressive treatments will often be needed. In many cases angioplasty is an initial revascularisation procedure that delays the need for CABG.

6.7 CROSSOVER CABG TO PTCA

Some patients undergoing bypass surgery will have inadequate revascularisation, while in others angina will develop again because of graft occlusion or progression of native disease. In addition, stenoses can develop in saphenous vein grafts, either in the area of the anastomosis or in the grafted artery distal to the insertion. Recurrence of symptoms is often caused by a single new lesion in a patient with multiple grafts. Repeat surgery can frequently be avoided in such patients by an angioplasty, either of the coronary artery or of the graft.

The implications for future planning in the United Kingdom are that increased PTCA facilities will be required to deal with the rising number of patients whose symptoms are returning after bypass graft operations, while surgical facilities will also be needed as future PTCA patients crossover to surgery.

6.8 IMPACT OF PTCA ON SURGICAL WAITING LISTS

Because many patients undergoing revascularisation are being treated by PTCA the number of bypass graft operations might be expected to fall, but experience has shown that this is not so—even in the United States. The Cleveland Clinic experience cites as a major factor the inability to obtain complete revascularisation in patients with chronic occlusions. Until recently most PTCA patients had single vessel disease while surgical patients almost invariably required multiple grafts. The removal of single vessel disease from surgical referrals makes little impact on waiting lists. The prevalence of multivessel disease is such that surgical facilities in most countries are saturated and all cardiac surgical centres in the United Kingdom have a large pool of untreated patients on long waiting lists. Similar situations exist in all other European countries.

The increasing ability of interventionists to treat multivessel disease by angioplasty cannot be expected to alter the CABG situation in the United Kingdom for many years because trained operators and PTCA facilities are themselves very limited.

Resource planning in the United Kingdom cannot proceed on the basis that the need for CABG will be reduced by angioplasty. Although this point could theoretically be reached it has not been achieved even in the United States where PTCA and CABG are both being performed at a level of approximately 1000 cases per million population per year, far in excess of the figures in the United Kingdom.

7 Financial aspects

7.1 COST OF PTCA

The initial costs of the procedure are determined very largely by the number of balloons used, because these cost approximately £500–£600 each and cannot be used for another patient. Additional less important factors are whether the arm or leg approach is used, whether both left and right coronary arteries need to be cannulated, and which manufacturer’s equipment has been chosen. It is often necessary for very tight stenoses to be dilated
first with a small balloon which is then changed for a larger size to allow full opening of the lesion. In the United Kingdom the average number of balloons per case was 1.2 in 1986 and 1.4 in 1987. Marginal costs (that is, disposables only) averaged over 100 procedures from six different centres in the United Kingdom during 1988 gave a figure of £1000 per case. This cost would be reduced if apparatus was resterilised and used again. Resterilisation of apparatus intended for single use only has been practised in the United Kingdom and is fairly common in some European centres. We do not recommend that it continues in the United Kingdom despite the financial advantages. Characteristics of balloons, guiding catheters, or inflation pressure gauges may be significantly different after use and resterilisation. Furthermore, quality control of cleaning, removal of protein, and resterilisation is almost impossible to achieve under hospital conditions. Each item is designated by the manufacturer for single use only and we have been informed by hospital solicitors as well as by malpractice insurance societies that there would be no defence against a claim from a patient who suffered a complication when resterilised equipment had been used.

A hospital stay of two or three days must be added to the marginal costs. Comparison with the cost of CABG is inappropriate because we regard the procedures as complementary, not alternatives, for most patients. The economic benefit to the country is most likely to occur because after PTCA a patient can undergo full activities almost immediately and return to work without prolonged convalescence. Even though revascularisation by PTCA is cost effective for an individual patient the very large number of patients who can potentially benefit represents a large future financial commitment.

A projection for the United Kingdom, based on PTCA becoming available at only one third of figures in the United States, suggests that appropriate future planning should allow for 300 to 500 patients per million population treated yearly by coronary angioplasty within five years. This is approximately twice the total number of patients revascularised in the United Kingdom by surgery and angioplasty combined at present.

Such planning will need to identify a realistic growth rate, related to financial resources and also to availability of trained staff. Any catheterisation centre expanding its PTCA service will require at least two laboratories or it will become impossible to perform sufficient diagnostic angiograms.

8 Facilities for coronary angioplasty

8.1 CATHETERISATION LABORATORIES

The minimum requirements do not differ from those necessary for a modern suite in which diagnostic cardiac catheterisation is performed. High resolution fluoroscopic and cineangiographic or digital x ray unit, the ability to display different magnifications, and to perform craniocordial views are essential. The imaging system must be capable of showing a narrow (0.010 inch) guidewire clearly in all projections and of displaying still "road map" frames simultaneously with real time screening. High resolution video or digital storage systems meeting these requirements are still rare in United Kingdom laboratories. Particular attention should be paid to radiation protection because times are likely to be considerably longer than in diagnostic catheterisation. A display system continually drawing the operator's attention to the elapsed fluoroscopy time is highly desirable. It is mandatory for operators to wear protective glasses and thyroid shields in addition to the usual lead apron.

A considerable inventory of stock is also necessary, including a selection of balloon catheters with dimensions from 2.0 to 3.5 mm, and a wide selection of guiding catheters. Several inflation/deflation devices should be available and an ample supply of guidewires. Devices for use in complications are becoming more widely available and are an additional cost.

8.2 OPERATOR TRAINING

The safety and success of coronary angioplasty depend greatly on the skill, experience, and training of the operator; the potential for disaster is very much greater than during diagnostic catheterisation. Good results can be achieved only when a continuous high number of cases are treated. It seems likely that this will be achieved in the United Kingdom for each cardiothoracic centre because the number of potential patients is so large and the number of centres relatively small. The number of operators should be restricted so that those performing the procedure have high enough volume to maintain their skills. In suggesting the following guidelines for the training of angioplasty operators the working group does not wish to be restrictive but to encourage the expansion and most effective use of opportunities.

(i) Candidates training as angioplasty operators should already be skilled in diagnostic coronary arteriography.

(ii) Attendance at formal training courses is encouraged.

(iii) The most important aspect is hands on experience which should initially be obtained by assisting an experienced operator. We suggest that 50 procedures should be performed in this way before the trainee acts as a primary operator. After these 50 cases an experienced angioplasty operator should be available nearby to advise and if necessary take over the procedure in case of difficulty.

9 Policy

We do not recommend that experience in PTCA should be a requirement for accreditation in cardiology but the importance to the NHS of training an adequate number of operators should be recognised by the granting of appropriate study leave and expenses to suitable candidates. These recommendations are in keeping with guidelines expressed by the ACC/AHA Task Force Report22 and the International Society and Federation of Cardiology/World Health Organisation Task Force on Coronary Angioplasty23 as well as the present practices adopted by major angioplasty centres abroad.28
10 Future developments

10.1 COMPARATIVE TRIALS

It is well documented that CABG improves the prognosis compared with medical treatment but it is too soon for comparable data to be available for PTCA. Future clinical practice is likely to be influenced by the results of several trials under way at the moment to compare PTCA with alternative treatments. These include the British RITA (Randomised Intervention Treatment of Angina) trial, the German GABI (German Angioplasty Bypass Surgery Investigation) trial, the European CABRI (Coronary Angioplasty Bypass Randomization Investigation) trial, the American BARI (Bypass Angioplasty Randomization Investigation) trial, and the Emory University EAST (Emory Angioplasty versus Surgery Trial). In addition, a trial comparing PTCA with medical treatment (ACME) Angioplasty Compared to Medicine trial) is under way at Paracelsus, Austria. By the end of 1989 approximately 2500 patients had been entered into these randomised trials, the first of which began in 1986. Because most protocols require a follow up of five years clinical decisions cannot be postponed until results are available.

10.2 TECHNICAL ADVANCES

Equipment used for angioplasty is improving very rapidly and new techniques are under active investigation. These include transluminal atherectomy, lasers, intracoronary stents, high speed and low speed rotation devices, ultrasonic fragmentation, hot-tip catheters of various types, and spark erosion catheters. All must be regarded as still experimental. Both the results of the trials and the development of experimental technical devices emphasise the need for this report to be revised within a few years.

The very rapid development of angioplasty during its first 10 years leads inevitably to the conclusion that the potential for treating more complicated disease will greatly increase and the number of patients who can benefit will be very much larger.

11 Comments and conclusions

The increase in coronary angioplasty treatment in the United Kingdom has been slower than in most European countries, and this method of treatment is available to a smaller proportion of the population than elsewhere. Major limiting factors are the pressure for diagnostic catheterisation, which competes for time with angioplasty procedures in the catheter room, the relatively few trained operators, and the increasing cost of large numbers of procedures. There is no justification for the view that increase in angioplasty will reduce the need for cardiac surgery in the United Kingdom in the foreseeable future. Future planning should consider provision of additional catheter laboratories to accommodate the need for PTCA and take particular note of the rate of growth which is likely to follow the same pattern as elsewhere in Europe. Even a modest regular increase in availability of angioplasty in the United Kingdom over the next few years, without attempting to match levels in the United States, requires provision for approximately 25,000 patients yearly. This will involve the training of new operators, which must be started now if they are to be ready to deal with the increased workload in a few years’ time.

We thank the catheter room sisters and colleagues in centres throughout the country who have freely provided information.