

# Early results after percutaneous transluminal coronary angioplasty in 400 patients

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**SUMMARY** In a consecutive series of 400 patients treated by percutaneous transluminal coronary angioplasty 212 had single vessel disease, 142 had multivessel disease with only one vessel dilated, and 46 had multivessel dilatation. In addition sequential stenoses were dilated in the same vessel in all groups. There was no mortality among patients with single vessel disease. Success rates varied from 83% to 90% according to the artery in which angioplasty was attempted. Urgent surgery was required by 3.8%. Primary success was lower (74%) in the presence of multivessel disease and complications were more frequent, with four deaths (2.8%). In 46 patients with multivessel disease in whom all important lesions were dilated during the same procedure the overall primary success rate was 76% and within the last year of the study it was 91%. One (2%) patient died and three (7%) required urgent surgery. Twelve (86%) out of 14 stenosed vein grafts were successfully dilated and eight (53%) chronically occluded vessels were re-opened; in both groups there were no deaths, no infarctions, and no need for urgent surgery. In all groups symptoms improved greatly and pre-discharge exercise tests showed that there was no reversible ischaemia in 94% of patients with single vessel disease or in 65% of patients with incomplete revascularisation. Six months after the procedure 95% of the patients had improved symptomatically and 80% had normal exercise tests after one year.

Percutaneous transluminal coronary angioplasty is the method of choice in single vessel disease and its use also results in a high proportion of other patients becoming symptom free. Complication rates are low and for selected patients results that are equivalent to those of cardiac surgery are obtained.

Since the first report of coronary angioplasty in a patient by Gruentzig *et al* in September 1977<sup>1</sup> the procedure has been increasingly used. In 1984 40 000 patients were treated in this way in the United States.<sup>2</sup> We estimate that during the same year only about 500 patients were treated by coronary angioplasty in the United Kingdom. We present our results after the first angioplasty procedure in a consecutive series of 400 patients treated over the past five years. Three per cent of the patients we describe were treated up until the end of 1981 and a further 12% were treated during 1982. The remaining 85% were treated in the subsequent

2½ years, indicating the same rapid increase in the use of this technique as has been reported in other countries.

## Patients and methods

This series includes 342 men (mean age 52.3 years, range 29-76) and 58 women (mean age 53.2 years, range 32-75). All gave a history of angina, which in 73% was provoked by minimal exertion or occurred at rest (grades 3 and 4). One hundred and fifty nine (39%) patients had previous myocardial infarction. This was anterior in 84 (21%) of the series, inferior in 64 (16%), and multiple in 11 (3%). Thirty two (8%) had undergone previous graft operation, 52 (13%) presented as emergency cases of uncontrolled angina despite full medical treatment in hospital, 12 (3%) were treated after intravenous streptokinase

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had been given early in the development of myocardial infarction, and four (1%) underwent the procedure during the early stages of infarction in an attempt to reverse the process.

#### ANGIOPLASTY

Angioplasty was carried out according to methods originally described by Gruentzig *et al*<sup>3</sup> and subsequently modified throughout the series as new techniques and new equipment were introduced.<sup>4,5</sup> Initially, non-steerable balloons were used but steerable guide wires were subsequently used to cross the stenosis and these were followed by the balloon catheter. Apparatus produced by several different manufacturers was used, particularly Schneider (Zurich), Advanced Cardiovascular Systems (USA), American Hospital Supplies, Meditech (USA), and SciMed (USA). Both brachial and femoral arteries were used with the choice of access depending upon whether the vessel had been recently catheterised, in which case it was not used for the angioplasty approach. A history of intermittent claudication was regarded as a relative contra-indication to the femoral route. The procedure was carried out via the brachial approach in 102 (men 91, women 11) and from the leg in 298 (men 251, women 47). The results did not differ and the figures have been combined in this paper. The degree of stenosis was judged by more than one observer as the obstruction in luminal diameter, taking account of all available views and not only the view showing the greatest obstruction. If an artery filled antegradely but no visible connection could be seen between proximal and distal portions (that is, it was "disconnected") the stenosis was classified as 98%. An artery was classified as being occluded if there was no antegrade filling.

All patients were pretreated with 10 mg nifedipine liquid sublingually and were given both sublingual and intracoronary nifedipine or isosorbide dinitrate or both in the event of spasm. In all cases the contrast medium was Omnipaque 350 (Nyegaard) and frequent injections of half strength medium were given proximally and distally to confirm the position of the wire and balloon. The balloon was inflated for 30–60 s and occasionally longer at pressures of 5–10 atm (505–1010 kN/m<sup>2</sup>). Inflations were repeated until dye injections showed wide dilatation of the stenosis and any gradient had been effectively eliminated. After removal of the guide wire and the balloon, full strength contrast was injected to visualise the artery before the introducer was removed. Transstenotic gradients were measured before and after each inflation whenever possible (81% of procedures). Some makes of catheter could not be used to measure gradients. There was no significant

difference in the frequency with which gradient could be successfully measured in different vessels.

At the start of the procedure patients were given 10 000 units of heparin intra-arterially. They were also given 1000 units of heparin/h intravenously for 24 hours after the procedure. In addition, an intravenous infusion of isosorbide dinitrate (usually 5 mg/hour) was maintained for 24 hours. This dose was reduced if the blood pressure fell and was increased if chest pain or ST segment changes appeared. The patients were then mobilised and treated with oral isosorbide and nifedipine for the first six weeks and with soluble aspirin 300 mg daily for the first year.

In successful cases we used a treadmill exercise test with the Sheffield modification of the Bruce protocol<sup>6</sup> on the third day after the procedure and before the patient's discharge from hospital. Exercise testing was repeated after six months and then every year.

The initial dilatation was classified as a primary success if (a) the lesion was crossed with a balloon and dilated to leave  $\leq 50\%$  obstruction of the transluminal diameter that was compared with the adjacent normal vessel; (b) the transstenotic gradient, where measurable, was reduced to 10 mg Hg or less; and (c) there was no serious complication (patient death, artery occlusion, referral for urgent surgery). These three criteria are considerably more stringent than that of a simple reduction in degree of stenosis by 20% which is often used to define success. Various definitions of stenosis have been assessed in Rotterdam and the presence or absence of a 50% luminal diameter stenosis has been shown to be the most satisfactory angiographic criterion and has been adopted by most centres.<sup>7</sup>

Where more than one lesion was present in the same artery the result for that artery was classified as a success only if all the stenoses were successfully dilated. When more than one artery was attempted the procedure was classified as a success only if all stenoses in all the arteries attempted were successfully removed at the same procedure.

## Results

#### SINGLE VESSEL DISEASE

Two hundred and twelve patients (mean age 51.5, range 29 to 76 for men and 51.4, range 32 to 76 for women) had disease in only one vessel. There was a total of 248 stenoses (1.2 stenoses/patient) and all were attempted. Two hundred and seven stenoses in 172 vessels were successfully dilated, giving primary success rates of 83% for stenoses and 81% for both arteries and patients.

If only non-occluded vessels are considered then

the primary success rate was 86% for the left anterior descending, 90% for the circumflex, and 88% for the right coronary artery.

In vessels where the stenosis was successfully dilated the mean obstruction was 89% and this was reduced to 8% after a mean of 6.4 dilatations. The transstenotic gradient could be measured in 165 patients and had a mean value of 60 mm Hg. This was reduced to 2.1 mm Hg after angioplasty.

There were no deaths related to the procedure. Eight (3.8%) patients were referred for urgent surgery and nine (4.3%) patients had electrocardiogram changes confirming myocardial infarction. Of these six had non-specific creatine kinase enzyme activities exceeding 1000 units/l (laboratory activity to 220 units/l). An additional six patients had slightly raised creatine kinase activities (mean 300 units/l). This was not associated with any cardiac incident or electrocardiogram change and we attribute it to local changes at the site of catheterisation.

#### MULTIVESSEL DISEASE—ONE VESSEL DILATED

There were 142 patients in this group (mean age 52.3, range 31–75 for men and mean age 51.2 years, range 35–66 for women). The total number of diseased arteries was 374 and the total number of stenoses was 401, giving an average of 2.6 diseased vessels and 2.8 stenoses/patient.

The primary success rate was appreciably lower for stenoses (74%) and for both arteries and patients (68%). The complication rate in this group was also higher than in those with single vessel disease and there were four (2.8%) procedure related deaths. Twelve (8.4%) patients were referred for urgent surgery and 10 (6.5%) patients had myocardial infarction, with two of the deaths occurring in these patients.

#### MULTIVESSEL DILATATION

Forty six patients had more than one vessel dilated at the same procedure and this group was made up of 38 men (mean age 53.4 years, range 36–74) and eight women (mean age 53.8, range 40–66). Twenty had previous infarction—anterior in 10, inferior in nine, and both inferior and anterior in one of the patients. Forty one patients had two vessels dilated and five had three vessels dilated. A total of 110 stenoses in 95 arteries were attempted, giving overall rates of 2.4 stenoses and 2.1 arteries per patient attempted. Eighty four of the stenoses were dilated (primary success rate of 76%) and all lesions were dilated in 69 (73%) of the 95 arteries. One (2%) patient died, six (13%) developed myocardial infarction, and three (6.5%) were referred for urgent surgery. It seems likely that operator experience is a major fac-

tor in treatment of multiple lesions and our current results show primary success rates of 91% for stenoses and 88% for arteries over the last year.

#### GRAFTS

Stenosed vein grafts were attempted in 14 patients (12 men and two women). In 12 (86%) cases the lesion was successfully removed with the stenosis being reduced from a mean of 82% to 7%. There were no deaths, no patients suffered myocardial infarction, and there were no referrals for urgent surgery.

#### OCCLUDED VESSELS

Attempts were made to reopen chronically occluded vessels (blocked more than three months) on 15 occasions and were successful in eight (53%). There were no deaths, no myocardial infarction, and no referrals for urgent surgery.

#### LEFT MAIN STEM DISEASE

This was present in seven (1.8%) of the patients and dilatation was performed in three. One of these had a patent graft to the circumflex artery, one had a stenosed graft to the left anterior descending artery which was also dilated at the same procedure, and one had no grafts. The mean stenosis in these three arteries was 80%, and the final value was 13% after a mean of nine dilatations. One additional patient had occlusion of the left main stem, left anterior descending, circumflex, and right coronary arteries with an 85% stenosis in a graft to the right coronary artery. This graft was dilated but an attempt to reopen the occluded left main stem was unsuccessful. There were no deaths, no patient had an infarction, and there were no referrals for urgent surgery.

#### LESIONS NOT DILATED

A total of 523 stenoses were attempted in the 400 patients and 412 (79%) of these were successfully dilated. The table shows the degree of stenosis in the major vessels in successful and unsuccessful attempts.

Table Results of percutaneous transluminal angioplasty

	LAD (%)	Cx/OM (%)	RCA (%)
Success:			
Initial stenosis	90	87	85
Range	58–98	60–98	60–98
Final stenosis	11	11	14
Failure:			
Initial stenosis	94	82	89
Range	80–98	60–98	75–98

LAD, left anterior descending coronary artery; Cx/OM, circumflex obtuse marginal coronary artery; RCA, right coronary artery.

There is no significant difference in the degree of stenosis and we attribute these failures to the position of the stenosis in the arterial tree, to the anatomical structure including the presence of calcification, and to operator inexperience. Many of these stenoses were crossed with a guide wire but we were unable to follow this with the balloon because the guiding catheter was displaced.

#### EXERCISE TESTING

Predischarge exercise tests were performed by all patients who had one or more lesions successfully dilated, who did not suffer myocardial infarction, and who were not referred for urgent surgery. In patients with single vessel disease the results of 94% of the tests were completely normal but where additional vessels were diseased only 65% had normal tests. Of the patients followed for at least one year 80% had completely normal exercise tests at that point.

#### EFFECT ON ANGINA

The severity of symptoms was graded from 1 (angina on vigorous exertion only) to 4 (angina at rest or on trivial movements) and the symptoms that were present before percutaneous transluminal coronary angioplasty were compared with those one month after angioplasty. Fifty three (13%) patients had improved by four grades and another 42% had improved by two or three grades. The results at six months considered on an "intention to treat" basis show that 95% of the patients had improved. When the patients who were treated surgically either initially or within this six months follow up period because of relapse are excluded the improvement rate is 97%.

#### CLINICAL RELAPSE

Patients were classified as having relapsed if any of the following criteria were met: (a) recurrence of any degree of angina in a patient who had previously been symptom free; (b) deterioration by two grades in the level of angina in patients who had not become symptom free; (c) appearance of ischaemic changes on exercise testing in a patient who previously had a normal test.

Fifty four patients developed one of these criteria within the first six months—a clinical relapse rate of 14%. All these patients are being restudied by angiography, and in many cases treatment by further percutaneous transluminal coronary angioplasty has already been possible. Full details of the relation between results of exercise testing, symptoms, relapse, and angiographic findings over the five year period will be reported elsewhere.

#### Discussion

Results for primary success in percutaneous transluminal coronary angioplasty have varied over the past few years with relatively low figures for operators in the early stages of the learning curve. The National Heart, Lung, and Blood Institute Registry reported a success rate of 67% in 1981 and recently a rate of 52% has been reported elsewhere for patients with stable angina.<sup>8</sup> In both studies success was established by an increase in the luminal diameter of  $\geq 20\%$ .<sup>9</sup> With improved operator experience and the introduction of new techniques figures of 80% to 90% or higher are currently being reported from many centres<sup>10</sup> and this is in keeping with our own figures for patients with single vessel disease. The situation is confused by the use of several different definitions of success and it no longer seems reasonable to include patients in whom a 90% lesion was reduced to a 70% stenosis. Our initial experience of a lower primary success rate in the presence of multivessel disease has been reported elsewhere<sup>11 12</sup> although it is not universal and Hartzler's group recently reported 92% success in primary dilatation in patients with multivessel disease.<sup>13</sup> Our current figure is 91%.

The National Heart, Lung, and Blood Institute Registry has reported that primary success is lower in women<sup>14</sup> but our own data show that in single vessel disease 83% of the stenoses attempted were successfully dilated in both women and men; these included multiple stenoses in the same artery. Despite the inability to measure gradients with some of the dilatation equipment available and occasional technical problems caused by damping from the guide wire, we consider elimination of a gradient to be valuable confirmatory evidence that a stenosis has been successfully relieved. This view is supported by others,<sup>2</sup> and a report on a large group of patients from Emory University has shown that a final transstenotic pressure gradient of  $\leq 15$  mm Hg was associated with a low restenosis rate.<sup>15</sup> The current range of dilatation equipment again allows recording of transstenotic gradients.

The attempted disobliteration of totally occluded arteries is a relatively recent development and the long term results cannot yet be adequately assessed. Our early findings of 53% primary success, however, resemble those (57%) in 49 patients presented by Serruys *et al*<sup>16</sup> and in 76 patients reported by Kereiakes *et al* (53%).<sup>17</sup> Success rates for acute occlusions are likely to be considerably higher.

The aim of percutaneous transluminal coronary angioplasty and of coronary artery bypass grafting is total revascularisation, but considerable relief can be obtained by dilatation of one vessel in patients with

multivessel disease and this finding is now being widely reported.<sup>18</sup> When revascularisation is incomplete it is not surprising that maximum tolerance exercise tests produce ischaemic changes even if the patient is symptom free in ordinary life, and it is not yet clear whether minor lesions should be attempted. We did not attempt to dilate stenoses of  $\leq 50\%$  obstruction (table). A follow up study in patients where lesions of  $\leq 60\%$  stenosis were dilated showed that restenosis was often more severe and that the disease process may even be accelerated<sup>19</sup> and so at present it seems reasonable to attempt dilatation only in lesions producing obstruction of 50%.

The problem of early reocclusion after an apparently successful angioplasty is well recognised.<sup>20</sup> The cause of these early stenoses is largely unknown, although early intimal hyperplasia, medial dissection, and new fibrous plaques have all been suggested as likely explanations.<sup>21</sup> Our symptomatic relapse rate of 14% in six months does not include those patients with recurrent lesions that can only be diagnosed by angiography. As a result the figure is lower than that found in series followed up by routine angiography.

In patients with one vessel disease the complication rate has been remarkably low with no mortality and only a 4% myocardial infarction rate; 85% of the patients were completely free of angina at four weeks, and this early symptomatic benefit is well sustained beyond six months. Provided long term results remain satisfactory it appears that percutaneous transluminal coronary angioplasty for single vessel disease is the treatment of choice and can be carried out with a very low complication rate and a high chance of success.

The implications for the future depend mainly on the outcome of multivessel or multilesion procedures. It is already becoming clear that revascularisation so that no major vessel is left with a stenosis of  $> 50\%$  is an important factor in preventing recurrent symptoms and provided this can be achieved it is suggested that patients with multivessel disease may achieve results similar to those with single vessel disease.<sup>22</sup> Despite the lack of complete revascularisation in multivessel disease in which only one vessel was dilated, 59% of the patients obtained complete relief of angina and most became symptom free in ordinary life. Only 8% of these patients with multivessel disease continued to suffer severe symptoms (angina grades 3 or 4) four weeks after angioplasty. The application of the technique to patients with unstable angina or even with early infarction enlarges the indications for angioplasty as does the demonstration that completely occluded vessels can often be reopened.

This method of treatment has immediate economic benefits to the patient who can leave hospital within a few days and does not need a lengthy convalescent period. Although restenosis remains a problem, further angioplasty is almost always possible and frequently achieves better results than the initial procedure, unlike repeat coronary artery bypass grafting which carries a higher risk of complications and mortality<sup>23</sup> and can only be repeated once or twice.

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