Long term angiographic follow up, cardiac events, and survival in patients undergoing percutaneous transluminal coronary angioplasty

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SUMMARY The results of percutaneous transluminal coronary angioplasty were studied in 1352 consecutive patients. The angioplasty procedure was angiographically successful in 1163 (86%) patients and the success rate increased gradually with time. There were no significant differences in success rates in different vessels or indications. The success rate for repeat coronary angioplasty was 92%. In 85% of the patients the clinical course was uncomplicated. Myocardial infarction occurred in 3.6%, emergency coronary bypass grafting in 2.6%, elective bypass surgery in 4.6%, and there were 10 deaths (0.7%). There were 16 deaths (10 non-cardiac) during follow up in the 1163 patients in whom the first procedure was successful. Actuarial analysis showed that after a first angioplasty 77.9% remained free of symptoms and cardiac events for five years and that after a second angioplasty 76% did so. Angiographic follow up showed restenosis in 24% of patients but the overall clinical success rate was 86.2%. On the basis of the intention to treat the procedure was successful in 74.3% of all 1352 patients. Coronary artery bypass surgery was eventually performed in 11.6% of all patients.

The long term angiographic success rate of coronary angioplasty is higher than previously suggested.

We report the angiographic and long term clinical results in a large number of consecutive patients who were treated with percutaneous coronary angioplasty.

Patients and methods

PATIENTS

From April 1980 to October 1985, 1889 patients had coronary angioplasty at the St Antonius Hospital in Utrecht (which is now in Nieuwegein). We have included only those patients in whom follow up lasted at least six months—that is 1352 patients who had coronary angioplasty before 1 January 1985. Eighty per cent of the patients were men.

All the patients had angina pectoris that responded poorly to medical treatment. In all

patients with stable angina signs of myocardial ischaemia were demonstrated by exercise electrocardiographic studies or exercise scintigraphy. Seventy two per cent of the patients had angina pectoris of Canadian Heart Class III or IV. In 4% of the patients the severity of angina could not be coded properly because of recent thrombolytic (streptokinase) treatment.

Coronary angioplasty was performed as an elective procedure in 896 (66%) patients and in 355 (26%) patients it was performed because of impending myocardial infarction, which was defined as pain at rest accompanied by electrocardiographic ST-T changes without signs of myocardial necrosis occurring less than one week before the angioplasty procedure. Seventy two (5%) patients had had streptokinase treatment because of an acute myocardial infarction more than twelve hours before coronary angioplasty and in 17 patients the angioplasty attempt took place immediately after thrombolytic treatment. In 12 patients with an acute

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myocardial infarction the acutely occluded vessel was approached with the balloon catheter without previous thrombolytic treatment.

Six per cent (82 cases) of the patients had aorto-coronary bypass grafts and 9% (113 cases) had previous percutaneous transluminal coronary angioplasty. Nineteen per cent (259 cases) had suffered a myocardial infarction in the area related to the stenosis that was treated by angioplasty, 11% (143 cases) had an infarction elsewhere, and 1% (16 cases) had suffered myocardial infarctions both in stenosis related and unrelated areas.

ANGIOGRAPHIC PROFILE

Seventy per cent of the patients had single vessel disease. Left ventricular function was normal in 55% of the patients. Complete revascularisation (successful dilatation of all stenoses >50%) was thought to be possible in 78% of the patients. The severity of the stenosis was assessed by the means of multiple (angulated) angiographic views. The luminal diameter of the vessel at the narrowest portion of the stenosis was expressed as the percentage of the luminal diameter of the adjacent (normal) diameter, measured from a 12 fold magnified projection of the cine film on which the vessel contours were outlined by hand and measured with mechanical callipers.

PROCEDURE

Transluminal coronary angioplasty was performed via the femoral artery in 97% of the patients. After the first 361 patients had been treated a steerable balloon catheter system was used exclusively. In patients with multiple vessel disease the site considered to be the primary cause of the symptoms was first attempted. Multiple vessel disease was defined as stenoses of >50% in more than one major epicardial vessel.

An attempt at angioplasty was considered to be a success if the stenosis was reduced by >20% of the luminal diameter without complications that lead to myocardial infarction, coronary bypass operation, or death.

MEDICATION

After the first 100 patients all patients were routinely treated with anticoagulants, which ideally were started before angioplasty, and with heparin, dextran, and aspirin during the procedure, and anti-coagulants plus either aspirin or dipyridamole for at least six months after the procedure.

FOLLOW UP ANGIOGRAPHY

Follow up angiography was performed in 62% (723) of cases. All patients were encouraged to have a fol-

low up angiographic examination six months after the angioplasty. Naturally the proportion of patients with symptoms in the angiographic follow up group was higher than it was in the initial group. A restenosis was defined as a loss of >50% of the initial gain.

STATISTICAL ANALYSIS

The significance of differences was assessed by χ^2 analysis. Event free actuarial curves were based on the absence of recurrence of angina pectoris, myocardial infarction, repeat angioplasty, coronary bypass grafting, and death. The significance of difference between actuarial curves were assessed by the log-rank or Mantel-Haenszel test.

Results

The angioplasty attempt was successful in 1163 (86%) patients. The success rate was 87% (1281/1480) for stenoses. There was a clear increase in success rate with time and after the introduction of the steerable angioplasty system. There were no significant differences in success rates in different vessels.

The success rates in patients with stable angina and with impending myocardial infarction were not significantly different. The success rate for a repeat angioplasty was 92%. The success rate in patients with an immediate coronary angioplasty at the time of an acute myocardial infarction was 92% (11/12), the success rate for patients with an acute myocardial infarction who had coronary angioplasty immediately after thrombolytic treatment was 100% (17/17), and the success rate in patients who had coronary angioplasty ≥ 12 hours after thrombolysis was 87.5% (63/72).

Table 1 shows the clinical course in all 1352 patients. In 85% it was uncomplicated. Myocardial infarction occurred in 3.6%, emergency coronary

Table 1 Clinical course in 1352 patients

Course	No	%
Uneventful	1146	85
MI:		
STT	20	1.5
QRS	29	2.1
Emergency CABG*	36	2.6
Elective CABG	64	4.6
Deaths	10	0.7
Minor problems	48	3.5

STT, myocardial infarction without QRS changes; QRS, myocardial infarction with new Q waves on the electrocardiogram; CABG, coronary artery bypass grafting.

Minor problems include successful redilatations after occlusion of the vessel without myocardial infarction, ST changes without an increase in serum enzyme activity, and arrhythmias.

*One patient died.

artery bypass grafting was done in 2.6% (one of these 36 patients died after operation), elective bypass surgery was performed in 4.6%, and there were 10 deaths (0.7%). Angioplasty of the proximal left anterior descending artery was attempted in all but two of the patients who died, and it appeared to be successful initially. Minor problems such as ST changes without signs of myocardial infarction or arrhythmias occurred in 3.5% of the patients.

CLINICAL FOLLOW UP

Sixteen of the 1163 patients in whom the initial angioplasty procedure was successful died during follow up. There were six proven or suspected cardiac deaths and 10 proven non-cardiac deaths. Coronary bypass surgery had to be performed because of recurrence or progression of coronary artery disease or both in 58 (5%) patients. A second angioplasty was attempted in 95 (8%) patients.

In 13% of patients coronary angioplasty was performed in another vessel segment because of progression of atherosclerotic disease. Acute myocardial infarction occurred in the area related to the angioplasty site in six (0.5%) patients and in a non-related area in five (0.4%) patients. One patient who had successful angioplasty after thrombolytic treat-

ment eventually underwent heart transplantation because of persisting severe left ventricular failure. Table 2 shows the late events.

Figure 1 shows the actuarial event free curve for all 1163 patients in whom the first coronary angioplasty procedure was successful. Angina generally recurred in the first six months, after this there were only a few cases of recurrence, and after five years 77.9% of the patients were free of symptoms and events. The mean follow up was 23.8 months. Exclusion of patients with previous coronary artery surgery, in whom symptoms recurred more often

Table 2 Late events in 1163 patients in whom a first coronary angioplasty procedure was successful

Event	No	%
Total late mortality:	16	1.4
Cardiac	6	0.5
Non-cardiac	10	0.9
ACBG	58	5
Re-PTCA	93	8
PTCA other segments	13	1
AMI	6	0.5
AMI (non-related area)	5	0.4
Heart transplantation	1	

ACBG, aortocoronary bypass grafting; PTCA, percutaneous transluminal coronary angioplasty; AMI, acute myocardial infarction.

Fig 1 Event free survival (actuarial) after successful coronary angioplasty in 1163 patients. No CABG, patients who had not previously undergone coronary bypass surgery. CABG, patients who had previously undergone coronary bypass surgery. Event free, no angina, myocardial infarction, death, redilatation, or bypass surgery. Broken lines indicate ± 1 SE.

produced a more level event free curve with 79.2% of the remaining patients being symptom free and having had no myocardial infarction, repeat coronary angioplasty, or coronary bypass grafting. Only 46.4% of the patients who had coronary bypass grafts were free of symptoms five years after angioplasty ($p < 0.001$ (fig 1)).

Patients who had coronary angioplasty because of stable angina pectoris and those with impending myocardial infarction had similar event free curves. After five years 78.6% of the patients with impending myocardial infarction at the time of successful coronary angioplasty are symptom free as are 74.5% of the patients with stable angina at the time of successful coronary angioplasty. Any symptoms associated with angiographic evidence of restenosis generally recur within six months (mean (SD) 4.8 (6.8)) of angioplasty. In the 40 patients without angiographic evidence of restenosis but with progression of the disease elsewhere symptoms recurred 17.6 (14.5) months after angioplasty.

The recurrence of angina was not influenced by the presence of complete or incomplete revascularisation after coronary angioplasty. This may be because the study group contained many patients with an occlusion elsewhere that had been present for a long time and was no longer causing symptoms.

After exclusion of patients who had had previous coronary artery bypass surgery, 76% of the patients who had a second coronary angioplasty because of a recurrence of the stenosis after a successful first procedure were angina free five years after the second procedure (mean follow up of only 17.4 months). This result is not statistically different from that (79.2%) in the patients who were symptoms free five years after a first coronary angioplasty.

ANGIOGRAPHIC FOLLOW UP

Angiographic follow up examination was performed in 728 (63%) of the 1163 patients in whom angioplasty had been initially successful a mean of 4.5 months before. In 98% of the symptom free patients who had angiographic follow up there was no restenosis. Twenty five per cent of the patients who had angiographic follow up had symptoms and 75% of these patients had angiographic evidence of recurrence. Of the patients who had no angiographic follow up, 96% were symptom free. Restenosis was seen 185 times in 174 (24%) patients. Even if a restenosis is defined as a stenosis of $>50\%$ of the luminal diameter, the restenosis rate remains approximately the same (177 times in 167 patients). Figure 2 shows the difference between the degree of stenosis immediately after and late after a successful dilatation. Of the 797 stenoses that were successfully

Fig 2 The difference between the degree of stenosis immediately after and late after successful coronary angioplasty. When the stenosis decreased further with time the difference has a minus sign. Recurrences, therefore, are on the right hand side of this diagram.

dilated in these 728 patients, the main difference between the initial and follow up angiographic appearance was a mean (1SD) decrease in lumen diameter of 14.1 (29.0%). At repeat angiography 528 segments (66.2%) were unchanged (a change in diameter of $\geq 20\%$ compared with the luminal diameter immediately after dilatation). These data suggest that the degree of stenosis at the end of the procedure does not predict the result at follow up angiography. Only two (8%) of the 25 patients who had two follow up angiograms had a late recurrence. Angiography at follow up showed progression of disease elsewhere in 10% of patients in whom angioplasty had been successful. There were no differences in the restenosis rate between patients with stable or unstable angina at the time of angioplasty. Repeat balloon dilatation was successful in 92% of 115 restenoses. Fifty one of these patients had angiographic follow up. A second restenosis occurred in 17 (33%) patients.

In 17 patients who had a successful coronary angioplasty immediately after thrombolytic treatment, 10 had a follow up angiogram and recurrences were seen in three. In 63 patients who had a successful coronary angioplasty some time after thrombolytic treatment, 46 had a follow up angiogram and recurrences were seen in seven (15.2%). Eight of the 11 patients with successful coronary angioplasty at the time of an acute myocardial infarction without thrombolytic treatment had a follow up angiogram and recurrences were seen in four (50%).

Discussion

Many reports indicate that balloon coronary angioplasty is effective in dilating coronary artery stenoses and relieving the associated symptoms of angina. This report suggests not only that short term but

also that longer term relief of angina pectoris can be achieved. Patients who remain symptom free for the first six months after successful coronary angioplasty are likely to remain free of angina for the next five years. Only 2% of the symptom free patients who had repeat angiography showed evidence of restenosis without infarction or symptoms.

In the patients who have important restenosis at the site of the coronary angioplasty, anginal complaints usually recur within six months, whereas in the patients without angiographic evidence of recurrence but with considerable progression of the disease elsewhere symptoms usually occur later than one year after coronary angioplasty. This suggests that if symptoms recur after six months they are more likely due to progressive disease elsewhere rather than restenosis. This accords with the angina free curve after successful coronary angioplasty (without previous coronary artery bypass grafting) which demonstrates a rather steep drop to 87% in the first six months, after which the percentage of angina free patients drops to 81% over the next four and a half years. We do not know why 86% of our patients without previous coronary bypass surgery were symptom free after one year whereas in another report (from the Mayo Clinics) only 74% of similar patients remained free of angina after one year.¹ The medical treatment after coronary angioplasty is not specified in the Mayo Clinic report and it may be that differences in medical treatment have influenced the outcome in these two studies. Also the choice of the balloon size, pressure gradient determination at the end of the procedure, and other technical differences may influence the results. Reported percentages of angiographically proven recurrences of stenosis vary widely (range 12–47%)^{2–4} and depend on the definition of restenosis. Systematic angiographic follow up data are generally lacking except in the studies of Kaltenbach *et al*^{2,3} and Jutzy *et al*⁵ and the percentage of patients with a follow up angiography in most other series varies widely. Patient selection must have influenced the percentage (24%) of angiographic recurrences in our series because patients with symptoms had repeat angiography more often than patients without ($p < 0.001$).

On the basis of intention to treat 1005 (14.3%) out of the original 1352 patients had a completely successful angioplasty. Neither the initial success rate nor the recurrence rates for angina pectoris, myocardial infarction, or angiographic restenoses were different in patients with stable or unstable angina at the time of coronary angioplasty. This accords with reports that coronary angioplasty is effective in patients with unstable angina that is refractory to medical treatment.^{6,7} Our study was not designed to

investigate the role of coronary angioplasty after thrombolytic treatment for acute myocardial infarction. In our series there was a high initial success rate for coronary angioplasty during acute myocardial infarction and immediately after thrombolytic treatment. It appears, however, that long term patency rates are higher if coronary angioplasty can be postponed for 12 hours or more after successful thrombolytic treatment.

If a restenosis occurs, a second coronary angioplasty can be performed effectively and safely in most cases. In the 115 restenoses for which a second coronary angioplasty was done, both the initial success rate (92%) and the late angiographic patency rate resemble those of the first coronary angioplasty. Forty eight months after the second dilatation 76% of these patients were angina free. This accords with the good results obtained with repeat coronary angioplasty in other series.⁸

Coronary artery bypass surgery was eventually performed in 158 (11.6%) patients—in 64 because of failure of the coronary angioplasty, in 36 (2.6%) because of an emergency during the angioplasty attempt, and in 58 because of recurrence of the stenosis and/or progression of the disease elsewhere after successful coronary angioplasty. These results indicate that angioplasty could prevent or postpone coronary bypass surgery in many patients with angina pectoris.

Conclusion

Angiographically successful coronary angioplasty offers a better chance of long lasting relief of symptoms than previously suggested. We do not know whether our figures were influenced more by the technical aspects than by medical treatment after angioplasty. If a restenosis occurs a second coronary angioplasty can be done with good initial and late results.

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