Should coronary arteries with less than 60% diameter stenosis be treated by angioplasty?

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ABSTRACT We evaluated all patients receiving percutaneous transluminal coronary angioplasty (PTCA) in the past year for mild stenosis (60% or less diameter narrowing, n = 64, group 1) and compared them with a random sample of 330 patients with greater than 60% stenosis (n = 66, group 2) treated during the same year. The degree of coronary stenosis before PTCA was 52 ± 7% (mean ± SD) in group 1 and 79 ± 11% in group 2. The primary success rate was 90% (58 of 64 patients) in group 1 vs 86% (57 of 66 patients) in group 2. The incidence of complications requiring coronary surgery after PTCA failed was similar in both groups (3 of 64 in group 1, 4 of 66 in group 2), but there were four occurrences of myocardial infarction in group 1 and none in group 2 (p < .05). Recurrence of stenosis was judged on the basis of objective data, 76% of which were angiographic data, in 97% of the patients with primary success. At a mean interval of 5 months with a mean follow-up period of 7 months, 17 of 58 patients (29%) with primary success in group 1 and 24 of 57 patients (42%) in group 2 developed restenosis. In group 1, restenosis was markedly more severe (73 ± 15%) than initial stenosis (p < .005), which was not the case in group 2. In conclusion, PTCA in mild stenosis has favorable primary and long-term results, yet carries the risk of myocardial infarction and emergency operation and may, in some cases, even accelerate the disease process.


INTRODUCED into the treatment of coronary artery disease in 1977 as an alternative to coronary artery bypass grafting (CABG) primarily in single-vessel disease, percutaneous transluminal coronary angioplasty (PTCA) has proved to be an effective and safe procedure. In 5 years of application, indication for PTCA has expanded to bypass grafts, multivessel disease, and lesions that are technically more difficult to treat. However, the rapidly increasing use of PTCA and its growing popularity may cause a trend toward its preventive application for mild stenoses at an earlier stage of coronary artery disease. To examine whether this is justified, we retrospectively evaluated early and late outcome of PTCA in a series of consecutive patients with 60% or less diameter stenosis in comparison with a random sample of patients with tight stenosis.

Methods

Patients All patients receiving their first PTCA for a luminal diameter stenosis of 60% or less in a native vessel from December 1980, through December 1981, (n = 64, group 1) were evaluated and compared with a one out of five random sample of 330 patients undergoing their first PTCA for a greater than 60% luminal diameter stenosis within the same time (n = 66, group 2). The random sample was drawn to have similar group sizes and to facilitate acquisition of complete objective follow-up data.

A 60% degree of luminal diameter narrowing corresponds to a cross-sectional stenosis of 84% and may represent a borderline hemodynamically significant lesion. All patients presented with angina pectoris that, according to the referring physician, was poorly controlled by previous drug treatment. The indication for PTCA in these patients was based on the angiographic finding of an accessible coronary lesion, on the candidacy of these patients for coronary surgery as a result of their clinical status, and on the clinical data provided by the referring physician. The results of exercise testing (treadmill exercise according to the Bruce protocol) or nuclear studies (thallium scintigraphy or technetium first-pass study) in patients at rest and during exercise, although routinely performed before and after PTCA, did not influence the indication established by the criteria mentioned above.

PTCA. PTCA was performed according to the technique described elsewhere. To assess the result of coronary angioplasty, selective coronary angiography was performed immediately before and after PTCA. The luminal diameter stenosis was calculated as the mean of three oblique projections with a computerized caliper (A2D Cinematic Viewer and Prodical 1101
Programmable Digital Caliper). This method has been shown to be more reliable in judging the degree of coronary stenosis than those in which only one projection is used and concurs with recommendations derived from pathohistologic studies. According to the National Heart, Lung, and Blood Institute (NHLBI) criteria, a reduction of at least 20% of the initial degree of stenosis was considered a successful dilatation if no coronary surgery (CABG) was required during hospitalization. In all cases, pressure was routinely monitored and pressure gradients across the stenosis were recorded, with the guide catheter representing aortic pressure and the mean lumen of the dilatation catheter transmitting distal coronary pressure. Pressure gradients were calculated from the mean proximal and distal pressures by a computerized program (Meddars 300, Honeywell).

Drug treatment. Oral nitroglycerin and nifedipine therapy was started in all patients before the procedure and was continued for 2 months thereafter. During dilatation, heparin and low-molecular weight dextran were routinely administered and intracoronary nitroglycerin was given to prevent coronary spasm. Patients in both groups received warfarin (Coumadin, 2 x partial thromboplastin time) or aspirin in low doses (325 mg) in the follow-up period of 6 months after PTCA as part of an ongoing randomized study. This did not influence our results because 20 patients in each group were on warfarin (31% vs 30%).

Follow-up. All patients were asked to take a treadmill exercise test, whether or not they also underwent nuclear study, during follow-up and to have a control coronary angiogram at 6 months after PTCA if they were symptom-free. If symptoms recurred, they were advised to have a repeat angiogram as soon as possible. Outside restudy films were usually sent to us and assessed by us in the fashion mentioned above. Questionnaires and phone calls to the patients or their referring physicians were used to complete our follow-up information.

The follow-up period ranged from 1 to 16 months (mean 7.1) in group 1 and from 3 to 15 months (mean 7.4) in group 2. Objective follow-up data were obtained in all but two patients in each group; in 76% of group 1 patients (43 of 58) and 83% of group 2 patients (47 of 57) angiographic data were available. Restenosis (recurrence), judged angiographically as a mean of three projections, was defined as a more than 50% loss of gain in luminal diameter achieved with the previous PTCA. For example, a 90% stenosis is reduced to 10%, which is a gain of 80% in luminal diameter. A 50% loss of this diameter improvement is 40% and therefore a stenosis of more than 50% (10% + 40%) at restudy would be considered a recurrence. Besides angiographic data, follow-up data consisted of exercise test results in patients who underwent nuclear study and those who did not. A positive exercise treadmill test result during follow-up after a negative result after PTCA was considered indicative of recurrent stenosis of the dilated vessel if no angiogram was available.

This was the case in one patient in group 1 and in three patients in group 2. An exercise treadmill test result that continued to be negative after PTCA was considered to be indicative of continued success if no angiogram was available. This was the case in eight patients in group 1 (one exercise treadmill test result was considered equivocal) and four patients in group 2. Subjective follow-up data were obtained in only two patients in each group. PTCA in these patients was considered a continued success because the patients have reported continued improvement of symptoms.

Statistics. Data collection and random sampling were aided by a computerized cardiac data bank. Student’s t test and the chi-square test were used to evaluate statistical significance. A p value greater than .05 was considered nonsignificant and results were expressed as mean ± SD.

Results

Primary success. Group characteristics are described in table 1. The patient characteristics of the random sample (group 2) match well those of the consecutive patients of group 1 with the exception that there was a prevalence of left anterior descending coronary artery (LAD) lesions in patients referred to us for PTCA of a mild stenosis. This may reflect the common opinion that because of the myocardium at risk, a mild lesion in the LAD is more readily considered an indication for PTCA.

Primary success was similar in both groups, 90% (58 of 64 patients) in group 1 vs 86% (57 of 66 patients) in group 2. Successful initial angioplasty reduced coronary stenosis from 52 ± 7% to 23 ± 11% in group 1 and from 79 ± 11% to 31 ± 13% in group 2. The mean pressure gradient across the lesion correlated well with the degree of stenosis before and after PTCA (table 2).

Failures occurred in six patients of group 1, three of which (two right coronary artery [RCA], one LAD) were due to the inability to reach or cross the lesion (one patient needed CABG 2 days after PTCA), one could not be dilated (LAD) and two had an acute closure of the artery (LAD) with subsequent CABG and myocardial infarction. Two patients (LAD) in whom PTCA was considered a primary success, had a side branch closure with evidence of myocardial infarction.

In group 2 there were nine failures, seven of which were due to the inability to reach or cross the lesion (two patients needed CABG the next day), and two were due to dissection of the artery (RCA and LAD) with subsequent CABG. Comparing group 1 with group 2, there were four occurrences of myocardial infarction in group 1 and none in group 2 (p < .05, table 3); three patients needed CABG in group 1 and four patients in group 2 needed CABG. None of the

### TABLE 1

<table>
<thead>
<tr>
<th>Characteristics of group 1 and group 2 patients</th>
<th>Group 1</th>
<th>Group 2</th>
<th>p value</th>
</tr>
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<tbody>
<tr>
<td>n</td>
<td>64</td>
<td>66</td>
<td>NS</td>
</tr>
<tr>
<td>Age (years)</td>
<td>52 (37–70)</td>
<td>53 (34–71)</td>
<td>NS</td>
</tr>
<tr>
<td>Male (%)</td>
<td>70</td>
<td>80</td>
<td>NS</td>
</tr>
<tr>
<td>SVD (%)</td>
<td>92</td>
<td>94</td>
<td>NS</td>
</tr>
<tr>
<td>Stenoses</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LAD (%)</td>
<td>83</td>
<td>67</td>
<td>&lt; .05</td>
</tr>
<tr>
<td>RCA (%)</td>
<td>16</td>
<td>26</td>
<td>NS</td>
</tr>
<tr>
<td>LCX (%)</td>
<td>1</td>
<td>7</td>
<td>NS</td>
</tr>
<tr>
<td>Previous MI (%)</td>
<td>20</td>
<td>20</td>
<td>NS</td>
</tr>
</tbody>
</table>

SVD = single vessel disease; RCA = right coronary artery; MI = myocardial infarction.
patients of group 1 who had CABG and/or myocardial infarction had angiographically demonstrable collaterals to the diseased vessel on the pre-PTCA angiogram, while two of the four patients of group 2 did show collateral circulation. Dissections and side branch closures not resulting in myocardial infarction or CABG were seen in one and six patients, respectively, among the primary successes of group 1 and group 2.

**Follow-up results.** As shown in figures 1 and 2, in 72% of all group 1 patients (46 of 64) and in 67% of all group 2 patients (44 of 66) in whom PTCA was attempted, the operation was a long-term success (= total success) as determined after repeat dilations. In detail, at a mean interval of 4.8 months (range 2 to 10) 17 of 58 patients (29%) with primary success in group 1 and 24 of 57 patients (42%) in group 2, at a mean interval of 4.5 months, were judged by objective data to have recurrent stenosis at the previously dilated site of the coronary artery (figures 1 and 2). The recurrence rate of LAD stenoses was 33% (16 of 49, group 1) and 46% (17 of 37, group 2) as compared with the recurrence rate of 13% (1 of 8, group 1) and 31% (6 of 16, group 2) of RCA stenoses and the even lower recurrence of left circumflex stenoses (0 of 1 vs 1 of 4). One patient in each group was found to have recurrence of chest pain due to a new coronary stenosis in a different vessel. In group 1, 11 of 17 patients with restenosis underwent repeat angioplasty. The remaining six patients with recurrent stenosis were controlled by medical treatment. Five patients in group 1 reported persistence of previous symptoms and had a normal coronary angiogram. On two patients in group 1 and one patient in group 2 no follow-up information was available. Two patients died during follow-up in group 1, one due to renal failure and one due to aortic dissection with mediastinal necrosis in the presence of aortic insufficiency. In group 2, 14 of 24 patients with restenosis had repeat PTCA and seven patients underwent elective CABG; three patients continued medical treatment. All but two of the other patients of both groups had normal follow-up coronary angiograms or objective data that indicated patency of the dilated vessel.

In group 1 patients who underwent angiographic restudy, restenosis was markedly more severe (73 ± 15%) than the degree of stenosis before initial PTCA (52 ± 7%; p < .005; figure 3). A typical example is given by figure 4, which shows the left anterior oblique (LAO) projections of the coronary angiogram of H. B., a 51-year-old male patient who had a 4 month history of angina pectoris before PTCA. In figure 4, A, the proximal LAD stenosis before PTCA was judged to be a 47% diameter narrowing in LAO 60° projection, 54% narrowing in right anterior oblique (RAO) 30° projection, and 42% narrowing in lateral projection, which led to a mean of 48% diameter stenosis. Accordingly, stenosis after PTCA was judged to be 27% (figure 4, B). Recurrent angina after 3 months led to restudy, which revealed a 77% restenosis (figure 4, C). Repeat PTCA reduced stenosis to 30% (figure 4, D).

In group 2, by contrast, the degree of recurrent stenosis (82 ± 12%) was similar to the degree of the initial stenosis (83 ± 11%, NS; figure 3).

**Repeat PTCA.** Repeat PTCA was performed in 11 of 17 patients with recurrent stenosis in group 1 and in 14 of 24 patients with recurrent stenosis in group 2. Repeat PTCA was successfully performed in all patients of both groups except in one patient of group 1, who required emergency CABG. No difference between the groups was noted in degree of stenosis and pressure gradients after repeat dilatation. Two patients in each group underwent elective CABG 2 to 4 months after repeat PTCA. More than 2 of 3 (67%) of the patients of both groups who had received repeat PTCA are symptom-free at a mean follow-up interval of 7 months (range 2 to 13), which exceeds the 4.6 month time frame in which the restenoses occurred in our series.

**Discussion**

Refined catheter technology and the growing skill of operators have allowed a primary success rate of 90% to be achieved in appropriately selected patients. These results justify enthusiasm and a more aggressive patient selection in terms of coronary anatomy, but do

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>Primary results of initial PTCA</th>
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<tbody>
<tr>
<td></td>
<td>Group 1</td>
</tr>
<tr>
<td>n</td>
<td>64</td>
</tr>
<tr>
<td>Primary success</td>
<td>58 (90%)</td>
</tr>
<tr>
<td>Stenosis (%)</td>
<td></td>
</tr>
<tr>
<td>Before PTCA</td>
<td>52±7</td>
</tr>
<tr>
<td>After PTCA</td>
<td>23±11</td>
</tr>
<tr>
<td>Pressure gradient (mm Hg)</td>
<td></td>
</tr>
<tr>
<td>Before PTCA</td>
<td>38±15</td>
</tr>
<tr>
<td>After PTCA</td>
<td>15±10</td>
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</table>

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>Complications of PTCA</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1</td>
</tr>
<tr>
<td>MI</td>
<td>4</td>
</tr>
<tr>
<td>CABG</td>
<td>3</td>
</tr>
</tbody>
</table>

MI = myocardial infarction.
not necessarily imply an expansion of clinical indication,\textsuperscript{1,5} which originally was based on the patient's need for coronary surgery. In all previous studies on effectiveness and safety of PTCA, dilatation was performed in patients with an average degree of stenosis of more than 70% luminal diameter narrowing.\textsuperscript{1,2,3,5} No data has been available supporting the use of PTCA in patients with milder coronary stenosis with less than 60% luminal diameter narrowing. The value of coronary angioplasty in this subset of patients should be determined by its primary success rate, its complications, and long-term results.

As one would expect, primary success rate is higher in patients with mild stenosis, but the difference of 90% in the mild stenosis group vs 86% in the control group is not statistically significant.

Complications requiring bypass surgery, however, were equally frequent in both groups. The incidence of myocardial infarction is even higher in patients with mild stenosis, which might be explained by the lack of sufficient collateral blood flow in case of complication, although angiographically demonstrable collaterals have not been shown to guard necessarily against myocardial infarction after failure of PTCA.\textsuperscript{13}

FIGURE 1. Follow-up results of patients with 60% or less diameter stenosis (group 1). Med Tx = medical treatment; EM CABG = emergency coronary bypass surgery; el. CABG = elective coronary bypass surgery; $\dagger$ = death.

FIGURE 2. Follow-up results of patients with greater than 60% diameter stenosis (group 2). Abbreviations are as in figure 1.
Recurrence rate is lower in mild stenosis, but the difference was not significant (29% vs 42%) due to small group sizes. The prevalence of LAD stenoses in group 1 enhances this difference since LAD lesions have the highest recurrence rates. The total number of long-term successes of all group 1 patients in whom PTCA was attempted is only slightly higher than the total number of successes of all group 2 patients in whom PTCA was attempted.

However, the severity of recurrent stenosis in patients with originally mild stenosis significantly exceeds the initial degree. This is in disagreement with the finding that progression appears to be directly related to the initial severity of stenosis and our own experience with disease progression of individual lesions. Acceleration of the disease process by mechanical dilatation (intimal damage) might be an explanation.

In a number of patients with mild stenoses, symptoms before PTCA persisted after dilatation, which suggests that several patients in group 1 were inappropriately selected to receive PTCA. Coronary spasm superimposed on fixed coronary disease may be the problem in these patients. Since we once noted a total coronary occlusion after administration of intravenous ergonovine, we did not routinely test our patients with ergonovine before PTCA. However, these patients, who present with various manifestations of chest pain not clearly verifiable and or linkable to fixed coronary disease, represent the challenge and the burden of daily diagnostic work.

Thus, PTCA in patients with mild stenoses has favorable primary and long-term results, yet carries a considerable risk of myocardial infarction and CABG and may in some cases accelerate the disease process of the dilated coronary lesion.

**Clinical implications.** The natural course of coronary atherosclerosis is progressive and unpredictable. However, progression of coronary disease is clearly related to time and may affect more than 40% of patients with angiographically documented disease within 1 year. Coronary disease is an accelerating process, with increasing severity of arterial involvement, mortality, and progression rate rise.

In an effort to avoid operating again, it increasingly has become the practice of coronary surgeons to bypass not only severe stenoses but also mildly diseased arteries with the anticipation that disease will progress.

Since reliable prognosticators of disease progression have not yet been determined, timely early intervention by PTCA before double- and triple-vessel disease develops and irreversible myocardial damage occurs might appear logical and justified, even though symptoms are mild.

Most of the candidates for PTCA have single-vessel disease and are commonly considered to have a good prognosis, particularly if their symptoms are only mild. However, it has been shown recently that more than a third of the survivors of a myocardial infarction had single-vessel disease. Therefore, patients with single-vessel disease do not represent a homogeneous patient population. Some patients may have a poorer prognosis and a more urgent need for an intervention, especially if the stenosis is located proximally with a large amount of myocardium at risk. From this point of view PTCA seems to be justified. However, before PTCA is undertaken the risks of emergency CABG, myocardial infarction, and rapid disease progression at the dilatation site, as demonstrated in group 1, should be considered and the patient should be informed of the risk. The clinical course of these patients and the angiographic morphology of their coronary stenoses may help identify these patients at high risk and establish a more individual and valid indication for PTCA in patients with milder ste-
noses. This also applies to patients who undergo PTCA for a severe stenosis and have an additional mild lesion in another vessel, the "preventive" dilatation of which in the same operating session is tempting. The possible complications and a recurrence rate of almost 30% with potential disease acceleration in the dilated lesion should caution against the application of PTCA in patients with mildly diseased vessels.

References
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