Prediction of long-term clinical outcome with final translesional pressure gradient during coronary angioplasty

JOHN M. HODGSON, M.D.,* STEVEN REINERT, M.S., ALBERT S. MOST, M.D., AND DAVID O. WILLIAMS, M.D.

ABSTRACT The final translesional pressure gradient measured during coronary angioplasty correlates with immediate angiographic and clinical results. Whether the pressure gradient is of value in predicting late clinical outcome has not been determined. We therefore obtained complete follow-up information on 159 patients with single-vessel disease who underwent successful coronary angioplasty. Mean follow-up time was 15 ± 10 months. The occurrence of repeat angioplasty, coronary bypass surgery, recurrent anginal chest pain, or a positive postangioplasty stress test were considered clinical events indicative of late failure. Of the variables age, gender, initial and final translesional pressure gradient, extent of initial and final arterial narrowing, site of dilatation, type of balloon catheter used, number of inflations, and maximal inflation pressure, only the final translesional pressure gradient was predictive of late failure when analyzed by multivariate techniques. Thus, the final translesional pressure gradient is of value in predicting both immediate and late outcome after coronary angioplasty. Circulation 74, No. 3, 563-566, 1986.

THAT CORONARY ANGIOPLASTY can immediately relieve both subjective and objective manifestations of ischemia in properly selected patients with coronary artery disease is well acknowledged.1-6 Sustained clinical improvement, however, is not uniformly observed over the long term: recurrent ischemic events may occur in a significant proportion of patients.7,8 Both the degree of coronary artery narrowing, as determined angiographically, and the final translesional pressure gradient have been found to correlate well with early outcome. Thus, if coronary artery narrowing is reduced to less than 50% or if the final gradient is less than 25 mm Hg, indexes of ischemia are improved.1-3,9 Since preliminary studies have suggested that the final gradient correlates with the development of angiographically detected restenosis,10 we designed an investigation to determine the value of this variable in predicting late clinical outcome.

Methods

Patient selection and clinical variables. Consecutive patients with single-vessel coronary artery disease who underwent successful percutaneous transluminal coronary angioplasty (PTCA) between November 1978 and June 1984 at the Rhode Island Hospital (n = 167) were reviewed. This time period was chosen to enable a minimum of 1 year of follow-up. An angioplasty procedure was considered successful if, after balloon dilation, residual arterial stenosis was less than 50% diameter reduction, and patients did not experience nonfatal infarction, coronary bypass surgery, or death during their hospitalization. Translesional gradients were unavailable in seven patients due to technical limitations; these patients were excluded from analysis. Baseline clinical characteristics of these seven patients did not differ from those of patients in whom gradients were recorded. Two of these seven required repeat PTCA for restenosis. One additional patient could not be located at the 1-year anniversary (completeness of follow-up 99%). Hence the study population consisted of 159 patients.

Follow-up information was obtained by telephone interview at yearly intervals after the initial procedure. End point variables specifically addressed included (1) presence and frequency of anginal chest pain, (2) repeat coronary angioplasty, (3) coronary artery bypass surgery, (4) coronary arteriography, (5) exercise stress test, (6) myocardial infarction, and (7) death due to cardiac causes. If history was obtained for variables 2 to 7, further documentation was obtained to verify the exact details of the event or examination.

Clinical failure was defined as the occurrence of any of the following during the period of follow-up: (1) anginal chest pain more frequent than once per month; (2) repeat coronary angioplasty or coronary artery bypass surgery specifically for the initially dilated vessel; (3) ischemic response on the exercise stress test; (4) myocardial infarction, or (5) death due to cardiac causes. Patients who underwent diagnostic coronary cineangiography because of recurrent angina pectoris and who had evidence of new, significant coronary arterial stenosis and no restenosis of the originally dilated lesion were not counted as
clinical failures. Patients were not continued on antianginal medications after angioplasty, and all patients in whom treatment was a continued success were angina free on no medication.

To permit a meaningful analysis, several variables other than pressure gradient were also considered. These included age, gender, the gradient before angioplasty, the vessel dilated, the type of dilatation catheter used, the maximal inflation pressure used, and the extent of coronary stenosis before and after balloon dilatation.

**Procedure and pressure measurement.** All angioplasty procedures were performed with the use of preformed guiding catheters and via the Judkins technique. Angioplasty was accomplished with one of three different balloon catheter systems: a nonsteerable balloon catheter in 67 patients, a steerable balloon catheter in 82 patients, and a low-profile steerable balloon catheter in 10 patients. All patients received oral nifedipine at the outset of the procedure. Other vasodilators were not used routinely and patients rarely received intracoronary vasodilators.

Pressures were measured with fluid-filled catheters, Statham-Gould pressure transducers, and an Electronics for Medicine physiologic recorder with an on-line pressure integrator. The final translesional pressure gradient was defined as the difference between the guide catheter pressure and the dilating catheter pressure obtained with the balloon catheter distal to the lesion minus this difference obtained with the balloon catheter proximal to the lesion (intrinsic gradient). The final pressure gradient was obtained at least 10 min after the final balloon inflation and at least 2 min after injection of intracoronary contrast.

**Statistical analysis.** Data were analyzed both by Cox stepwise proportional-hazards multivariate analysis and stepwise logistic regression with the use of SAS Institute (Cary, NC) statistical software. Probability values <.05 were considered indicative of a significant difference. Group data are expressed as the mean ± 1 SD.

### Results

**Clinical characteristics of the study group.** Characteristics of the study population are listed in table 1. The mean age was 55 ± 11 years. Site of dilatation was the left anterior descending coronary artery in 106 patients (67%), the left circumflex or obtuse marginal artery in 18 patients (11%), and the right coronary artery in 35 patients (22%). The average stenosis before dilatation was 78 ± 12% and that after dilatation was 25 ± 11%. The average translesional gradient before dilatation was 53 ± 15 mm Hg and that after dilatation was 16 ± 9 mm Hg.

The average length of follow-up was 15 ± 10 months. Fifty-seven patients (36%) experienced clinical events indicating failure during follow-up. Table 2 lists all of the events occurring among these patients. The most common manifestation of clinical failure was recurrent angina pectoris (55 of 57 patients). In the two patients without angina a negative thallium stress test immediately after angioplasty was converted to a positive result at late follow-up. Repeat PTCA for restenosis was performed in 25 patients and 12 patients underwent coronary bypass surgery. Forty of the 57 patients in whom PTCA failed had more than one event. The mean time between initial angioplasty and the earliest event indicating failure was 6.5 ± 6.2 months.

Age, sex, translesional gradient before and after PTCA, percent of luminal narrowing before and after PTCA, vessel location, type of balloon catheter used, total number of inflations, and maximal inflation pressure were analyzed for association with late clinical failure at 1 year with the use of stepwise logistic regression. Only the final translesional pressure gradient was significantly related to subsequent failure (p = .0002). The probability of failure (P) could be calculated with the equation

$$ P = \frac{1}{1 + e^{-(0.0857 \text{ gradient} - 1.9356)}} $$

These same variables were analyzed with a Cox proportional-hazard model. Again, only the final translesional gradient was related to late clinical failure (chi square = 12.75, p = .0004).

The relationship between the final pressure gradient and the occurrence of late failure is illustrated in figure 1. The majority of patients with final pressure gradients greater than 26 mm Hg experienced clinical failure. In those with values less than 26 mm Hg, and in particular those with values less than 15 mm Hg, sustained success was more commonly observed. Importantly, both success and failure occurred within each of the pressure gradient ranges.

### Discussion

Although the accuracy of measurement of the translesional gradient has been questioned,11-13 these gradi-
TABLE 2
Events indicating clinical failure among 159 patients in whom PTCA was initially successful

<table>
<thead>
<tr>
<th>Type of event</th>
<th>No. of events</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recurrent angina pectoris</td>
<td>55</td>
</tr>
<tr>
<td>Repeat PTCA</td>
<td>25</td>
</tr>
<tr>
<td>Abnormal exercise test result</td>
<td>12</td>
</tr>
<tr>
<td>Myocardial infarction</td>
<td>4</td>
</tr>
<tr>
<td>CABG</td>
<td>12</td>
</tr>
<tr>
<td>Death</td>
<td>0</td>
</tr>
<tr>
<td>Total all events</td>
<td>108</td>
</tr>
</tbody>
</table>

Distribution of events

<table>
<thead>
<tr>
<th>No. of patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>One event</td>
</tr>
<tr>
<td>Two events</td>
</tr>
<tr>
<td>Three events</td>
</tr>
<tr>
<td>Four events</td>
</tr>
<tr>
<td>Total all events</td>
</tr>
</tbody>
</table>

Event values correlate with severity of anatomic lesions, coronary flow reserve, and immediate clinical success. In the current study, we have demonstrated that the final translesional gradient is predictive of long-term clinical success. None of the other variables analyzed demonstrated such a relationship.

In this investigation, only patients with single-vessel disease were included. This population was chosen to avoid the confusion that might occur in patients with multivessel disease with respect to identifying the coronary lesion responsible for clinical failure. Since only one stenosis was present, any subsequent events could be logically attributed to this initial stenosis. It is possible that some patients with clinical failure had developed new lesions to account for their symptoms. Fifty-five of the 57 patients who had late failure experienced recurrent angina, with the average time to onset of recurrent angina being 6 months. The time interval is suggestive of restenosis, and in 34 patients, angiography did document restenosis of the initially dilated lesion. Those patients who underwent diagnostic coronary angiography for recurrent angina and demonstrated new disease in other vessels were not included in the clinical failure group in this study.

A substantial proportion of patients (36%) developed recurrent angina pectoris after initially successfully angioplasty. Such a result should not be considered as indicative of the overall efficacy of angioplasty for relieving angina pectoris in patients with coronary artery disease. Repeat angioplasty may often be performed in patients with restenosis, with a favorable long-term outcome. In addition, this finding must be interpreted in light of our definition of recurrent angina (>1 episode/month), which was intentionally strict so as not to overlook any potential failures.

Although relatively few patients in our study underwent follow-up angiography to document continued anatomic success, the purpose of our study was to demonstrate a relationship between translesional gradient and sustained clinical efficacy. Indeed, since angioplasty is primarily performed to relieve symptoms of angina pectoris, it may be reasonable to determine success based on the clinical status of the patient rather than on the arteriographic appearance of the lesion.

The translesional pressure gradient can be readily measured during coronary angioplasty and can serve as a valuable on-line aid in making judgments regarding the efficacy of the angioplasty procedure. This investigation indicates that a lower post-PTCA pressure gradient, particularly one less than 15 mm Hg, is benefici
cial in obtaining not only short-term but also sustained clinical success.

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