

High-fidelity translesional pressure gradients during percutaneous transluminal coronary angioplasty: Correlation with quantitative coronary angiography

A fiberoptic pressure sensor mounted on an 0.018-inch guidewire (Pressure Guide) was used to measure the transstenotic pressure gradient in 30 patients undergoing percutaneous transluminal coronary angioplasty (PTCA) with lesions considered suitable for quantitative coronary angiographic (QCA) assessment. The aim of the study was to correlate pressure gradients with parameters obtained with QCA. After intracoronary injection of 125 μ g of nitroglycerin, multiple angiographic views were taken of the lesion. The Pressure Guide fiberoptic sensor was then positioned distal to the stenosis and the pressure gradients were recorded before and after PTCA. There was a significant correlation between mean pressure gradients (ΔP) and percent diameter stenosis ($r = 0.73$; $p < 0.001$) and absolute stenosis diameter ($r = -0.67$; $p < 0.001$) and with percent area stenosis ($r = 0.69$; $p < 0.001$) and absolute stenosis area ($r = -0.63$; $p < 0.001$). The closest relationship, though, was found with stenotic flow reserve (SFR), which is an integrated parameter calculated from QCA. This relationship can be described by the equation: $\Delta P = 65.2 - 12.6 \cdot \text{SFR}$ ($r = -0.79$; $p < 0.001$). With a measured gradient of >15 mm Hg, the sensitivity was 94% and the specificity 96% to predict an SFR <3.5 . In conclusion, a statistically significant relationship could be found between stenosis pressure gradients and angiographic parameters in this study with lesions without complicated morphology. The independent information obtained by pressure gradient measurement may be of particular value in intermediately severe lesions or in stenoses where the angiographic assessment otherwise is difficult. (AM HEART J 1993;126:66-75.)

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Although computer-assisted quantitative coronary angiography (QCA) allows a more user-independent and reproducible stenosis evaluation in comparison with visual assessment, it still carries several inherent limitations. For example, estimation of the stenotic area by using edge detection assuming a circular model may be less accurate if the lumen is slit-like or irregular. After percutaneous transluminal coronary angioplasty (PTCA) contours are sometimes hazy as a result of a split of the intimal surface or a dissection. More than one orthogonal projection

and the use of densitometry will help to improve the coronary artery analysis, but there will still be situations when the angiographic method is suboptimal. Identification of the "normal" reference diameter can also be controversial, especially in ostial lesions, in highly tapering lesions, and when diffuse disease is present.¹

Measurement of translesional pressure gradients has been used as a physiologic method of evaluating coronary stenoses, especially during PTCA.² The conventional technique has been to measure the distal coronary pressure through the lumen of the balloon catheter and to compare it with the pressure measured through the lumen of the guiding catheter in the ostium of the coronary artery. By using this technique, the pressure drop across the stenosis will be falsely increased even in moderate narrowings because of the reduction of the true luminal area.³⁻⁸ Another disadvantage is the low-frequency response obtained when measuring pressure through the thin

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liquid-filled lumen of the balloon catheter. Because of these technical drawbacks, the interest for pressure gradient measurements has diminished. The initial experiences with the Pressure Guide (Radi-Medical Systems, Uppsala, Sweden) a new fiberoptic pressure sensor for intracoronary use, have recently been reported.⁹ The sensor element is mounted on an 0.018-inch guidewire and will pass through standard angioplasty balloon catheters that accept this size guidewire. The cross-sectional area of the sensor guidewire (0.17 mm²) is substantially lower than that of a balloon catheter (>0.9 mm²) and will to a lesser extent falsely increase the pressure gradient.^{8, 10}

Transstenotic pressure gradients and stenotic flow reserve (SFR) may be calculated using standardized values for aortic pressure and coronary flow velocity taking into account angiographically measured values of stenosis length and cross-sectional area.¹¹⁻¹³ SFR has been proposed as a useful parameter for describing the physiologic importance of a coronary stenosis, and it has been shown in animal experiments to correlate better with direct measurements of coronary flow reserve than with single stenosis parameters like percent-diameter stenosis, obstructive area, or stenosis length.¹¹ However, the validity of the theoretic pressure gradient and the calculated SFR in the clinical situation has not yet been fully established. The aim of this study was to correlate the magnitude of transstenotic pressure gradients as recorded with the Pressure Guide fiberoptic sensor before and after PTCA with the morphologic severity of the stenosis measured from QCA. In addition, comparison of the physiologic importance of the lesions were made by correlating pressure gradients and predicted SFR.

METHODS

Patients. Thirty patients scheduled for coronary angioplasty were included in the study. There were 5 women and 25 men, with a mean age of 59 years (47 to 78 years). Twenty-eight patients had stable angina and evidence of ischemia on a stress test, and two patients had unstable angina. Eight patients had suffered a subendocardial myocardial infarction before PTCA. The two patients with unstable angina and another patient with diabetes had a moderately reduced left ventricular ejection fraction (45% to 51%), whereas the remaining 27 patients all had normal LV function (ejection fraction >60%). Twenty patients had one-vessel disease, 7 had two-vessel disease and 3 patients had three-vessel disease. The left descending artery was dilated in 17 patients, a diagonal branch was dilated in 1 patient, the circumflex artery was dilated in 6 patients, and the

right coronary artery was dilated in 6 patients. Lesions selected for the study had to be considered suitable for QCA and for stenosis gradient measurement. This included proximal, concentric, or eccentric stenoses in a straight segment of the vessel, whereas ostial, long (>20 mm), tortuous, diffuse, or sequential lesions were excluded. The morphologic characteristics of the stenoses are summarized in Table I.

Quantitative coronary angiography. The anatomy before and after PTCA was analyzed by using Philips DCI angiography equipment (Philips Medical Systems, Eindhoven, The Netherlands). The angiograms of the first 10 patients were analyzed from cine films by the computer-based Cardiovascular Angiography Analysis System (CAAS) (Pie Data Medical B.V., Maastricht, The Netherlands) as previously described.¹⁴ In principle, the CAAS analysis is based on digitized cine frames. The contours of the coronary segment are automatically detected. The reference diameter is identified by an automated interpolation technique, manual corrections are made if necessary, and correction for pin-cushion distortion is included. Calibration of the diameter data in absolute values is achieved by detecting the boundaries of a segment of the catheter and comparing the computed mean diameter with the known size in millimeters. In vivo validation of the CAAS system has been performed by using precision drilled phantom stenoses implanted in porcine coronary arteries.¹⁵

The remaining 20 patients were analyzed on-line in the catheterization laboratory with Philips' Automated Coronary Analysis (ACA) program (Philips Medical Systems).¹⁶ The images are stored directly in digital form with a 512 × 512 matrix. The analysis, including the calibration procedure, is based on the same technique as the CAAS system for contour detection and identification of the reference diameter. However, in the ACA program no correction for pin-cushion distortion is included. The ACA program has recently been validated in comparison with the CAAS system and was found to provide highly reliable measurements.¹⁷

For all stenoses a theoretic pressure gradient may be calculated.¹⁸ These calculations can be derived from fluid dynamics of narrow tubes. The following equation was used: $\Delta P = f \cdot Q + s \cdot Q^2$, where ΔP is the theoretic pressure gradient across the stenosis, f is the Poiseuille resistance, and s is the turbulent resistance. Q is the mean coronary volume flow in milliliters per second. From stenosis geometry, constants f and s can be deducted. Volume flow is calculated from the interpolated reference cross-sectional area, assuming a coronary blood flow velocity of 20 cm/

Table I. Morphologic characteristics of the lesions before and after angioplasty, respectively

Patient	Before						After					
	MLD (mm)	PDS (%)	STL (mm)	STS	ΔP (mmHg)	SFR	MLD (mm)	PDS (%)	STL (mm)	STS	ΔP (mmHg)	SFR
1	0.91	74	4.59	0.61	25	2.20	2.34	50	4.49	0.33	2	4.90
2	0.69	68	5.80	0.15	43	1.75	1.23	39	7.10	0.44	28	4.00
3	0.61	65	5.74	0.42	46	1.50	0.81	64	2.24	0.58	24	2.50
4	0.87	54	7.76	0.62	45	2.75	1.78	15	3.98	0.04	5	4.90
5	0.61	74	3.37	0.60	60	1.10	2.08	19	2.07	0.96	12	4.95
6	1.92	49	6.63	0.40	3	4.16	2.66	29	2.03	0.24	4	4.75
7	0.72	67	5.20	0.16	28	2.00	0.92	57	8.77	0.22	32	2.50
8	1.30	63	21.05	0.86	54	2.43	2.08	41	10.77	0.36	12	4.15
9	1.00	63	12.15	0.77	34	2.50	1.92	19	2.12	0.96	4	4.82
10	1.17	71	16.46	0.55	46	1.37	1.87	44	12.84	0.35	9	3.53
11	1.20	55	12.69	0.75	43	2.79	1.70	33	5.51	0.17	6	4.51
12	0.97	61	14.17	0.73	5	2.25	3.29	4	1.94	0.69	0	4.98
13	1.32	54	6.00	0.90	0	3.52	1.65	35	4.79	0.64	0	4.70
14	1.09	64	11.09	0.38	71	2.48	4.27	0	8.89	0.64	5	4.75
15	1.03	65	10.96	0.42	75	2.13	2.71	29	6.10	0.35	3	4.70
16	1.05	62	11.25	0.85	37	2.04	2.62	23	2.50	0.79	1	4.45
17	1.29	63	12.52	0.79	51	2.49	2.04	45	5.22	0.55	0	4.78
18	1.42	50	11.65	0.61	3	3.53	1.76	32	4.48	0.18	0	4.60
19	0.80	62	18.91	0.73	34	1.85	1.14	44	9.39	0.80	8	3.54
20	1.49	61	8.73	0.80	46	2.54	2.51	32	5.52	0.24	0	4.62
21	0.97	71	8.10	0.62	21	1.63	2.48	26	6.10	0.41	5	4.79
22	0.83	79	13.50	0.83	43	0.36	2.98	22	7.65	0.64	1	4.76
23	1.24	52	12.60	0.91	39	3.22	1.84	26	2.60	0.50	6	4.82
24	1.58	48	7.32	0.86	9	4.31	3.36	14	7.12	0.33	4	4.90
25	0.32	87	10.16	0.68	39	0.34	2.42	21	2.72	0.80	7	4.88
26	1.50	61	13.61	0.98	32	2.49	3.28	21	9.46	0.78	4	4.90
27	1.85	40	11.86	0.41	13	4.30	2.50	25	8.76	0.57	10	4.82
28	0.89	73	14.55	0.96	67	1.75	1.65	52	10.00	0.40	15	3.77
29	1.07	66	9.24	0.74	59	2.45	1.90	41	10.25	0.77	12	4.55
30	1.52	49	14.92	0.34	27	3.70	2.59	24	2.41	0.91	1	4.77
Mean	1.11 \pm 0.37	62 \pm 10	10.75 \pm 4.26	0.65 \pm 0.23	37 \pm 20	2.40 \pm 1.01	2.21 \pm 0.77	31 \pm 15	5.93 \pm 3.17	0.52 \pm 0.25	7 \pm 8	4.45 \pm 0.66
\pm SD												

MLD, Minimal luminal diameter; PDS, percent diameter stenosis; STL, stenosis length; STS, stenosis symmetry index, where 1.0 indicates a concentric lesion and values closer to 0 increasing eccentricity¹⁶; ΔP , mean pressure gradient; SFR, stenotic flow reserve.

sec.¹⁸ By inferring increasing flow rates and combining these with the theoretically calculated pressure drop, an SFR value was calculated for each stenosis. This calculation is based on the assumption of a standardized aortic pressure of 100 mm Hg, a resting coronary flow velocity of 20 cm/sec, and an SFR of 5.0 if no stenosis is present.

Pressure measurement. The sensor, which has a diameter of 0.45 mm (0.17 mm²), and the optic fiber are integrated into an 0.018-inch guidewire (Pressure Guide) which can be used in angioplasty balloons with large enough inner lumen. The sensor element is located 3 cm proximal to the floppy tip. The principle of this fiberoptic device is that light is emitted from a control unit and transmitted through a beam-splitter along the fiber to the sensor (Fig. 1). Pressure-induced elastic movement of the sensor modulates the intensity of reflection, and the signal is then

transmitted back through the same optic fiber and detected by a photo diode in the control unit. The sensor has been validated in vitro with regard to signal transfer characteristics, linearity, compliance, and frequency response.^{19, 20}

The control unit is the interface between the optic sensor and the signal output and can be connected to the ordinary pressure recording systems in the catheterization laboratory. Acquisition of data was done with a personal computer equipped with special hardware. The analogue electrocardiogram (ECG) and pressure signals were continuously sampled with 1 KHz per channel and stored on the hard disk for the off-line investigation. The linear working range of the pressure sensor is -20 mm Hg to +300 mm Hg and within 0.0 Hz and 200 Hz and the upper frequency of the interface between the fiberoptical and electrical systems is >1 kHz.

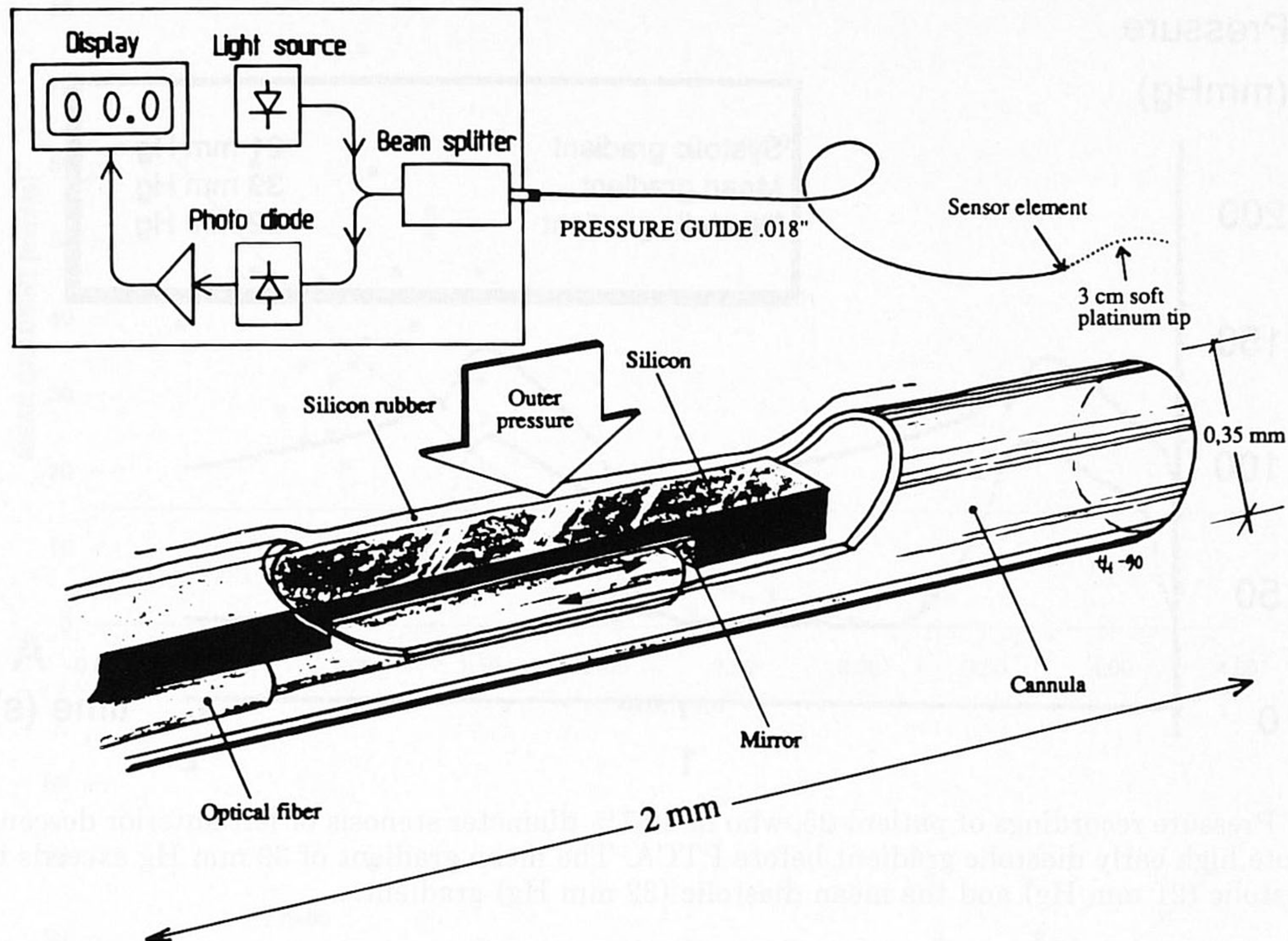


Fig. 1. Construction of fiberoptic sensor.

Procedure. Angiography was performed before and after PTCA following intracoronary administration of 125 μ g of nitroglycerin. A mean of 2.0 (range 1-3) projections was used. The same projections were used both before and after PTCA. For balloon angioplasty, a Pinkerton balloon catheter (Advanced Cardiovascular Systems Inc., Santa Clara, Calif.) was used. In proximal lesions in straight vessels the Pressure Guide fiberoptic sensor could be positioned directly without the support of the balloon catheter. However, this was done only in six patients; in the remainder, an 0.014-inch guidewire (High Torque Floppy, Advanced Cardiovascular Systems, Inc., Santa Clara, Calif.) was used to negotiate the stenosis. The balloon was then positioned at the site of the stenosis, after which the guidewire was withdrawn and replaced by the Pressure Guide fiberoptic sensor. With the balloon retracted into the guiding catheter, the pressure gradient was measured by pulling back the wire slowly until the sensor was proximal to the stenosis, but the tip still distal. Eight cardiac cycles were sampled for subsequent analysis of pressure values in each position. The wire was then repositioned distal to the lesion, and PTCA was performed according to clinical practice. After the dilatation procedure, new measurements were performed similarly to pretreatment. The study was approved by the ethical committee at the Göteborg University.

Statistical analysis. Least squares linear and non-linear regression analyses were used to define the best-fit relations between the pressure gradient and coronary angiographic variables. A p value of <0.05 was considered statistically significant.

RESULTS

In four patients only moderate stenoses (range 40% to 55%) and low-measured gradients (range 0 to 13 mm Hg) were found initially. As a result of convincing clinical findings, PTCA nonetheless was performed in all cases. In five patients the final measurements were done after implantation of a stent (four Palmaz-Schatz [Johnson & Johnson Interventional Systems Co., Warren, N.J.] and one Wiktor stent [Medtronic Inc., Minneapolis, Minn.]). A pressure gradient >15 mm Hg and a stenosis diameter of $>50\%$ was found in three patients after PTCA. In two of these cases this was due to coronary dissection; in the third case the stenosis recoiled immediately and no satisfactory result could be obtained.

Fig. 2 shows the pressure recordings of patient 25. Before PTCA the distal coronary pressure falls rapidly in the early diastolic phase compared with the proximal pressure, providing peak transstenotic gradient. The systolic gradient in this case is intermediately high and because of the short duration of the systolic phase, contributes little to the mean value.

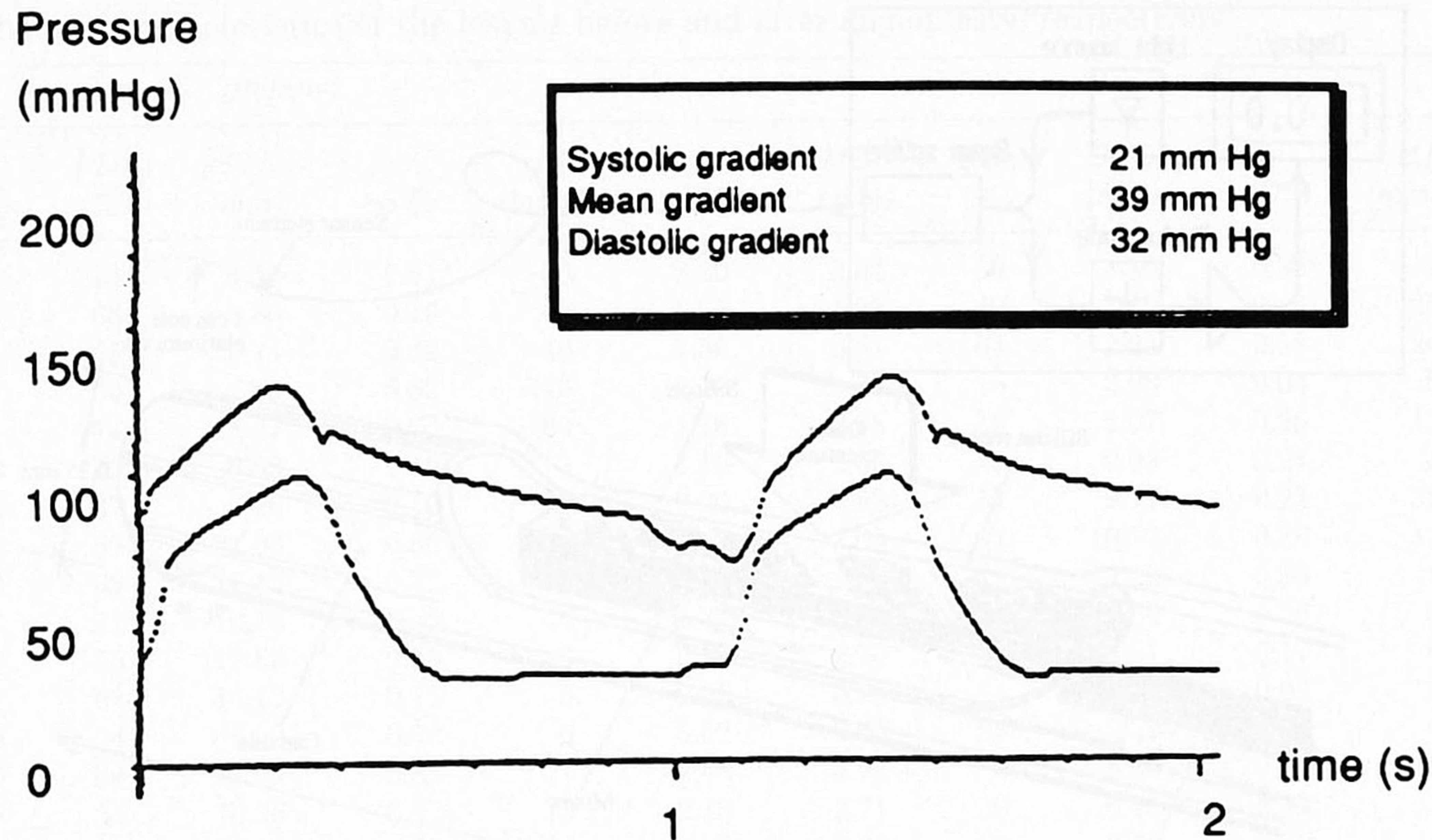


Fig. 2. Pressure recordings of patient 25, who had 87% diameter stenosis of left anterior descending artery. Note high early diastolic gradient before PTCA. The mean gradient of 39 mm Hg exceeds both the peak systolic (21 mm Hg) and the mean diastolic (32 mm Hg) gradient.

The mean gradient thus will be higher than the peak systolic and the end-diastolic gradients.

In Fig. 3, A, the relationship is shown between mean gradient (ΔP) and the minimal luminal diameter (MLD), including the best fit curve. Figure 3, B, illustrates the corresponding relationship with the percent diameter stenosis for all patients. The relationship between ΔP and minimal luminal cross-sectional area (MLCA) is shown in Fig. 4, A, and between ΔP and percent area stenosis (A%) in Figure 4, B. The regression lines follow the equations $\Delta P = 5.8 + 21.0/MLCA - 1.5/MLCA^2$ ($r = -0.63$; $p < 0.001$) and $\Delta P = 0.8 + 4.5[100/(100 - A\%)] - 7.9[100/(100 - A\%)^2]$ ($r = 0.69$; $p < 0.001$), respectively.

The relationship between ΔP and the predicted SFR values of all stenoses before and after PTCA is shown in Fig. 5 and can be described by the following equation: $\Delta P = 65.2 - 12.6 \cdot SFR$ ($r = -0.79$, $p < 0.001$). The sensitivity, specificity, and positive and negative predictive values for a measured gradient of >15 mm Hg to predict an MLD < 1.3 mm, MLCA < 2.0 mm², or SFR < 3.5 is shown in Table II.

DISCUSSION

General considerations. The conventional technique for measuring intracoronary pressure gradients via a liquid-filled balloon catheter is associated with dampening of the curves, and the pressure drop over the stenosis is falsely increased even across low-grade

coronary stenoses.^{6-8, 10, 21} Leiboff et al.¹⁰ have studied the importance of the variables that influence the transstenotic pressure gradient measured through a catheter positioned across the stenosis. They found that the ratio of the size of exploring catheter-to-stenosis diameter was the most important parameter. Native vessel diameter, stenosis length, and blood flow also influence the pressure drop over the stenosis, but to a lesser extent. These data have recently been corroborated by de Bruyne et al.⁸ by using a fluid-filled 0.015-inch guidewire.⁸ Only in small-sized coronary arteries with tight stenosis ($>85\%$ area reduction) can a clinically significant overestimation of the pressure gradient be expected. The Pressure Guide fiberoptic sensor used in the present study has a diameter of 0.45 mm (0.018 inch). Applying the results of Leiboff et al., the increase of the transstenotic gradient caused by the presence of the guidewire in the vessel lumen will be $>10\%$ only if MLD is <1.2 mm. A low-grade or moderate coronary stenosis most often has an MLD that exceeds 1.2 mm; this is also the case in most dilated segments after a successful PTCA. In addition, the Pressure Guide fiberoptic sensor has a high-frequency response resulting in high-fidelity pressure recordings.

Should we use systolic, mean or diastolic gradients? Ganz et al.^{22, 23} have measured gradients in coronary arteries through a 2F perfusion catheter and observed that the gradients often are largest in the early diastolic phase. Bateman et al.²⁴ recorded gradients

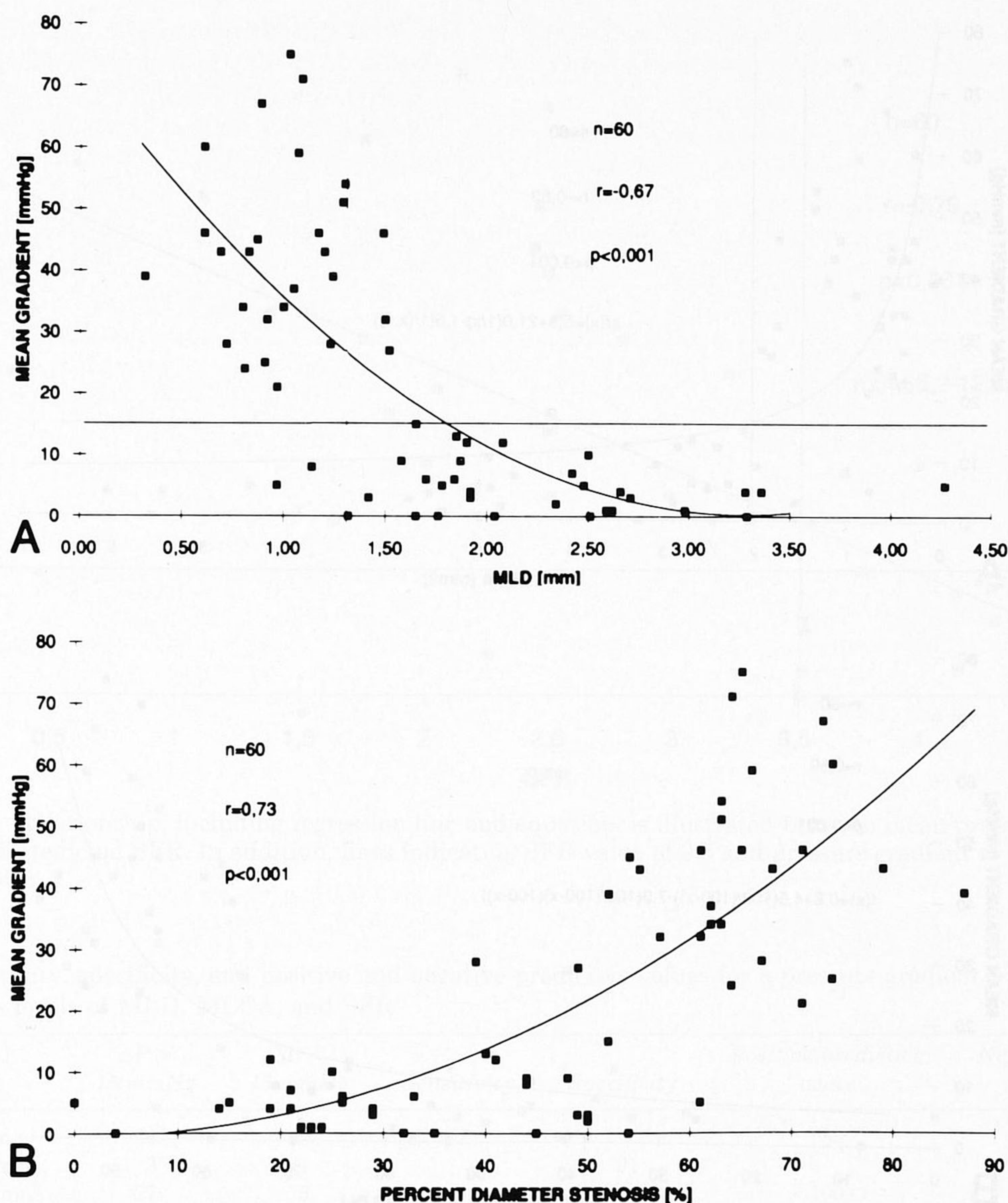


Fig. 3. Relationship between mean pressure gradient and minimal luminal diameter (MLD, **A**). **B**, Relationship between gradient and percent diameter stenosis. Best fit curves are shown. In **A**, lines indicating MLD of 1.3 mm and pressure gradient of 15 mm Hg have been interposed.

in vein grafts during a by-pass operation and thus did not have to cross the lesion with a catheter.²⁴ They likewise preferred to use the diastolic gradient as a measure of stenosis severity. In this study we have also found that the gradient during diastole usually contributes most to the mean gradient value. A common pattern is a steep fall in distal coronary pressure early in diastole, which sometimes leads to a mean gradient that is higher than the mean systolic and end-diastolic gradients. Consequently, neither mean systolic, mean diastolic, nor end-diastolic gradients adequately reflect the physiologic nature of the stenosis, especially because the systolic gradient

shows a large scatter and may be higher, equal to, or lower than the diastolic gradient in different patients. For these reasons we have considered the mean gradient during the entire cardiac cycle to be the most representative parameter for use in correlation with QCA variables in this study.

Relation of pressure gradient to angiographic severity. A curvilinear relation was found between pressure gradient and stenosis diameter and area, respectively. The relation was strongest between pressure gradient and MLCA. Thus a mean gradient >15 mm Hg was highly predictable of an obstructed area of <2 mm². On the other hand, if the gradient were <15 mm

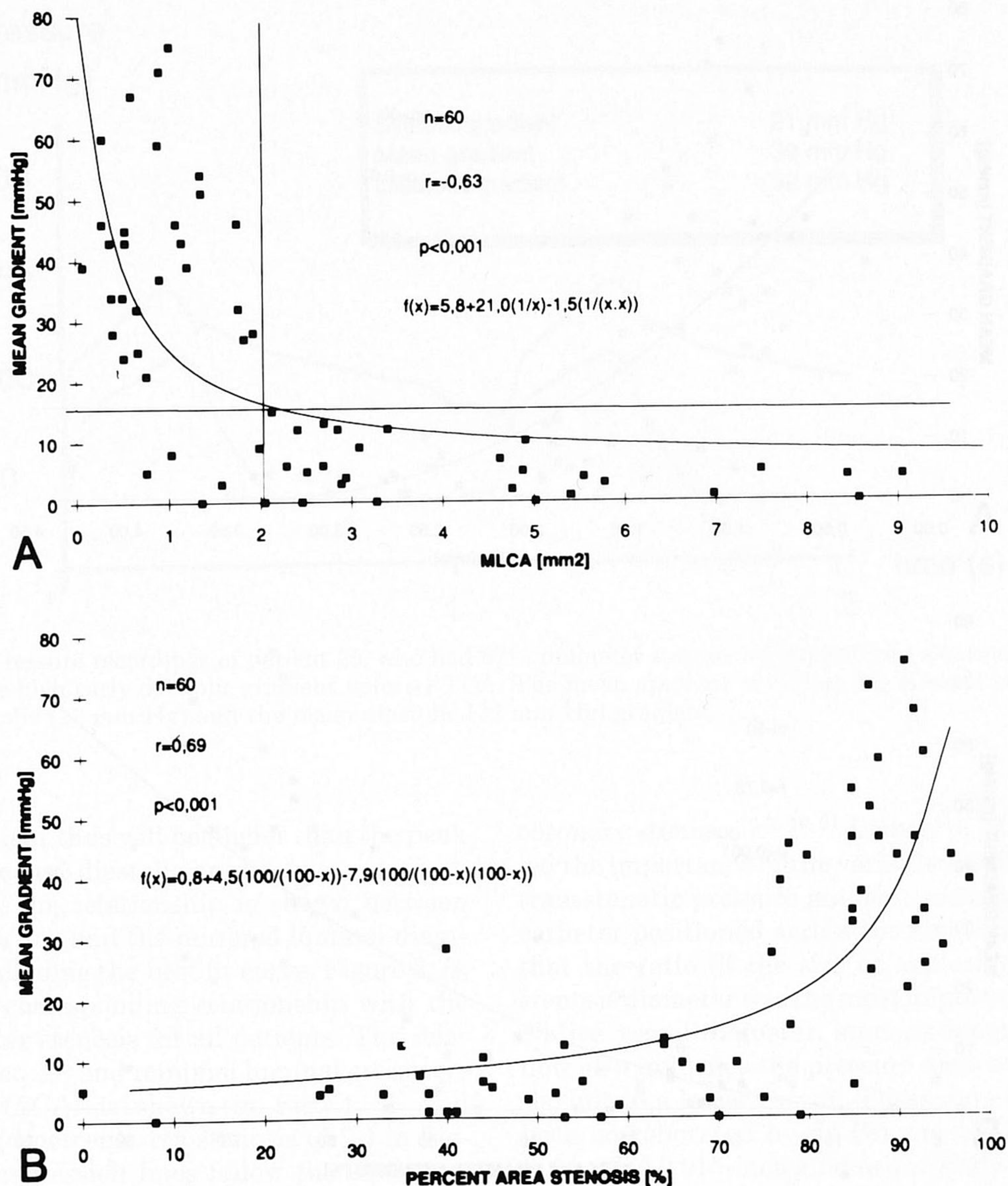


Fig. 4. Relationship between mean gradient and minimal luminal cross-sectional area (MLCA; **A**) and between gradient and percent area stenosis (**B**). Regression lines and corresponding equations are indicated. In **A**, lines indicating MLCA value of 2.0 mm² and pressure gradient of 15 mm Hg have been added.

Hg the area range was broad (0.76 to 8.5 mm²). A reasonable interpretation of these findings might be that a gradient of >15 mm Hg is virtually always associated with a stenosis of significant physiologic importance. The correlations found between pressure gradient and MLCA in our study were very similar to those obtained in another study in PTCA patients in whom a 0.015-inch fluid-filled guidewire was used.⁸

Relation of pressure gradients to predicted physiologic parameters. SFR may be derived by combining the theoretically calculated pressure drop across a stenosis with various flow levels under standardized

physiologic conditions. Kirkeeide et al.¹¹ found in an experimental study in dogs that angiographically predicted SFR correlated better with true flow measurements of coronary flow reserve than did relative or absolute obstructive area. Vogel et al.²⁵ and Wilson et al.^{26, 27} found a good correlation between pressure gradients recorded at rest and coronary flow reserve measured by angiographic densitometric technique and Doppler technique, respectively. In studies in man, Zijlstra et al.^{28, 30} demonstrated a better correlation between the calculated transstenotic gradient and measured coronary flow reserve than with

how much. Ideally, the Pressure Guide fiberoptic sensor should be placed as the primary wire to avoid this problem. However, refinements of steerability and floppiness are required before this may become possible in all cases. Another limitation of this study might be that pressure gradients were only measured in the resting position and not during maximal vasodilatation. Because the predicted pressure gradients and SFR are calculated assuming hyperemic conditions, it is conceivable that the correlation with SFR might be different (and theoretically better) after papaverine or adenosine administration.

Rationale for the clinical use of pressure measurement. It may be argued that because the angiographically predicted physiologic parameters and the measured pressure gradients seem to yield similar information about the importance of the stenosis, the need for gradient measurement would be relatively limited. However, it is important to note that although not only discrete, short, type A lesions were included in this study, lesions were avoided where QCA evaluation would be dubious, such as tandem lesions and ostial lesions. In two patients a post-PTCA dissection occurred, a situation where the angiographic evaluation is often difficult. In these and similar situations the measured pressure gradient probably would be superior to the angiographic analysis. Furthermore, measured gradients provide actual physiologic information in contrast to the theoretic gradient or the SFR, which are parameters calculated under standardized physiologic conditions.

It can be deduced from basic fluid dynamic principles that relative coronary flow reserve and myocardial flow reserve, respectively, may be calculated by measurement of the transstenotic pressure gradient, coronary artery wedge pressure, and central venous pressure.³⁰ In a similar way the contribution of collateral flow to total coronary flow can be assessed. This model has successfully been validated in dog experiments, but experience in human beings is still limited. The animal data are intriguing because they offer information of relative flow through the different parts of the coronary circulation from pressure measurements only. They also demonstrate that only transstenotic gradient recording is an incomplete approach to describing stenosis severity because it does not take into account the collateral flow. Finally, with improved technologic ability of measurement of coronary flow velocity, it is soon possible to achieve recordings of instantaneous pressure-flow and pressure gradient-flow relationships. In animal models these parameters have proved to be hemodynamically independent indexes of the physiologic significance of coronary stenoses.³⁰

Conclusions. This study demonstrates a significant correlation between the transstenotic pressure gradient and morphologic measures of a stenosis acquired with QCA, at least in lesions with relatively uncomplicated geometry. The closest relationship was found with SFR, which is a parameter derived from QCA, taking several stenosis characteristics into account. The independent information provided by pressure gradient measurement may be of particular value in intermediately severe lesions or in stenoses where the angiographic assessment otherwise is difficult. Future studies will clarify whether the pressure gradient should be combined with some other parameter, such as coronary artery wedge pressure, coronary flow, or flow velocity to obtain an optimal determinant of the physiologic significance of a coronary stenosis.

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