Circulation

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Abstract

Background The long-term angiographic outcome after successful dilatation of coronary occlusions remains unclear. The objective of this study was to examine long-term restenosis after successful balloon dilatation of coronary occlusions at a predetermined time interval with quantitative angiography and compare this with a control population of stenoses.

Methods and Results The study population comprised 2950 patients (3583 lesions) prospectively enrolled in and successfully completing four major restenosis trials (86% quantitative angiographic follow-up). Cineangiographic films were processed and analyzed at a central core laboratory with the use of an automated interpolated edge detection technique. The study population comprised 266 occlusions (7%) defined as total when there was absent anterograde filling beyond the lesion (109 lesions) and functional (157 lesions) when faint, late anterograde opacification of the distal segment was seen in the absence of a discernible luminal continuity; 3317 lesions were defined as stenoses (93%). Restenosis was significantly higher after successful dilatation of occlusions than of stenoses. With the categorical (>50% diameter stenosis at follow-up) approach, the restenosis rate was 44.7% in occlusions compared with 34.0% in stenoses (P<.001; relative risk, 1.575; CI, 1.224 to 2.027). Similarly, the absolute loss (defined as the change in minimal lumen diameter between post coronary angioplasty and follow-up; in millimeters, mean±SD) (0.43±0.68) in occlusions was significantly higher than in stenoses (0.31±0.51, P<.001), as was the relative loss, defined as the change in minimal lumen diameter between postangioplasty and follow-up, adjusted for the vessel size (0.17±0.28 versus 0.12±0.20, P<.001). The higher restenosis rate in the occlusions group was due predominantly to an increased number of occlusions at follow-up angiography in this group (19.2% compared with 5.0% for stenoses, P<.001). Within the occlusions group, there were no significant differences in long-term outcome between total and functional occlusions (restenosis rate, 45.0% versus 44.6%; reocclusion rate, 23.9% versus 15.9%; absolute loss, 0.53±0.69 versus 0.36±0.67; relative loss, 0.21±0.28 versus 0.15±0.28; P=NS).

Conclusions These results indicate that successfully dilated coronary occlusions, both total and functional, have a higher rate of angiographic restenosis at 6 months than stenoses. This is due chiefly to a higher rate of occlusion at follow-up angiography in this group of lesions. Measures aimed at reducing restenosis after successful dilatation of coronary occlusion should be focused in this direction.

After the introduction of coronary angioplasty by Grüntzig et al in 1979,[1] the indication for its use were at first tentatively and subsequently more strikingly expanded to include patients with total occlusions.[23456] Although a number of factors are known to influence the acute success rate,[4789] relatively little is known regarding long-term luminal renarrowing after successful dilatation of total occlusions. A number of studies have investigated this, but uncertainty continues with restenosis rates in the literature varying from 20% to 65%.[23561011121314151617] This variation has three primary sources. First, most studies have been retrospective analyses that use small patient numbers and no control group.[2311121516] Second, the angiographic follow-up rates have been low and performed for the recurrence of symptoms rather than at a predetermined time interval, thus introducing important selection bias.[5617] Finally, some have used visual assessment to estimate angiographic severity, which is subject to wide interobserver and intraobserver variability.[18] This study attempted to overcome these limitations by using a validated automated edge detection technique to evaluate restenosis prospectively in a large series of patients undergoing successful balloon angioplasty and routine follow-up angiographic assessment at a predetermined time interval. Furthermore, a control cohort of patients with stenoses was used to directly compare the long-term results.

Methods

Patients

The study population comprised 3582 patients with significant primary stenoses in native coronary arteries who were prospectively enrolled in four major restenosis trials[19202122] and who underwent successful coronary angioplasty (postprocedural stenosis <50%). These trials demonstrated that active therapy had no effect on restenosis or clinical outcome in the first 6 months after balloon angioplasty, so for the purposes of this study, the data for the active and placebo groups were pooled. Men or women were eligible for study entry if they were symptomatic or asymptomatic with stable or unstable angina pectoris and proven angiographically significant narrowing in one or more major coronary arteries. Informed consent was obtained in all cases before the coronary angioplasty procedure. Patients with evolving myocardial infarction and significant left main disease were excluded from the study.

Angioplasty Procedure and Follow-up Angiography

Coronary angioplasty was performed with a steerable, moveable guide wire system by the femoral route. Standard balloon catheters were used. The choice of balloon type and brand, inflation duration, and inflation pressure was left to the discretion of the operator. Patients were followed up for 6 months; then a follow-up study was performed. If symptoms recurred within 6 months, coronary angiography was performed earlier. If no definite restenosis was present and the follow-up time was less than 4 months, the patient was asked to undergo further coronary arteriography at 6 months.

Quantitative Angiography

In total, three coronary angiograms were obtained for each patient—before and after percutaneous transluminal coronary angioplasty (PTCA) and at angiographic follow-up. To standardize the method of data acquisition and to ensure exact

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faint, late anterograde opacification of the distal segment was present in the absence of a discernible luminal continuity.[1725]

Occlusion at Follow-up Angiography

Occlusion at follow-up angiography was defined as the presence of an absolute or functional occlusion at the previously dilated angioplasty site on angiographic follow-up.

Angiographic Parameters Assessed

Vessel size refers to the reference diameter of the relevant coronary segment and is represented by the interpolated reference diameter pre-PTCA because this is the closest and most objective approximation of the disease-free vessel wall.

Minimum luminal diameter (MLD) is the point of maximal luminal narrowing in the analyzed segment.

Many criteria have been proposed for the assessment of restenosis.[262728] For the purposes of this study, two approaches were used: the categorical approach with the traditional cutoff point of >50% diameter stenosis at follow-up and a continuous approach that used absolute and relative loss, which reflect the behavior of the lesion during and after angioplasty and may be more representative of the pathological process involved during follow-up.[2829]

Absolute gain and absolute loss represent the improvement in MLD achieved at intervention and the absolute change during follow-up respectively, measured in millimeters. Absolute gain is post-PTCA MLD minus pre-PTCA MLD. Absolute loss is post-PTCA MLD minus MLD at follow-up.

Relative gain and relative loss depict the improvement in MLD achieved at intervention and the change during follow-up respectively, normalized for vessel size. Relative gain is (post-PTCA MLD minus pre-PTCA MLD) divided by vessel size. Relative loss is (post-PTCA MLD minus MLD at follow-up) divided by vessel size.

The absolute net gain is the MLD at follow-up minus pre-PTCA MLD. The net gain index is the net gain normalized for the vessel size. The net gain index is (MLD at follow-up minus pre-PTCA MLD) divided by vessel size.

The loss index is the relation of late loss to acute gain: loss index is (MLD at follow-up minus post-PTCA MLD) divided by (post-PTCA MLD minus pre-PTCA MLD).

Statistical Analysis

Data were analyzed with the SAS statistical software package. Categorical variables are presented as absolute numbers (%). Continuous variables are expressed as mean value±SD. Differences between groups were evaluated with adjusted χ^2 tests for categorical variables and Student's *t* tests for continuous variables. The contributions of clinical, angiographic, and procedural variables to the categorical outcome parameters were evaluated with logistic regression analysis. For the continuous outcome parameter (absolute loss), multiple linear regression analysis was used. Categorical variables were dichotomized and entered into the analysis as indicator variables with values of 0 and 1. Selection of variables was achieved in a stepwise fashion. The adjusted R^2 was used as the criterion for model selection. Probability values <.05 were considered significant.

Results

Patient Characteristics and Clinical Follow-up

The study population comprised 2950 patients (3583 lesions, 1.21 lesions per patient) who successfully completed the study and had follow-up quantitative angiography. The overall angiographic restudy rate was 86% of all patients undergoing successful PTCA. We found that 266 lesions in 249 patients out of 3583 lesions in 2950 patients complied with the angiographic definition of total occlusion. Of these, 109 were absolute and 157 were functional total occlusions.

Tables 1 and 2 summarize the clinical and angiographic characteristics of the 249 patients with occlusions compared with the 2701 with stenoses. Patients with total occlusions were younger and had a significantly higher rate of previous myocardial infarction than patients with stenoses. Furthermore, the duration of angina in this group was significantly shorter than in stenoses. Additionally, the presence of thrombus either before or after PTCA was significantly higher in occlusions. Of the procedural characteristics, the nominal size of the largest balloon was significantly higher in stenoses, while the total number of balloon inflations required, total duration, and maximum inflation pressure were higher in occlusions. Within the occlusions group, there were no significant differences between lesions with total and functional occlusions.

Table 1. Baseline Clinical Characteristics of Patients With Occlusions and Stenoses Before Coronary Angioplasty

	Lesion Type	
	Occlusion	Stenoses
Patients, n	249	2701
Men, %	85.1	81.4
Age, y	54.4±9.6	57.4±9.3[1]

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Previous myocardial infarction, %	54.2	>41.1[1]
Previous CABG, %	1.6	4.5
Previous PTCA, %	3.6	5.0
Diabetes mellitus, %	10.8	10.2
History of hypertension, %	30.1	30.5
History of hypercholesterolemia, %	33.3	31.5
History of peripheral vascular disease, %	3.6	5.1
CCS anginal class, %		
None	6.0	5.6
I	10.0	11.2
II	33.7	32.4
III	28.9	30.2
IV	21.3	20.6
Duration of angina, wk	69±126	114±207[1]
Medication at screening, %		
Nitrates	57.6	66.2
Calcium antagonists	69.1	69.5
β-blockers	57.4	49.8
Anticoagulants	1.6	1.5
Aspirin	80.2	82.0
Laboratory investigations		
Total cholesterol	5.58±1.30	5.85±1.23
Hemoglobin	8.89±0.80	8.86±0.83
Hematocrit	0.42 ±0.04	0.42±0.04
Platelet count	259±58	257 ±71

CABG indicates coronary artery bypass grafts; PTCA, percutaneous transluminal coronary angioplasty; and CCS, Canadian Cardiovascular Society.

[1]*P*<.05.

Table 2. Baseline Angiographic and Procedural Data of Patients With Occlusions and Stenoses Before Coronary Angioplasty

	Lesion Type	
	Occlusions	**Stenoses**
Lesions, n	266	3317

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2-VD	34.5	27.5
3-VD	3.6	7.8
Lesion location, %		
LAD	39.4	44.2
LCx	26.9	24.0
RCA	33.7	31.7
Type of lesion, %		
Multiple irregularities	6.9	8.0
Side branch in lesion	21.1	20.2
Lesion calcification	12.0	12.4
PTCA procedure		
Nominal size of largest balloon, mm	2.74±0.43	2.89±0.43[1]
Balloon to artery ratio	1.14±0.18	1.13±0.19
Total number of inflations	4.6±3.2	3.47±2.2[1]
Total duration of inflation, s	404±341	303±261[1]
Maximum inflation pressure, atm	8.80±2.59	8.45±2.50[1]
Post-PTCA result, %		
Dissection at the dilated site	39.8	34.5
Thrombus visible (before or after PTCA)	12.9	>4.2[1]

SVD indicates single-vessel disease; 2-VD, two-vessel disease; 3-VD, three-vessel disease; LAD, left anterior descending; LCx, left circumflex artery; RCA, right coronary artery; and PTCA, percutaneous transluminal coronary angioplasty.

[1]*P*<.05.

Seventy-one (28.5%) of the patients with successfully dilated total occlusions and 598 (22.1%) of the patients with stenoses had clinical end points (additional PTCA, coronary artery bypass graft [CABG] surgery, acute myocardial infarction, or death) during follow-up. The difference was statistically significant (*P*=.026). The individual components of death, myocardial infarction, CABG, and re-PTCA were 0%, 3.6%, 3.6%, and 21.3%, respectively, for occlusions and 0.2%, 2.8%, 2.4%, and 16.7%, respectively, for stenoses. The differences in the individual clinical end points between the two groups were also statistically significant (*P*=.022). Fig 1 summarizes the time course of clinical end points. Although the mean time to clinical follow-up was similar in the two groups, when we compared the pattern of occurrence of clinical end points by way of the log-rank test, clinical end points in the occlusions group were found to occur earlier than in stenoses (*P*=.022).

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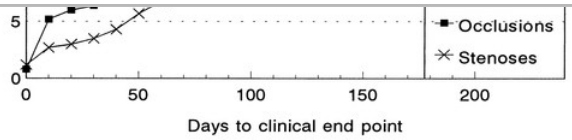

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Figure 1. Graph showing cumulative distribution curves of clinical end points over time for total occlusions and stenoses. Numbers given are mean±SD (days). *P<.05.

Interestingly, when lesions that went on to occlude at follow-up angiography were excluded from the analysis, 50 patients (25.1%) with occlusions and 541 patients (21.1%) with stenoses reached a clinical end point, and the difference was no longer statistically significant (P=.217). The individual clinical end points and the time to a clinical end point were also no longer significantly different (P=.238 and .214, respectively).

Quantitative Angiographic Analysis

A mean of 2.12 matched angiographic projections per lesion had satisfactory quantitative analysis performed at the central Angiographic Core Laboratory before and after PTCA and at follow-up (Table 3). The reference diameter was significantly lower in occlusions than in stenoses, and this difference remained at follow-up. As expected, the MLD increased substantially more after dilatation of occlusions than of stenoses, which was reflected in the substantially greater relative gain. Nevertheless, the post-PTCA MLD was significantly lower in occlusions, perhaps reflecting the smaller vessel diameter in this group (Fig 2a). When this was taken into account, the percent stenosis after PTCA was similar in both groups (Fig 2b). At follow-up, previously occluded lesions deteriorated significantly more in terms of both absolute and relative loss (Fig 3, Table 3), resulting in a smaller follow-up MLD and higher percent stenosis (Fig 2a and 2b, Table 3). Thus, in addition to restenosis being higher when the continuous, absolute, and relative loss approach was used, the restenosis rate when the categorical approach was used was also significantly higher (44.74% in occlusions compared with 33.95% in stenoses; P<.001; relative risk, 1.575; CI, 1.224 to 2.027).

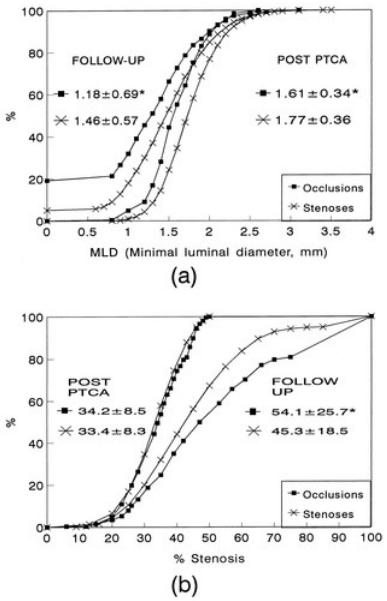

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Figure 2. Graphs showing (a) cumulative distribution curves of mean luminal diameter (MLD) after percutaneous transluminal coronary angioplasty (PTCA) and at follow-up for total occlusions and stenoses and (b) cumulative distribution curves of percentage stenosis after PTCA and at follow-up for total occlusions and stenoses. Numbers given are mean±SD. *P<.001.

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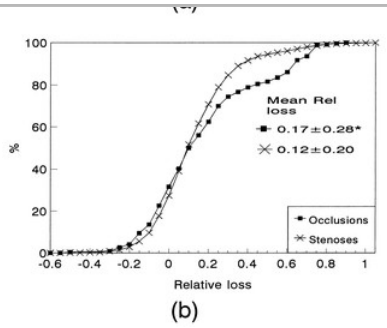

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Figure 3. Graphs showing (a) cumulative distribution curves of absolute loss (Abs) (change in mean luminal diameter [MLD] from before percutaneous angioplasty to follow-up) for total occlusions and stenoses and (b) cumulative distribution curves of relative (rel) loss (change in MLD from before percutaneous angioplasty to follow-up corrected for vessel size) for total occlusions and stenoses. Numbers given are mean±SD. *P<.001.

Table 3. Quantitative Analyses of 266 Lesions in 249 Patients With Occlusions and 3317 Stenoses in 2701 Patients Included in the Analysis

	Lesion Type		Significance Level
	Occlusions, n=266	Stenoses, n=3317	
Reference diameter, mm			
Before angioplasty	. . .	2.61 ±0.54	. . .
After angioplasty	2.46±0.49	2.67 ±0.51	<0.001
At follow-up	2.60±0.55	2.69 ±0.56	0.026
MLD, mm			
Before angioplasty	0	1.08±0.29	. . .
After angioplasty	1.61±0.34	1.77±0.36	<0.001
At follow-up	1.18±0.69	1.46±0.57	<0.001
Differences in MLD, mm			
Absolute gain	1.61±0.34	0.69 ±0.34	<0.001
Relative gain	0.66±0.09	0.27 ±0.13	<0.001
Absolute loss	0.43±0.68	0.31 ±0.51	<0.001
Relative loss	0.17±0.28	0.12 ±0.20	<0.001
Absolute net gain	1.18±0.69	0.38 ±0.53	<0.001
Net gain index	0.48±0.28	0.14 ±0.21	<0.001
Loss index	0.26±0.43	0.53 ±3.88	0.255
Percentage stenosis			
Before angioplasty	100	57.83±9.86	. . .

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MLD indicates minimal luminal diameter; DS, diameter stenosis.

Although angiographic restenosis was higher in occlusions than stenoses, there were no significant differences in the presentation of restenosis between the two groups. Of recanalized total occlusions with angiographic restenosis, 40% were symptom-free, while 18.5% complained of angina and 41.5% had a clinical end point. This compares with 39.9%, 18.7%, and 41.4%, respectively, for stenoses with angiographic restenosis.

The higher restenosis rate in the occlusions was due predominantly to an increased number of occlusions at follow-up angiography in this group (19.2% versus 5.0% for stenoses, *P*<.001). Thus, recanalized occlusions accounted for 23.5% of all occlusions at follow-up angiography even though they formed only 7% of the total study population. The relative risk for occlusion at follow-up angiography was 4.503 (95% CI, 3.196 to 6.344).

Subgroup Analysis of Occlusions Group

Subgroup analysis of the occlusions group revealed 109 absolute and 157 functional occlusions (Table 4). The reference diameter after angioplasty was significantly higher in absolute than in functional occlusions, but this difference did not persist to follow-up angiography. There were no significant differences in the MLD or percent stenosis after PTCA or at follow-up (Table 4) between the two groups. The categorical restenosis rate (>50% diameter stenosis at follow-up) was almost identical (44.95% versus 44.59%) in the two groups. Although the reocclusion rate in absolute occlusions tended to be higher than in functional occlusions (23.9% versus 15.9%), this did not reach statistical significance (*P*=.06). By use of the continuous measurements of restenosis, the absolute and relative loss tended to be lower in functional occlusions (Table 4), resulting in a significantly higher net gain index and a significantly lower loss index.

Table 4. Quantitative Angiographic Analysis of 109 Total and 157 Functional Occlusions Included in the Analysis

	Lesion Type		Significance Level
	TIMI 0, n=109	TIMI 1, n=157	
Reference diameter, mm			
Before angioplasty	. . .	. . .	. . .
After angioplasty	2.55±0.52	2.40 ±0.56	0.015
At follow-up	2.66±0.55	2.56 ±0.54	0.200
MLD, mm			
Before angioplasty	. . .	. . .	. . .
After angioplasty	1.65±0.35	1.58±0.34	0.096
At follow-up	1.12±0.74	1.21±0.65	0.285
Differences in MLD, mm			
Absolute gain	1.65±0.35	1.58±0.34	0.096
Relative gain	0.65±0.09	0.66±0.08	0.440
Absolute loss	0.53±0.69	0.36±0.67	0.051
Relative loss	0.21±0.28	0.15±0.28	0.063
Absolute net gain	1.12±0.74	1.21±0.65	0.285
Net gain index	0.44±0.29	0.51±0.28	0.037
Loss index	0.32±0.44	0.22±0.42	0.042
Percentage stenosis			
Before angioplasty	. . .	. . .	0.285
After angioplasty	34.61±8.69	33.86±8.32	0.481

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Univariate and Multivariate Analyses of Restenosis in Total Occlusions

Univariate analysis of the available clinical-, procedural-, and lesion-related characteristics was performed to assess whether any of these variables were associated with an increased categorical restenosis rate (Table 5). The only significant associations were with a shorter duration of angina, a longer balloon total inflation time, higher residual stenosis after PTCA, and a lower relative gain. Stepwise logistic regression analysis was used to further evaluate the relation between this dichotomous definition of restenosis and the above variables, as well as all other clinical, lesion, and procedural characteristics. The number of diseased vessels and the percent stenosis after PTCA were positively related; duration of angina (in days) was negatively related to the probability of restenosis at follow-up (Table 6).

Table 5. Univariate Analysis of Patient-, Lesion-, and Procedure-Related Characteristics Relevant to Long-term Restenosis[1] in 266 Occlusions

	Restenosis at Follow-up, n=119	No Restenosis at Follow-up, n=147	Significance Level
CCS anginal class, %			0.790
None	6.7	4.8	
I	8.4	11.6	
II	31.1	34.7	
III	31.1	29.3	
IV	22.7	19.7	
Duration of angina, wk	40±76	85 ±146	0.018[2]
Medication at screening, n			
Anticoagulants	1.7	1.4	1.000
Thrombocyte aggregation inhibitor	70.6	70.8	1.000
Aspirin	79.8	81.6	0.896
Persantin	14.3	9.2	0.400
Laboratory investigations			
Hemoglobin	8.83±0.77	8.95 ±0.80	0.235
Hematocrit	0.42 ±0.04	0.42±0.04	0.398
Platelet count	261±63	257±56	0.564
Lesion location, %			0.554
LAD	37.0	43.5	
LCx	27.7	24.5	
RCA	35.3	32.0	
Lesion characteristics, %			
Concentric	19.3	15.6	0.645
Multiple irregularities	5.7	8.0	0.661
Branch point in stenosis	30.2	20.8	0.430
Coronary artery bend	9.4	7.2	0.707

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Medium (partial perfusion)	25.6	21.9	
Major (complete perfusion)	12.8	16.8	
Not assessed	2.3	4.2	
PTCA procedure			
Nominal size of largest balloon, mm	2.74 ±0.43	2.75±0.43	0.846
Balloon to artery ratio	1.13±0.18	1.15±0.19	0.293
Total number of inflations	4.6±3.4	4.6±3.0	0.925
Total duration of inflation, s	452±390	365±293	0.043
Maximum inflation pressure, atm	8.92±2.63	8.69±2.44	0.464
Post-PTCA result, %			
Dissection at the dilated site	42.0	38.1	0.601
Thrombus visible (before or after PTCA)	15.1	9.5	0.227
Quantitative angiographic measurements			
Reference diameter after PTCA	2.48±0.48	2.44±0.50	0.590
Minimal luminal diameter after PTCA	1.59±0.35	1.62±0.34	0.474
Stenosis after PTCA, %	35.50±7.99	33.08 ±8.70	0.019[2]
Absolute gain	1.59±0.35	1.62 ±0.34	0.474
Relative gain	0.64±0.08	0.67 ±0.09	0.024
Lesion length after PTCA, mm	6.29 ±2.35	6.44±2.71	0.631
Time to follow-up, d	147 ±55	167±41	<0.001

CCS indicates Canadian Cardiovascular Society angina classification; LAD, left anterior descending; LCx, left circumflex; RCA, right coronary artery; and PTCA, percutaneous transluminal coronary angioplasty. Values are mean±SD.

[1]>50% diameter stenosis at follow-up angiography.

[2]Retained in multivariate model.

Table 6. Regression Analyses to Evaluate the Respective Contributions of Clinical, Angiographic, and Procedural Variables on the Categorical Restenosis Rate,[1] Absolute Loss, and Reocclusion During Follow-up

Variable	Regression Coefficient	Standard Error of Regression Coefficient	*P*
Categorical restenosis rate			
Duration of angina, d	−0.0007	0.0003	.032
Diseased vessels, n	0.649	0.307	.034
Stenosis after PTCA, %	0.043	0.023	.049
Absolute loss			
Total inflation time, s	0.0005	0.0001	.0004

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PTCA indicates percutaneous transluminal coronary angioplasty. Logistic regression analysis was used for the categorical restenosis rate and reocclusion at follow-up. Multiple linear regression analysis was used for absolute loss.

[1]>50% diameter stenosis at follow-up.

Univariate analysis of clinical, procedural, and lesion characteristics related to absolute loss showed the only significant associations to be with total inflation time (*P*=.0004), presence of thrombus (*P*=.0039), post-PTCA MLD (*P*=.0144), duration of angina (*P*=.0262), left anterior descending coronary artery location (*P*=.0418), and lesion calcification (*P*=.0443). Multiple linear regression analysis was used to further evaluate absolute loss. Of the variables assessed, total inflation time (in seconds) and the presence of thrombus were both positively related to absolute loss (Table 6).

Univariate and Multivariate Analysis of Occlusions at Follow-up Angiography

The finding that the higher restenosis rate after dilatation of occlusions was due predominantly to an increased number of reocclusions at follow-up angiography in this group prompted us to examine a number of variables predictive of reocclusion (Table 7). The clinical characteristics of the two groups were similar, although lesions that went on to reocclude had a shorter duration of angina (27±52 versus 74±132 weeks). Procedural characteristics were also similar, although lesions that went on to reocclude required a longer balloon inflation (537±478 versus 373±294 seconds). Logistic regression analysis was performed for the above and for all other clinical, angiographic, and procedural parameters thought to be associated with the occlusion at follow-up. Of these variables, the total inflation time (in seconds) was positively related and the post-PTCA reference diameter (in millimeters) was negatively related to reocclusion at follow-up angiography (Table 6).

Table 7. Univariate Analysis of Patient, Lesion, and Procedural Characteristics Relevant to Reocclusion During Follow-up in 266 Occlusions

	Reocclusion at Follow-up, n=51	No Occlusion at Follow-up, n=215	Significance Level, Univariate Analysis
CCS anginal class, %			0.125
None	9.8	4.7	
I	3.9	11.6	
II	25.5	34.9	
III	39.2	27.9	
IV	21.6	20.9	
Duration of angina, wk	27 ±52	74±132	0.044
Medication at screening, %			
Anticoagulants	0	1.8	0.733
Thrombocyte aggregation inhibitor	64.7	72.1	0.384
Aspirin	73.5	82.4	0.344
Persantin	11.8	11.5	1.000
Laboratory investigations			
Hemoglobin	8.82±0.81	8.91 ±0.78	0.505
Hematocrit	0.42 ±0.03	0.42±0.04	0.960
Platelet count	256±55	259±60	0.706
Lesion location, %			0.400
LAD	37.3	41.4	
LCx	23.5	26.5	

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Branch point in stenosis	13.3	22.8	0.365
Coronary artery bend	9.3	8.0	1.000
Calcified lesion	15.7	11.2	0.514
Degree of collateral supply, %			0.779
No collaterals	44.7	50.3	
Slight (minimal perfusion)	7.9	9.0	
Medium (partial perfusion)	31.6	21.6	
Major (complete perfusion)	13.2	15.6	
Not assessed	2.6	3.6	
PTCA procedure			
Nominal size of largest balloon, mm	2.67±0.47	2.76±0.42	0.214
Balloon to artery ratio	1.15±0.18	1.14±0.18	0.665
Total number of inflations	4.5±3.1	4.6±3.2	0.777
Total duration of inflation, s	537±478	373 ±294	0.003[1]
Maximum inflation pressure, atm	9.10 ±2.80	8.72±2.46	0.370
Post-PTCA result, %			
Dissection at the dilated site	43.1	39.1	0.708
Thrombus visible (before or after PTCA)	19.6	10.2	0.107
Quantitative angiographic measurements			
Reference diameter after PTCA	2.36±0.47	2.48±0.49	0.105[1]
Minimal luminal diameter after PTCA	1.54±0.36	1.62±0.34	0.123
Stenosis after PTCA, %	34.52±8.33	34.08±8.51	0.735
Absolute gain	1.54±0.36	1.62±0.34	0.123
Relative gain	0.66±0.08	0.66±0.09	0.693
Lesion length after PTCA, mm	6.17±2.47	6.42±2.58	0.519

CCS indicates Canadian Cardiovascular Society; LAD, left anterior descending; LCx, left circumflex; RCA, right coronary artery; and PTCA, percutaneous transluminal coronary artery. Values are mean±SD.

[1]Retained in multivariate analysis.

Discussion

Our study specifically addressed the problem of long-term luminal renarrowing after dilatation of total coronary occlusions in a large patient population with a control group, a high angiographic follow-up rate, and quantitative angiography at a predetermined time interval. We demonstrated using both a categorical and a continuous approach that restenosis is significantly greater after balloon dilatation of occlusions than of stenoses. Furthermore, we also showed that this is mainly

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factor is thought to be the presence of collateral vessels, which may exert competitive pressure even after they are no longer visibly functional[30] and thus lead to an increased restenosis rate.

Univariate analysis in our study confirmed significant associations between the categorical definition of restenosis (>50% diameter stenosis at follow-up) and a shorter duration of angina, a longer balloon total inflation time, higher residual stenosis after PTCA, and a greater relative gain. Multivariate analysis, however, suggested that the only significant positive relations were with the number of diseased vessels and the percent stenosis after PTCA, while duration of angina was negatively related to the probability of restenosis at follow-up. The positive relation between the number of diseased vessels and the percent stenosis after PTCA with a categorical definition of restenosis is in keeping with previous studies in both occlusions[6] and stenoses.[31] The negative relation with duration of angina is also in keeping with previous studies suggesting a positive relation between recent onset of symptoms and a higher risk of restenosis.[323334]

Interestingly, when we looked at the absolute loss as a marker of restenosis, an outcome measure that may better indicate the underlying pathological process involved, the above variables were no longer significant. The only significant relations were found to be with total inflation time and the presence of thrombus. Both of these were positively related to the subsequent absolute loss. The duration of balloon inflation as a positive risk factor may represent the sum total of the lesion characteristics and a more difficult, more complex procedure with a consequently higher risk of occlusion, thereby markedly influencing the absolute loss. In keeping with this is the fact that we also demonstrated total inflation time to be positively related to the subsequent risk of occlusion at follow-up angiography. The positive relation between the presence of thrombus and the subsequent absolute loss may also reflect a greater likelihood of subsequent occlusion, although we were unable to demonstrate this in our study. Previous studies, however, showed thrombus to be a risk factor for subsequent occlusion,[3536] perhaps acting as a nidus for further platelet deposition.

The main reason for the significantly higher rate of angiographic restenosis in recanalized occlusions in our study was the high rate of occlusion at follow-up angiography in this group (19.2% versus 5.0% after dilatation of stenoses). A number of reasons may account for this. First, this group may represent a subset of the total population that has an intrinsic hematological propensity to thrombosis. Although our laboratory data did not confirm this, there are other hematologic factors such as fibrinogen levels that we did not measure that may influence reocclusion covertly.[35]

Second, there are substantial morphological differences between lesions,[37] which may have considerable influence on the subsequent risk of occlusion. Angiography provides little information on this or on the pathway of subsequent recanalization, which may vary from subintimal to periatheromatous and transatheromatous.[38] What effect these variables may have on the subsequent reocclusion and indeed restenosis rates is unknown. Differences in these lesion characteristics may be reflected in the total inflation time, which was significantly higher in lesions more likely to reocclude.

Third, the coronary vasomotor responses after balloon angioplasty of chronic total occlusions may be abnormal. Distal vasoconstriction occurs frequently after angioplasty and correlates well with coronary perfusion pressure, suggesting that chronic hypoperfusion resets epicardial coronary autoregulation and that restoration of normal perfusion pressure after PTCA may provoke reflex vasoconstriction,[39] thus precipitating early reocclusion.

Finally, the increased reocclusion rate may relate to local flow dynamics. The reference diameters before and after PTCA and at follow-up were significantly lower in occlusions than in stenoses. Furthermore, within the occlusions group multivariate analysis suggested that there is a negative relation between vessel size and subsequent risk of reocclusion. Thus, successfully dilated occlusions in larger vessels were less likely to reocclude than those in smaller vessels. This is in keeping with experimental work that suggested that smaller vessel diameters and hence higher shear rates favor local platelet activation and deposition,[4041] resulting in a greater likelihood of occlusion.

In addition to being responsible for the higher rate of angiographic restenosis, the high reocclusion rate in recanalized occlusions also seems to have been responsible for the higher rate of clinical events in this group of patients. Patients with recanalized occlusions had a significantly higher proportion of clinical events, mainly in terms of myocardial infarction, CABG, and repeated PTCA. Furthermore, these occurred earlier in occlusions than in stenoses. When patients with occlusions that went on to occlude at the time of follow-up angiography were removed from the analysis, the differences between the two groups were no longer significant, suggesting that the excess risk relates to the higher rate of occlusion at follow-up angiography. Interestingly, despite the higher rate of reocclusion in recanalized occlusions, there were no significant differences in the presentation of restenosis between the two groups, with approximately 40% of patients with angiographic restenosis in both groups being symptom-free.

Although studies of total occlusions suggest that there are important differences in the acute success rates between total and functional occlusions,[78] our data suggest that in terms of restenosis and reocclusion, there is little difference between the two groups. Although reocclusion after successful dilatation of total occlusions was higher than in functional occlusions (23.9% versus 15.9%), this did not reach statistical significance. However, there was a tendency for functional occlusions to mount less of a fibroproliferative response, which was reflected in the significantly greater net gain index and lower loss index. The cause for this is unclear but is likely to reflect differences in the underlying pathological substrate.

Clinical Implications

Up to 20% of patients undergoing diagnostic catheterization have one or more total occlusions; thus, they make up 10% to 20% of the total angioplasty population.[42] Furthermore, in multivessel disease, they may make the difference in referring the patient for angioplasty or for CABG surgery. Although great attention has been paid to increasing the acute success rate with the use of sophisticated new devices such as the low-speed rotational angioplasty[43] and the Excimer laser,[44] relatively little attention has been paid to long-term restenosis and its amelioration. Our results suggest that the higher restenosis in

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whether the reocclusion rate can be ameliorated by additional (eg, stenting) or alternative percutaneous revascularization techniques (high-speed rotational atherectomy or laser angioplasty) with or without concomitant pharmacological therapy remains to be established.

Study Limitations

A number of limitations of the present study are to be acknowledged. First, the study was a retrospective analysis of prospectively gathered data and hence is subject to the limitations inherent in any retrospective study.

Second, there were minor variations in the entry criteria of the studies. In CARPORT and PARK, for example, patients were randomized before PTCA, whereas in MERCATOR and MARCATOR, patients were entered into the trial only after a successful angioplasty procedure.[19202122] Thus, we are unable to comment on clinical, angiographic, or procedural factors influencing the acute success rate of the procedure. Furthermore, patients taking part in large multicenter studies like these are selected in certain ways; therefore, care needs to be taken in extrapolating our results to the broader angioplasty population.

Third, for obvious reasons, the reference diameter in the occlusions group before PTCA could not be reliably measured, so we took the reference diameter after dilatation as the reference diameter before dilatation. The statistical analyses remain valid, however, because even if we substitute the post-PTCA reference diameter for the pre-PTCA reference diameter in the stenoses group, the significant differences between the two groups remain.

Fourth, because of the nature of the data, we unfortunately are unable to comment on whether certain previously documented risk factors for restenosis such as the degree of collateral supply[11] or the measured coronary wedge pressure[4950] may relate to reocclusion rather than to long-term restenosis.

Finally, data from the active therapy group and the placebo group were amalgamated. Although the drugs did not seem to influence the overall restenosis rate, the Ketanserin in the PARK study and the thromboxane A_2-receptor blocker in the CARPORT studies may have had a covert influence on the reocclusion rate after dilatation of occlusions that we were unable to detect.

Nonetheless, we believe that the merging of the data is justified because the data amalgamated were common to all studies and the angiographic criteria were standardized, with one central laboratory performing the quantitative angiographic analysis in all studies. Furthermore, the resulting large study population provides a unique opportunity to obtain accurate quantitative angiographic data at a predetermined time interval in a field where such few data currently exist.

Conclusions

These results indicate that successfully dilated coronary occlusions, both total and functional, have a higher rate of angiographic restenosis at 6 months than stenoses. This is due chiefly to a higher rate of occlusion at follow-up angiography in this group of lesions. Measures aimed at reducing restenosis after successful dilatation of coronary occlusions should therefore be focused in this direction.

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Footnotes

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