

## Abrupt Closure: The CAVEAT I Experience

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**Objectives.** This study sought to assess the incidence and consequences of abrupt closure in a series of patients undergoing directional coronary atherectomy versus percutaneous coronary angioplasty.

**Background.** Abrupt closure with coronary angioplasty has been associated with adverse outcome. The results from the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) I, a randomized trial of coronary angioplasty versus directional coronary atherectomy, were analyzed.

**Method.** This multicenter trial enrolled 1,012 patients from 1991 to 1992. All records from patients with abrupt closure, which was coded as a discrete complication, were reviewed.

**Results.** Abrupt closure occurred in 60 patients (5.9%) and was associated with a significantly longer hospital stay (median 8 vs. 3 days). Severe proximal target vessel tortuosity was more common in patients with abrupt closure (20.3% vs. 11.6%,  $p = 0.046$ ), as was preexistent coronary artery thrombus (30.5% vs. 18.3%,  $p = 0.02$ ). Abrupt closure was associated with a marked increase in

subsequent complications (myocardial infarction 46.7% vs. 2.1%, emergency bypass surgery 38.3% vs. 0.32%, death 33% vs. 0%) and occurred more frequently in the directional coronary atherectomy group (8.0% vs. 3.8%,  $p = 0.005$ ). In the coronary angioplasty group, the occlusion usually occurred at the target lesion (91%), presumably related to the effects of barotrauma. In the directional coronary atherectomy group, the site of the occlusion was the target lesion in only 58% ( $p = 0.045$ ). The remaining occlusions related to problems with the technique (guide catheter or nose cone trauma), reflecting the fact that directional coronary atherectomy is a more complex procedure.

**Conclusions.** Abrupt closure remains the principal determinant of adverse outcome after percutaneous procedures for the treatment of coronary artery disease. Although abrupt closure is more common with directional atherectomy than angioplasty, the sequelae are similar.

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Abrupt or threatened closure remains the most serious procedural complication of percutaneous transluminal coronary angioplasty. The incidence of this complication has remained relatively constant over time, occurring in 2% to 10% of procedures (1-12). In prior series, it has been associated with a marked increase in the major clinical sequelae of acute infarction (40% to 50% of patients), need for emergency coronary bypass surgery (30% to 70% of patients) and mortality (5% to 7% of patients) (1-3,5,9). Early series of patients with abrupt or threatened closure were limited to conventional angioplasty procedures. There are limited, well controlled, prospectively collected data on the incidence of this complica-

tion with newer interventional techniques such as directional coronary atherectomy (13,14). The purpose of the current study was to assess abrupt closure in the Coronary Angioplasty Versus Excisional Atherectomy Trial (CAVEAT) I and to evaluate its incidence, mechanisms and outcomes using each revascularization strategy.

### Methods

The CAVEAT I trial design, methods and primary end point results have been previously published (15). Briefly, 35 experienced centers randomized 1,012 patients with new native coronary artery lesions to undergo either coronary angioplasty or directional atherectomy from August 1991 to April 1992 (15). The primary end point was angiographic 6-month restenosis. All data were prospectively recorded at each site on case report forms and verified at the coordinating center at Duke University. To ensure data quality, the coordinating center audited all case report forms. In addition, a random 15% of the forms were confirmed using the individual site's medical records. All cine angiograms for the trial were analyzed by blind assessment at the Cleveland Clinic Core Angiographic

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Laboratory using quantitative coronary angiographic techniques.

Both the case report forms and the angiographic core laboratory evaluation included abrupt closure or coronary occlusion as a discrete complication for data entry and tabulation. For the present report, all records of patients with abrupt closure indicated either on the case report form or by the core angiographic laboratory were reviewed. In addition, all available angiographic films of abrupt closure were reviewed by two operators (D.R.H. and J.S.) for angiographic and procedural details. There were 15 cases in which the case report form documented that occlusion had occurred, but either it was not documented on the cine angiographic film or the film was not available.

**Definitions.** *Abrupt closure* was defined as Thrombolysis in Myocardial Infarction grade 0 or 1 flow in the target artery with clinical or electrocardiographic evidence of ischemia lasting >5 min that occurred after initiation of the procedure and before discharge from the hospital.

*Technical success* was defined as a residual stenosis ≤50% at the end of the procedure. *Clinical success* was defined as a residual stenosis ≤50% and no major complication (death, myocardial infarction or emergency coronary bypass surgery).

Myocardial infarction was diagnosed both clinically at each site and by an adjudication committee unaware of the treatment assignment. *Infarction* was defined as development of new Q waves, elevation of creatine kinase (CK) isoenzyme levels to more than three times the upper limit of normal or elevation of CK levels to more than two times the upper limit of normal for the individual site's laboratory if no isoenzymes were obtained.

Angiographic definitions are often imprecise. *Dissection* was considered to be present when there was contrast staining within the wall of the vessel. *Contrast staining* that occurred near the tip of the guiding catheter was judged to be guide catheter induced. If it occurred at the tip of the guide wire, it was judged to be related to the guide wire. If it occurred at the treated lesion, it was judged to be device related. *Thrombus* was considered present when there was an intraluminal filling defect or multiple defects, often with indistinct edges, or filling defects with contrast on each side. Finally, if *occlusion* occurred at the location of the tip of the atherectomy device, it was judged to be related to nose cone injury.

**Statistical analysis.** Continuous data are expressed as medians with 25th and 75th percentiles unless otherwise indicated. Baseline clinical and angiographic characteristics of each treatment group were compared by the chi-square test or Fisher exact test for categorical variables and Wilcoxon rank-sum test for continuous variables.

## Results

**Patients with abrupt closure.** In this study of 1,012 patients, abrupt closure was documented in 60 (5.9%). In 47 patients (78%), the abrupt closure occurred in the catheterization laboratory during the initial protocol procedure, and

**Table 1.** Baseline Clinical and Angiographic Characteristics of Patients With and Without Abrupt Closure

	Abrupt Closure (n = 60)	No Abrupt Closure (n = 952)	p Value
Male gender	43 (71.7%)	692 (72.7%)	0.863
Unstable angina	42 (70.0%)	648 (68.2%)	0.773
MI within 14 days	17 (28.3%)	216 (22.7%)	0.314
Diabetes mellitus	9 (15.0%)	182 (19.1%)	0.429
Target vessel			
LMCA	0 (0.0%)	7 (0.75%)	
LAD	30 (50.8%)	533 (56.9%)	
Cx	10 (17.0%)	106 (11.3%)	
RCA	19 (32.2%)	290 (31.0%)	0.572
Ejection fraction	60 (50, 65)	60 (50, 65)	0.681
Vessels diseased			
1	37 (61.7%)	618 (65.0%)	0.637
2	20 (33.3%)	280 (29.5%)	
3	3 (5.0%)	52 (5.5%)	

Data presented are number (%) of patients or median (25th, 75th percentiles). Cx = circumflex coronary artery; LAD = left anterior descending coronary artery; LMCA = left main coronary artery; MI = myocardial infarction; RCA = right coronary artery.

the remainder occurred after leaving the angiographic suite. There were no differences in baseline demographics of these patients with and without abrupt closure (Table 1). Specifically, there was no difference in the frequency of unstable angina or myocardial infarction. Seventy percent of patients with abrupt closure had unstable angina compared with 68.2% of those without abrupt closure.

There were few differences in lesion morphology between patients with and those without abrupt closure (Table 2). As can be seen, severe proximal target vessel tortuosity was more

**Table 2.** Lesion Characteristics

	Abrupt Closure (n = 60)	No Abrupt Closure (n = 952)	p Value
Length (mm)	9.1 (5.9, 12.9)	8.9 (6.5, 11.9)	0.895
Diameter stenosis (%)	71.9 (61.5, 78.7)	72.1 (63.0, 78.2)	0.870
MLD (mm)	0.79 (0.52, 1.06)	0.81 (0.61, 1.07)	0.785
Calcification	27 (45.8%)	361 (38.8%)	0.286
Eccentricity*	31 (52.5%)	513 (55.1%)	0.702
Severe proximal tortuosity (%)†	12 (20.3%)	108 (11.6%)	0.046
Preexistent lesion thrombus	18 (30.5%)	170 (18.3%)	0.020
Severe angulation (≥45°)	8 (13.6%)	131 (14.1%)	0.913
Significant branch vessel involvement	35 (59.3%)	595 (63.9%)	0.478

\*≥50% lesion asymmetrically positioned in one or more views, with one lumen edge within the vessel midline and the opposite lumen edge no more than one-half the distance between the normal edge and midline (16). †Two or more 60° bends in a vessel or at least one bend of 90°. Data presented are number (%) of patients or median (25th, 75th percentiles). MLD = minimal luminal diameter.

**Table 3.** Comparison of Acute Outcomes

	Abrupt Closure (n = 60)	No Abrupt Closure (n = 952)	p Value
Successful procedure (≤50% residual stenosis)			
Site	37 (64.9%)	930 (98.3%)	<0.001
Angio core lab	28 (70.0%)	773 (85.0%)	0.011
Total MI	28 (46.7%)	20 (2.1%)	<0.001
Q wave MI	11 (18.3%)	4 (0.42%)	<0.001
Non-Q wave MI	17 (28.3%)	16 (1.7%)	<0.001
Emergency CABG	23 (38.3%)	3 (0.32%)	<0.001
Death	2 (3.3%)	0	0.003
Length of stay (days)	8 (5.5, 10)	3 (3, 4)	<0.001

Data presented are number (%) of patients or median (25th, 75th percentiles). Angio core lab = angiographic core laboratory; CABG = coronary artery bypass graft surgery; MI = myocardial infarction.

common in patients with abrupt closure (20.3% vs. 11.6%,  $p = 0.046$ ), as was angiographic evidence of pretreatment coronary artery thrombus (30.5% vs. 18.3%,  $p = 0.02$ ). There were no other differences in lesion morphology between the two groups.

**Other complications.** Abrupt closure was associated with a marked increase in the incidence of other complications (Table 3). The only two deaths during the initial hospital period in the CAVEAT trial occurred in the abrupt closure group. Myocardial infarction rates were strikingly increased in patients with abrupt closure, occurring in 46.7% versus 2.1% of patients without abrupt closure ( $p < 0.001$ ). Emergency bypass surgery was performed in 38.3% of patients with abrupt closure compared with 0.32% of the other patients ( $p < 0.001$ ). The 5.9% of patients who experienced abrupt closure, therefore, accounted for 57% of all infarctions in CAVEAT I and 88% of all emergency bypass graft surgery procedures. The length of stay of patients with abrupt closure was significantly increased. Clinical success was achieved in 9.1% of patients with abrupt closure compared with 62.7% of patients without abrupt closure ( $p < 0.001$ ).

**Differences between treatment groups.** The incidence of abrupt closure varied significantly in the two treatment arms. Treatment received was an independent predictor of abrupt closure. In the directional atherectomy group, abrupt closure occurred in 41 patients (8%) versus 19 in the coronary angioplasty group (3.8%) ( $p = 0.005$ ). There was no difference in the timing of abrupt closure, which occurred during the initial procedure in 78% of the directional atherectomy group and 79% of the coronary angioplasty group (Table 4). The left anterior descending coronary artery was the most common artery treated in both groups, although in the directional coronary atherectomy abrupt closure group, there were more right coronary artery segments being treated than in the coronary angioplasty group. The numbers were small and did not reach statistical significance. Although abrupt closure occurred more frequently in the directional atherectomy

**Table 4.** Abrupt Closure During Directional Atherectomy Versus Angioplasty

	Directional Atherectomy	Angioplasty	p Value
Abrupt closure	41 (8.0%)	19 (3.8%)	0.005
During procedure	32 (78.0%)	15 (79.0%)	1.000
After procedure	10 (24.4%)	4 (21.0%)	1.000
Lesion location			
LAD	19 (46.3%)	11 (61.1%)	0.514
RCA	15 (36.6%)	4 (22.2%)	
Cx	7 (17.1%)	3 (16.7%)	
Patency restored	25 (62.5%)	15 (83.3%)	0.137
Emergency CABG	15 (36.6%)	8 (42.1%)	0.682
Total MI (site)	19 (46.3%)	9 (47.4%)	0.941
Q wave MI	8 (19.5%)	3 (15.8%)	1.000
Non-Q wave MI	11 (26.8%)	6 (31.6%)	0.704
Death	0	2 (10.5%)	0.097

Data presented are number (%) of patients. Abbreviations as in Table 1.

group, once it had occurred in either group, there was no significant difference in clinical outcome. Patency was restored successfully in 62.5% of the directional coronary atherectomy group and 83.3% of the coronary angioplasty group ( $p = 0.137$ ). Usually, patency was restored with repeat coronary angioplasty (53.3%); stents were used infrequently (3.3%), and thrombolytic therapy was very uncommon (6.7%). The incidence of myocardial infarction or coronary bypass surgery after abrupt closure did not differ between the directional coronary atherectomy and coronary angioplasty groups.

**Characteristics of occlusions.** The etiology and characteristics of abrupt closure were assessed in both treatment groups (Table 5). In 44 patients, the original cine angiographic films documenting the occlusion were available for review. In 15 patients there was either no cine angiographic documentation of abrupt occlusion or the cine film was not available. In these patients, the case report forms were used for assessment of factors associated with occlusion (e.g., dissection or thrombus). The specific location and mechanism of occlusion, such as guide catheter trauma, were analyzed only in those patients in whom the angiogram was reviewed.

The target artery was the vessel most commonly affected by

**Table 5.** Mechanism of Occlusion\*

	Directional Atherectomy (n = 41)	Angioplasty (n = 19)	p Value
Target artery	36 (87.8%)	17 (89.5%)	0.781
Occlusion-involved side branch	13 (31.7%)	7 (36.8%)	0.495
Mechanism			
Dissection	28 (68.3%)	11 (57.9%)	0.518
Thrombus	8 (19.5%)	4 (21.1%)	
Both	3 (7.3%)	1 (5.3%)	
Unknown	2 (4.9%)	3 (15.8%)	

\*For this assessment, information from cine film review was used; in those patients in whom cine film documenting the abrupt closure was not available, the case report form and site physician assessment were used. Data presented are number (%) of patients.

**Table 6. Location and Mechanism of Occlusion\***

	Directional Atherectomy (n = 33)	Angioplasty (n = 11)	p Value
Proximal to target lesion	10 (30.3%)	1 (9.1%)	0.184
At target lesion	19 (57.6%)	10 (90.9%)	0.045
Distal to target lesion	4 (12.1%)	0 (0%)	0.331
Cause			
Guide catheter trauma	10 (30.3%)	1 (9.1%)	0.378
Guide wire	2 (6.1%)	0 (0%)	
Nose cone injury	1 (3.0%)	0 (0%)	
Unknown	20 (60.6%)	10 (90.9%)	

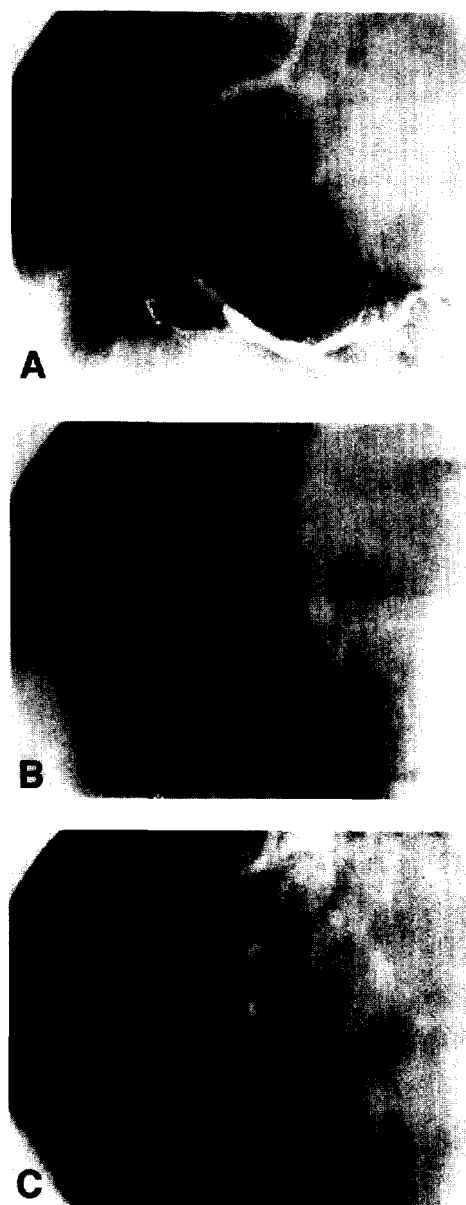
\*Assessed by review of cine angiographic details of occlusion. Data presented are number (%) of patients.

abrupt closure, although a side branch in the vicinity of the target lesion was involved in ~33% of cases. The most common cause of the abrupt closure—dissection—was seen in 68.3% of the directional coronary atherectomy group and 57.9% of the coronary angioplasty group ( $p = 0.518$ ). Thrombus was the next most frequent cause and did not differ between the two groups.

There were significant differences in the location of occlusion (Table 6). In the directional coronary atherectomy group, the location was proximal to the target lesion in 10 (30%), distal to the target lesion in 4 (12%) and at the lesion in 19 (58%). In contrast, in the coronary angioplasty group abrupt closure occurred at the target lesion in 10 (91%). In the directional coronary atherectomy group, occlusions proximal to the target lesion were usually related to guide catheter trauma (Fig. 1), whereas lesions distal to the target lesion were secondary to either guide wire manipulation (Fig. 2) or nose cone trauma (Fig. 3). In patients treated by coronary angioplasty, the cause of the occlusion was not apparent, and the balloon/artery ratio appeared appropriate by visual estimate. The occlusion appeared to be related to the unpredictable nature of the barotrauma to the arterial segment dilated.

### Discussion

Abrupt occlusion remains a major problem for interventional cardiology (1-12,17). Despite improvements in technology, increasing operator experience, more intensive heparin dosing and monitoring of activated clotting times, there has not been a major change in the incidence of periprocedural occlusion since the early days of interventional cardiology (1-3,5,8,9). In the most recent National Heart, Lung, and Blood Institute Percutaneous Transluminal Coronary Angioplasty (1,2) Registry from 1985 to 1986, 6.8% of patients had a periprocedural occlusion. In the present report of 1,012 patients from CAVEAT I with patient entry from 1991 to 1992, the incidence of abrupt closure was 5.9%. This is similar to other series over the past decade reporting on coronary angioplasty. In the past, abrupt closure has typically occurred in the angiographic laboratory (1-3,5,9). In the present series,



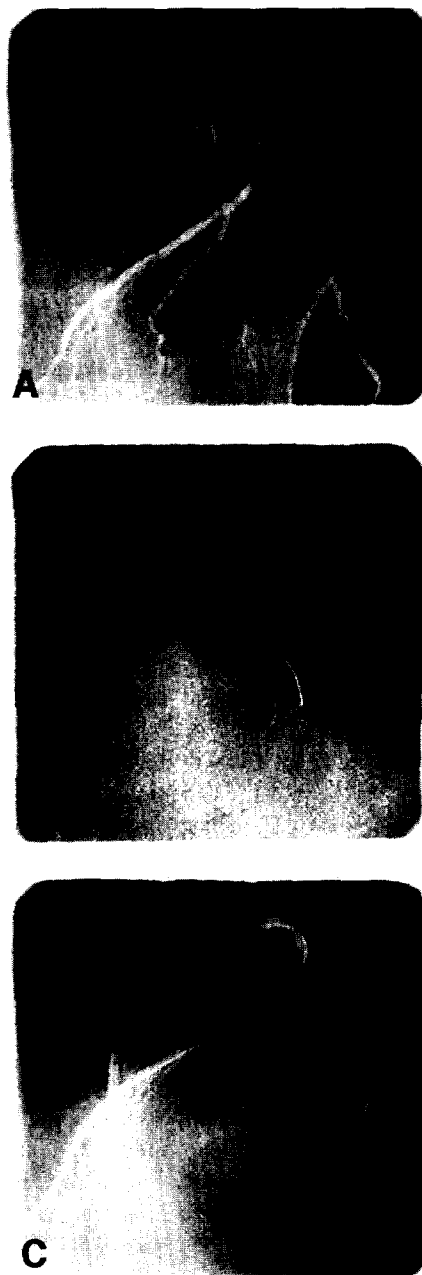
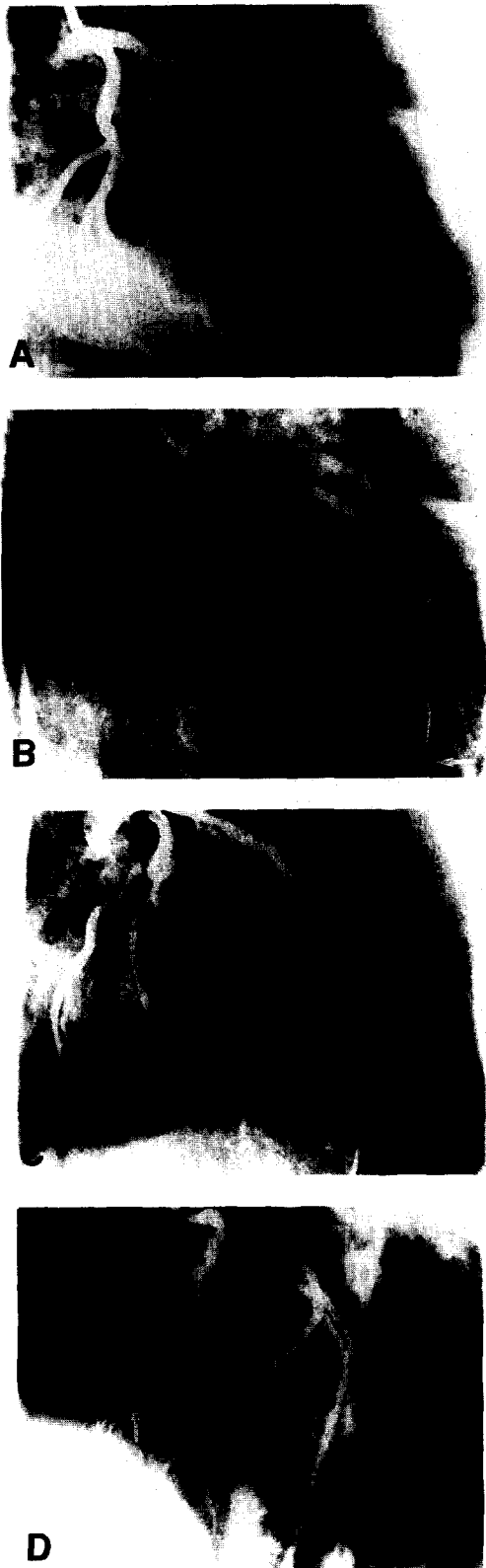
**Figure 1.** A, Left anterior oblique view of lesion to be treated in distal right coronary artery. B, Directional atherectomy was used. C, A dissection was found in the proximal right coronary artery beginning at the tip of the guiding catheter that propagated distally and occluded the vessel.

78% of abrupt closures occurred in that setting, and only 22% occurred after patients left the laboratory.

**Characteristics of increased risk.** Prior studies (3,8,9) have shown that certain baseline characteristics of patients are associated with increased risk of abrupt closure, particularly unstable angina, postinfarction angina and female gender. In the present series, there was no difference in these characteristics among patients with and without abrupt closure. The incidence of unstable angina was very high in each group (70% and 68%, respectively).

Specific lesion and vessel characteristics have also been found (3,5,8,10,11,18-20) to be associated with increased risk

**Figure 2.** **A**, Right anterior oblique view of left anterior descending coronary artery with a significant proximal stenosis. **B**, During atherectomy, the guide wire is looped in the mid-left anterior descending artery (arrow). **C**, After atherectomy, there is a dissection in the mid-left anterior descending artery at the site of the looped guide wire (arrow). **D**, This localized dissection results in occlusion of the mid-left anterior descending artery (arrow), seen in the left anterior oblique view.



**Figure 3.** **A**, Cranial left anterior oblique view of left main coronary artery documenting a severe eccentric proximal stenosis. **B**, During atherectomy, the guide wire is placed in the large diagonal branch. Nose cone is in the mid-left anterior descending coronary artery at the origin of the large diagonal branch. **C**, After atherectomy, the left anterior descending lesion has responded well. There is occlusion of the large diagonal branch at the site of the nose cone.

of abrupt closure. Preexisting coronary artery thrombus remains an important risk factor despite the use of increasingly large doses of heparin and antiplatelet agents (11). Thirty percent of patients with abrupt closure had preexistent lesion thrombus compared with 18% of those without abrupt closure. The only other lesion characteristic associated with increased abrupt closure was proximal vessel tortuosity, which may be a particularly difficult problem for directional coronary atherec-

tomy. Other angiographic factors, including lesion eccentricity and angulation, were not associated with adverse outcome. Because of the inclusion criteria for this trial, however, some of these other adverse lesion characteristics were infrequent in patients considered for inclusion in CAVEAT I. In addition, patients with some lesion characteristics, such as heavy calcification, which is associated with higher abrupt closure rates, were excluded from the trial.

**Outcomes after abrupt closure.** Abrupt closure has been recognized as the most important risk factor for adverse hospital outcome using in-hospital mortality, myocardial infarction and coronary bypass graft surgery as end points (2,3,5,9). These relations hold true for the present cohort. The only deaths during the initial hospital period in this trial occurred in patients with abrupt closure. Eighty-eight percent of all emergency coronary bypass surgical procedures and 57% of all myocardial infarctions also occurred in patients with abrupt closure. Although management strategies have changed (17,21-26), and perfusion balloons and other devices were widely available during this trial, they had little effect on outcome. In the entire trial, perfusion balloons were used in only 11% of patients, and stents or lasers in only 0.8%. In other series, stents have been shown (23-26) to decrease substantially the need for coronary bypass surgery and the frequency of acute myocardial infarction.

**Operator experience.** The ability to restore patency in the present group of patients with abrupt closure (62.5% for directional atherectomy and 83.3% for coronary angioplasty) is somewhat improved compared with previous cohorts of patients (2,3,7,9,12). This may be a result of the fact that for eligibility as an investigator, extensive interventional cardiology experience was required. Each operator had to have performed >400 dilation procedures and  $\geq 50$  atherectomy procedures. Increasing operator experience with patients undergoing percutaneous revascularization procedures may be important in optimizing outcome, although even in the present experience with large vessels and usually proximal stenoses, only 60% to 80% of patients had patency restored at the end of the procedure. There was no difference between the directional coronary atherectomy and coronary angioplasty groups in the incidence of myocardial infarction or coronary bypass surgery.

**Time course and etiology of abrupt closure.** Although other studies (13,14,27-30) have reported complications with directional atherectomy versus coronary angioplasty, to our knowledge none has compared outcomes of therapy in the context of a randomized trial. In CAVEAT I, directional coronary atherectomy was associated with significantly increased abrupt closure compared with coronary angioplasty (8.0% vs. 3.8%,  $p < 0.005$ ). The time course of occlusion was similar for both procedures. Once the occlusion had occurred, there was no significant difference in clinical outcome, which was characterized by increased rates of myocardial infarction, both Q wave and non-Q wave, and performance of emergency coronary bypass surgery.

The etiology of the abrupt closure was also similar between

directional atherectomy and coronary angioplasty. As has been true with other series, dissection is the most common cause, followed by thrombus accumulation (5,8,10,20). Categorization of the etiology may be difficult because of the insensitivity of coronary angiography in documenting thrombus or small dissections. Irrespective of this problem, in the majority of patients with acute closure, an angiographically significant dissection appeared to play a dominant role.

Although the etiology of the abrupt closure, that is, dissection versus thrombus or a combination, was similar between directional atherectomy and coronary angioplasty, there were marked differences in specific patterns. With coronary angioplasty, the occlusion usually occurred at the target lesion site even though an appropriately sized balloon had been used. This result is due to the unpredictable nature of the barotrauma of balloon inflation. However, for directional atherectomy, the patterns were different and commonly reflected technical problems. Occlusion proximal to the target lesion was more common and often related to the large guide catheters required for the procedure. In addition, there were a small number of occlusions distal to the target lesion, either from nose cone injury or guide wire problems. The mechanisms of the etiology of the occlusion were, therefore, different between the two groups. The ability to restore flow after occlusion in the patients treated with directional coronary atherectomy was less than in patients treated with coronary angioplasty (62.5% vs. 83.3%). This was not statistically significantly different because of the small numbers involved but may reflect problems dealing with complete occlusion occurring at a different site than the initial target lesion.

**Future developments.** Significant advances in devices and adjunctive medical treatments will play an important role in the future treatment of patients with abrupt closure. Intracoronary stents have been shown (23-26) to significantly decrease complications of abrupt closure, but these were infrequently used in CAVEAT I. Newer antiplatelet regimens, specifically GPIIb/IIIa receptor blockers, may decrease ischemic complications of percutaneous revascularization procedures. These drugs may be particularly advantageous in patients treated with directional coronary atherectomy. In the Evaluation of 7E3 for Prevention of Ischemic Complications (EPIC) trial (31), patients treated with directional coronary atherectomy and a GPIIb/IIIa receptor-blocking drug had no increase in acute periprocedural infarction compared with patients treated with coronary angioplasty. This finding supports a distinct increased propensity of platelet thrombus as a mediator of complications with directional atherectomy.

**Conclusions.** In this randomized trial of new coronary artery lesions treated with either directional coronary atherectomy or coronary angioplasty, the incidence of abrupt occlusion was similar to that reported in older series, reflecting the fact that this phenomenon remains a clinical problem despite technologic improvements. When abrupt occlusion occurred, it was associated with a marked increase in morbidity and length of stay. The 5.9% of patients with abrupt closure accounted for 88% of emergency operations and 57% of the acute infarc-

tions. Abrupt closure occurred significantly more frequently in patients randomized to directional coronary atherectomy (8.0% vs. 3.8%). Once the abrupt occlusion occurred, the clinical outcome was similar irrespective of which randomized group the patient was in. Finally, the pattern of occlusion differed between directional coronary atherectomy and coronary angioplasty; directional coronary atherectomy remains more complex to perform, and technical factors more often lead to complete occlusion than with coronary angioplasty, in which the occlusion results from the unpredictable consequences of balloon inflation.

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