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Short-Term (4 Hours) Observation After Elective Coronary Angioplasty

Karel T. Koch, MD, Jan J. Piek, MD, Robbert J. de Winter, MD, George K. David, MD, Karla Mulder, and Kong I. Lie, MD

Since the introduction of percutaneous transluminal coronary angioplasty (PTCA) continuous refinements in technical equipment and increased operator experience have contributed to high primary success rates and a low incidence of complications.^{1,2} However, the increasing number of PTCA procedures has led to accumulating logistic constraints.³ A reduction in hospital stay and application of out-patient facilities are advocated to reduce procedure-related costs. At our center, the increasing number of angioplasty procedures and the limited availability of in-hospital beds made a short-term observation period after elective PTCA mandatory. Taking into account the complication rates known from several studies,^{4,5} as well as review of our own experience, we considered a 4-hour observation period after uncomplicated PTCA to be sufficient. This study was performed to evaluate the safety and appropriateness of this regimen prospectively.

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The study group consisted of 1,900 consecutive patients who underwent elective coronary angioplasty at the Academic Medical Center Amsterdam between August 1991 and October 1996. Patients were studied prospectively for short-term observation when they were referred to our center for PTCA from hospitals in a 40-mile area. Patients were excluded if angioplasty was performed for acute myocardial infarction or for unstable angina treated intravenously with nitrates and heparin. Patients with unstable angina of Braunwald class I and II severity were not excluded.⁶ Multivessel disease, previous PTCA or coronary bypass surgery, impaired left ventricular function, or angiographic variables were not exclusion criteria. Patients were excluded if scheduled for elective stent implantation, laser angioplasty, intraaortic balloon pump assistance, or angioplasty under general anesthesia. Elective stent implantation was an exclusion criterion until June 1995 because anticoagulation therapy after stent implantation was altered at that time from treatment with heparin-coumadin to ticlopidin.

Elective coronary angioplasty was performed by the femoral approach: 7Fr and 8Fr guiding catheters were used during the first half of the study; 904 procedures (47.6%) were performed with 6Fr guiding catheters that were used routinely since August 1994 except for atherectomy and the scheduled use of 6Fr incompatible stents. All patients were pretreated with

100 to 300 mg of aspirin taken orally. A standard dose of 5,000 IU of heparin was given as an intraarterial bolus dose after insertion of the arterial sheath. An additional dose of 2,500 IU of heparin was given when the procedure lasted >90 minutes.

The procedure was considered completed if the angiographic result remained satisfactory after a 5-minute waiting time after the last balloon inflation. The sheaths were removed immediately after completion of the procedure. Hemostasis was obtained by manual compression. A 12-lead electrocardiogram was obtained before and after completion of the procedure. The patients were observed in our center for another 4 hours without telemetry. Patients were returned to the referring hospitals in a 40-mile area to a regular bed without telemetry if they were free of symptoms and a repeat electrocardiogram remained unchanged. It was left at the discretion of the attending interventional cardiologist at any time after the procedure to prolong the observation period, with or without monitoring, to install additional heparin treatment, and to leave the sheath in place. The indications for prolonged observation and monitoring were recorded. Procedural complications and the incidence of complications during prolonged observation were documented. Clinical follow-up data after the 4-hour observation were obtained from the referring hospitals.

The safety of this strategy was evaluated prospectively. Primary end points were acute recurrent ischemia and the necessity to perform emergency repeat coronary angioplasty in patients discharged after the short-term observation period. Secondary end points were (1) overall procedural success, (2) the need for prolonged observation as determined at the operator's discretion, and (3) acute recurrent ischemia and the necessity to perform emergency repeat coronary angioplasty within 4 hours after PTCA in patients allocated to short-term observation. Procedural success was defined as <50% residual stenosis without death from any cause, acute myocardial infarction, or urgent coronary bypass surgery for failure of angioplasty.

During the study period, 3,990 patients underwent a percutaneous transluminal revascularization procedure at our center. The reasons for exclusion are summarized in Table I. Miscellaneous reasons for exclusion were, e.g., admission at our cardiology department or participation in various protocols necessitating in-hospital observation. The study population consisted of 1,900 patients involving a total of 2,852 coronary lesions. The clinical and angiographic characteristics of the patients are summarized in Table II.

The overall procedural success rate was 90.9%. The in-hospital mortality was 0.3% (95% confidence

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TABLE I Exclusion Criteria	
	Number (%)
All procedures during study period	3,990
Excluded	
Unstable angina (Braunwald class III) ^a	998 (25.0)
Acute myocardial infarction	372 (9.3)
Elective stent implantation*	155 (3.9)
Excimer laser angioplasty	121 (3.0)
Intraaortic balloon pump support	39 (1)
General anesthesia	20 (0.5)
Miscellaneous	385 (9.7)
Included	1,900 (47.6)
*Excluded until June 1995.	

TABLE II Patient Characteristics (n = 1,900 patients)	
	Number (%)
Mean age (yr) (mean $\pm$ SD)	61.1 ($\pm$ 10.9)
Range	25-88
Men	1,378 (72.5)
Previous myocardial infarction	941 (49.5)
Previous coronary angioplasty	477 (25.1)
Previous coronary bypass surgery	143 (7.5)
Risk factors	
Family history of coronary artery disease	722 (38)
Hypercholesterolemia	741 (39)
Smoking	798 (42)
Diabetes	209 (11)
Hypertension	665 (35)
Single vessel disease	969 (51)
Multivessel disease	931 (49)
Single lesion angioplasty	1,254 (66)
Multilesion angioplasty	646 (34)
Multivessel angioplasty	312 (16.4)
2,852 lesions (1.5/procedure)	
Left anterior descending artery	1,340 (47)
Right coronary artery	827 (29)
Circumflex artery	599 (21)
Left main	1 (0.1)
Saphenous vein graft	85 (3)
ACC/AHA classification	
Type A	168 (5.9)
Type B1	967 (33.9)
Type B2	1,121 (39.3)
Type C	596 (20.9)
ACC/AHA = American College of Cardiology/American Heart Association.	

interval [CI] 0.1 to 0.6); (n = 6); 4 patients died either immediately after the procedure (n = 2) or after emergency bypass surgery (n = 2). The other 2 patients died from a cerebrovascular cause after several days during hospitalization. Coronary bypass surgery within 24 hours was performed in 24 patients (1.3%; 95% CI 0.8 to 1.8). Repeat PTCA within 48 hours was performed in 17 patients (0.9%; 95% CI 0.5 to 1.3). The procedure was unsuccessful but without complications in 77 patients (4.1%; 95% CI 3.2 to 4.9).

After a 4-hour observation period, 1,680 of 1,900 patients (88.9%; 95% CI 87.5 to 90.4) were discharged and returned to the referring hospital (Table III). One patient returned the same day from the referring clinic with recurrent ischemia treated with recombinant tissue-type plasminogen activator; emer-

gency repeat angiography had a satisfactory result. However, creatine kinase-MB levels were elevated, suggesting a temporary thrombotic occlusion. The other patient was discharged from the referring hospital after uncomplicated short-term observation and readmitted the next day with recurrent chest pain but without evident electrocardiographic changes or cardiac enzyme elevation. Repeat angiography demonstrated a good result of the treated segment. All other patients remained stable for at least 3 days.

Prolonged observation was considered necessary in 187 patients (9.8%; 95% CI 8.5 to 11.2) mainly for coronary dissection, whether or not followed by "bail-out" stenting, temporary occlusion, loss of side branches, and angiographic evidence of intracoronary thrombus. The indications for prolonged observation are summarized in Table IV. In the early phase of the study, the use of intracoronary stents was limited to a bail-out for acute closure or threatened closure. These patients were hospitalized after stent implantation for intensive anticoagulation consisting of prolonged heparin treatment until coumadin therapy was adequately installed. In the later phase of the study, bail-out stent implantation, as such, no longer constituted a reason for prolonged observation.

The patients selected for prolonged observation were monitored, heparin treatment was continued in 170 of 187 patients (91%), and the sheaths were left in place until the next day. The remaining 17 patients were observed without continuation of heparin treatment for various reasons such as wire perforation after attempted recanalization of a coronary occlusion or a suspected cerebrovascular complication. The observed patients were discharged the following morning unless they had a complicated course. In 121 of these 187 patients (65%), the postprocedural course was uneventful (Table III). Myocardial infarction was documented by creatine kinase-MB elevation in 51 of the observed patients ($>2\times$ the upper limit in 43 patients, Q-wave myocardial infarction in 8 patients). The group selected for prolonged observation comprised 2 patients who died from a subsequent cerebrovascular accident, 1 during anticoagulation therapy after bail-out coronary stenting.

Emergency repeat angioplasty was performed in 7 patients for out-of-laboratory closure during the 4-hour observation period after removal of the sheaths, and in 5 patients already selected for prolonged observation and treated with additional heparin. Scheduled repeat angiography within 48 hours after the procedure subsequent to prolonged observation and heparin treatment was performed in 21 patients, followed by repeat angioplasty in 5 patients.

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The present study demonstrates the safety and feasibility of a short-term observation period in elective coronary angioplasty. The results of this prospective study in consecutive patients indicate that almost 90% of the patients can be discharged 4 hours after elective coronary angioplasty with a negligible risk of subacute closure after discharge. Short-term observation after coronary angioplasty has been reported earlier in

TABLE III Short-Term Versus Prolonged Observation (n = 1,900)

	Number (%)
Deaths	4* (0.2)
Emergency coronary bypass surgery	24 (1.3)
Allocated to 4-hour observation	1,687 (88.8)
Emergency repeat coronary angioplasty during 4-hour observation	7 (0.4)
Short-term observation completed and discharged	1,680 (88.4)
Acute recurrent ischemia after discharge	2† (0.1)
Allocated to prolonged observation	187 (9.8)
Deaths	2‡ (0.1)
Myocardial infarction	51 (2.7)
Emergency repeat coronary angioplasty	5§ (0.3)
Repeat coronary angioplasty after scheduled angiography	5 (0.3)
Other complication	3 (0.2)
Uncomplicated observation	121 (6.4)

*Including 2 patients after emergency coronary bypass surgery.

†Late coronary occlusion in 1 patient, no evidence of reclosure in the other patient.

‡Patients who died from a cerebrovascular accident under full anticoagulation therapy.

§Reclosure under heparin in 3 patients, after discontinuation of heparin in 2 patients.

TABLE IV Indications for Prolonged Observation (n = 187 patients)

	Number (%)
Dissection	43 (22.9)
Bail-out stent	32 (17.1)
Occluded side branch	26 (13.9)
Temporary occlusion	20 (10.7)
Suboptimal result	17 (9.1)
Angiographic thrombus	14 (7.5)
Prolonged pain	8 (4.2)
After emergency repeat coronary angioplasty	7 (3.7)
Miscellaneous	20 (10.7)

a small series of highly selected patients or has been suggested retrospectively in larger groups of patients.^{7,8} To our knowledge, no study has so far reported prospectively on a short-term observation period after angioplasty in a large group of patients undergoing elective PTCA. A total of 1,680 of the 1,900 patients included left our center after a 4-hour observation period, and only 1 patient met the end point of acute recurrent ischemia after discharge. Reclosure during the 4-hour observation period after the procedure occurred in 7 patients not selected for prolonged observation, indicating a beneficial, although relatively small, effect of a 4-hour observation in apparently uncomplicated cases.

In the present study, 187 patients (9.8%) were selected for prolonged observation. Immediate postprocedural findings that were considered to be predictive of subacute or late complications were the main reasons for prolonged observation. Postprocedural complications (i.e., significant myocardial infarction warranting electrocardiographic monitoring, repeat angioplasty after scheduled repeat angiography, and 5 emergency repeat angioplasties for acute closure) were indeed encountered in the group of patients selected for prolonged observation. The prolonged observation period was uneventful in 121 of the 187 patients (65%) selected for observation. This study

indicates that the immediate postprocedural result allows a proper selection of patients for short-term observation as demonstrated by the uncomplicated course of the 1,680 patients discharged after 4-hour observation.

In a previous report, we demonstrated prospectively in 1,375 patients that the routine use of 5,000 IU of heparin in elective coronary angioplasty is safe without an increased risk of ischemic complications.⁹ The level of anticoagulation in that study (activated clotting times were 259 ± 60 seconds 15 minutes after bolus injection, and 240 ± 41 and 212 ± 60 seconds, respectively, after 30 and 60 minutes) enabled sheath removal immediately after completion of the procedure without an increased risk of puncture site complications. Immediate sheath removal subsequent to angioplasty with low-dose heparin may be particularly useful in a patient population that appears to be eligible for short-term observation.

Most patients (170 of 187) selected for prolonged observation were also treated with additional heparin therapy. It has been suggested that prolonged intravenous heparin therapy may decrease the incidence of subacute closure, especially after a suboptimal result of angioplasty.^{10,11} Nevertheless, 3 patients in this group had an acute closure despite full heparin treatment. A temporal relation has been described between the cessation of heparin therapy and vessel reclosure²; this was observed in 2 patients who underwent repeat angioplasty after allocation to prolonged observation and heparin treatment.

From June 1995, the anticoagulation regimen after stent implantation was modified from heparin/coumadin to aspirin/ticlopidin, and from that time patients undergoing coronary stenting were also included in the short-term observation protocol. The percentage of patients included undergoing stent implantation grew from 9.4% (41 of 434 patients) in 1995 to 23% (108 of 468 patients) in the last year of the study, reflecting the evolving role of stent implantation in current angioplasty practice. At present, 85% of these patients are discharged from our hospital after a 4-hour observation.

In conclusion, short-term (4 hours) observation after elective coronary angioplasty is safe, with a negligible risk of vessel closure after this period. A selection of patients for prolonged observation can be performed appropriately after the immediate procedural result.

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Effects of Quinapril on Coronary Blood Flow in Coronary Artery Disease Patients With Endothelial Dysfunction

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Despite being histologically spared from atherosclerosis,^{1,2} coronary resistance vessels demonstrate impaired endothelium-dependent dilation in subjects with hyperlipidemia and/or mild (<40% narrowing) epicardial atherosclerosis.^{1–5} Impaired microvascular endothelial function may lead to altered regulation of myocardial perfusion and potentiate ischemia. Although recently reported to improve endothelial function in large epicardial coronary arteries, the influence of angiotensin-converting enzyme (ACE) inhibitors on microvascular function is unknown.^{6–8} This pilot study investigates the microvascular blood flow responses to endothelium-dependent and -independent vasodilators before and after ACE inhibition to obtain data to plan and conduct a definitive study. We chose quinapril because of its high binding affinity and potency for vascular ACE. Our hypothesis was that sustained ACE inhibition improves microvascular endothelial function.

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Twenty-nine patients enrolled in the the Trial on Reversing Endothelial Dysfunction (TREND) consented for this pilot study. The protocol and results of TREND have been reported previously.⁶ Briefly, patients had at least 1 major coronary artery with minimal (<40% diameter) stenosis that had never been revascularized but had endothelial dysfunction, defined as no dilation in response to acetylcholine; this was designated the *target artery*. Patients aged ≥ 75 years with a dominant right coronary artery as the only target artery, low-density lipoprotein cholesterol ≥ 165 mg/dl, systolic blood pressure > 160 mm Hg, or diastolic blood pressure > 90 mm Hg, coronary bypass or coronary spasm, myocardial infarction within 7 days, percutaneous revascularization within 3 months, ejection fraction $\leq 40\%$, juvenile onset diabetes, clinically significant hepatic or renal dysfunction, valvular heart disease, equal to greater than the second-degree heart block, or hypolipidemic agents within 6 months were excluded. The protocol was approved by the ethics committees of each institution and written informed consent obtained from all patients.

Patients discontinued vasoactive medications, except β blockers and sublingual nitrates, ≥ 12 hours before study. After 10,000 IU of heparin was administered and angiography was performed, a right ventricular pacing catheter was positioned. The pacer was set in the demand mode at a rate less than the baseline heart rate. Intracoronary Doppler blood flow velocity was recorded from either a 3Fr 20-MHz Mikro-Tip Doppler catheter (Model DC-201, Millar Instruments,