Two hour ambulation after coronary angioplasty and stenting with 6 F guiding catheters and low dose heparin

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Abstract

Objective—To evaluate the feasibility and safety of ambulation of patients two hours after elective coronary angioplasty or stenting, or both.

Methods—Coronary angioplasty and stenting were performed using 6 F guiding catheters by the femoral approach and a standard dose of heparin 5000 IU. There were no angiographic exclusion criteria except for planned atherectomy. Patients given oral anticoagulants or heparin were not eligible. All patients were given aspirin. Patients who underwent stent implantation also received ticlopidine 250 mg daily. The arterial sheath was removed immediately after the procedure. Haemostasis was achieved by manual compression and maintained with an inguinal compression bandage. Early ambulation was attempted after two hours of supine bed rest following removal of the bandage.

Main outcome measures—The incidence of bleeding at or during ambulation requiring compression and additional bed rest, and puncture site complications documented 48 hours after the procedure. **Results**—300 of 359 consecutive eligible patients were included for two hour ambulation. Stent implantation was performed in 32% of the procedures. The mean (SD) time to haemostasis was 9.6 (3.2) minutes. Bleeding at ambulation occurred in five patients (1.7%), and nine patients (3.0%) reached the secondary end point of haematoma > 5 × 5 cm at 48 hour follow up. All were treated conservatively without further sequelae. There was no late bleeding or vascular complications.

Conclusion—Ambulation two hours after elective balloon angioplasty or stent implantation with 6 F guiding catheters by the femoral route and low dose heparin is feasible and safe, with a low incidence of puncture site complications. This early ambulation protocol facilitates a short hospital stay.

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Keywords: angioplasty; heparin; ambulation; patient management

The increasing number of procedures in centres performing coronary angioplasty has led to logistic constraints that have altered patient management strategies. A reduction in hospital stay and the application of outpatient

facilities are advocated for treating larger number of patients at lower procedure related costs.¹ Early ambulation after coronary angioplasty may reduce in-hospital stay and add to the patient's comfort. This approach, however, may increase the risk of puncture site related complications, such as arterial bleeding, haematoma, pseudoaneurysm, and the need for surgical repair. We recently reported on the safety of early ambulation (four hours) after coronary angioplasty with 6 F guiding catheters and low dose heparin.² Others have found that early ambulation (two hours) can be achieved after diagnostic cardiac catheterisation by 5 and 6 F catheters.^{3,4} This study evaluates the feasibility and safety of ambulation two hours after elective coronary angioplasty and stenting using 6 F guiding catheters by the femoral approach.

Patients and methods

The study population comprised 300 consecutive patients who underwent elective coronary angioplasty using 6 F guiding catheters by the femoral approach. There were no angiographic exclusion criteria. 6 F guiding catheters (Pink-Power, internal diameter (ID) 0.061", Schneider, Zurich, Switzerland; petit Britetip ID 0.062", Cordis, Miami, Florida, USA) were used in all elective procedures except for intended directional or rotational atherectomy and planned implantation of stents requiring larger guiding catheters. The following stents were used—premounted system: Multilink 15 and 25 mm (Advanced Cardiovascular Systems (ACS), Santa Clara, California, USA) and Crown 30 mm (Cordis); hand crimped: NIR stent, 9, 16, 25, and 32 mm (Scimed-Boston Scientific, Maple Groove, Minnesota, USA), and Palmaz-Schatz 9 and 15 mm (Cordis). Angioplasty was performed with standard guidewires (Hi-Torque Floppy II 0.014", Traverse 0.014", ACS, and J-Flexy 0.012", Schneider) and rapid exchange balloon catheters (Goldie and Bonnie, Schneider and Comet, ACS) or over the wire balloon catheters (Takumi OTW, Schneider).

Patients who received oral anticoagulants or heparin before angioplasty and those who had a pre-existing haematoma after recent diagnostic angiography were not included. Patients were pretreated with aspirin 100 mg daily. A single dose of heparin 5000 IU was given immediately after insertion of the arterial sheath. This low dose regimen allowed the use of an additional dose of heparin 2500 IU if a procedure lasted for more than 90 minutes.

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Table 1 Non-eligible patients

	n	%
All procedures during study period	621	
Not eligible		
Preprocedural heparin treatment	211	34
Oral anticoagulant therapy	31	5
Pre-existent haematoma	12	2
Directional/rotational atherectomy	6	1
6 F incompatible stent	2	0.5
Not included due to		
Postprocedural heparinisation	33	5
Emergency bypass surgery	3	0.5
Logistic circumstances	19	3
Physicians' preference	4	1
Included	300	48

Table 2 Patient characteristics

Number of patients	300
Age (years)	60 (10.7)
Men	237 (80%)
Height (cm)	174 (9.3)
Weight (kg)	79 (12.3)
Single vessel coronary disease	175 (58%)
Multivessel coronary disease	125 (42%)
Previous myocardial infarction	153 (51%)
< 3 months	51 (17%)
Previous coronary angioplasty	88 (29%)
Previous coronary bypass	20 (7%)
Lesions (lesions/procedure)	392 (1.3)
Right coronary artery	97 (25%)
Left anterior descending coronary artery	194 (49%)
Left circumflex coronary artery	95 (24%)
Saphenous vein graft	6 (2%)
American College of Cardiology/American Heart Association	
Type A	9 (2%)
Type B1	119 (30%)
Type B2	175 (45%)
Type C	89 (23%)
Total coronary occlusion (TIMI-0)	58 (15%)
Bifurcation lesion	28 (9%)
Stent implantation procedure	95 (32%)
Procedural time (minutes)*	82 (38.8)
Fluoroscopy time (minutes)	27.9 (19.0)
Time to haemostasis (minutes)	9.6 (3.2)

Values are mean (SD) or number (%) of patients.

*Defined as time from start of arterial puncture to sheath removal.

Table 3 Puncture site complications (n = 300)

Bleeding at ambulation	5 (1.7%)*
48 hour follow up	
Late bleeding (< 48 hours)	None
Haematoma > 5 × 5 cm	9 (3%)*
Arteriovenous fistula	None
False aneurysm	None

Values are number (%) of patients.

*In three patients after balloon angioplasty, in two after stent implantation.

†In six patients after balloon angioplasty, in three after stent implantation; including one patient after bleeding at ambulation.

The attending interventional cardiologist assessed whether additional heparin was necessary during the procedure or whether heparinisation should be prolonged. Patients requiring prolonged heparinisation after angioplasty were excluded from early ambulation.

Arterial sheaths were removed immediately after completion of the procedure. Haemostasis was achieved by manual compression of the puncture site. Compression time to haemostasis and immediate postcompression puncture site status were documented. Haemostasis was maintained with an inguinal compression bandage. Early ambulation was attempted after two hours of bed rest in a supine position following removal of the compression bandage. The inguinal area was inspected for recurrence

of bleeding or the presence of a haematoma. Patients were monitored for an additional two hours and inguinal inspection was repeated. Delayed complications and late haematoma or bleeding after discharge were documented by a 48 hour follow up phone call and, if present, verified by a physician.

The primary study end point was bleeding at or during ambulation, defined as bleeding requiring further compression and additional bed rest. Secondary end points were puncture site complications defined as the presence of a major groin haematoma (palpable mass > 5 × 5 cm) and vascular complications such as pseudoaneurysm formation or arteriovenous fistula (confirmed by ultrasonography).

Results

During the study period, 621 patients underwent percutaneous transluminal coronary angioplasty (PTCA). Most non-eligible patients underwent emergency surgical procedures or primary angioplasty for acute myocardial infarction, or were treated with heparin intravenously for unstable angina (Braunwald III) (table 1).⁵ Prolonged postprocedural heparinisation was necessary in 33 patients (5.3%) because of major coronary dissection, side branch occlusion, suboptimal result, angiographic appearance of thrombus, or an unsatisfactory result after "bail out" stenting. Nineteen patients were not included for logistical reasons: these patients underwent angioplasty late in the afternoon and it was not possible to perform subsequent ambulation according to the protocol requirements by experienced cardiac catheterisation laboratory nursing staff.

There were no deaths among eligible patients (n = 359); emergency coronary bypass surgery was performed in three patients (0.8%), including one who had early coronary occlusion (four hours) after stent implantation during prolonged heparinisation. Therefore, this patient had already been excluded from early ambulation. The occluded coronary artery was successfully recanalised by repeat PTCA and coronary bypass surgery was subsequently performed. Early coronary occlusion occurred in two patients (0.6%) within two hours after the sheath had been removed, although neither patient was ambulant. These two patients underwent emergency repeat PTCA and subsequent heparinisation. One patient (0.3%) experienced a subacute stent thrombosis after 48 hour postprocedural heparin treatment for a suboptimal result after bail out stent implantation. Myocardial infarction defined as an increase in the activity of creatine kinase MB fraction of more than twice the upper limit was documented in 11 patients (3.1%).

A total of 300 patients were included in the two hour ambulation protocol. Table 2 lists the patients' characteristics. Twelve patients were treated with additional heparin 2500 IU at the discretion of the operator. Patients who had balloon angioplasty were treated with aspirin 100 mg daily, while those who had stent implantation (32%) were treated with ticlopidine 250 mg and aspirin 100 mg daily.

Table 3 gives the incidence of puncture site complications. Five patients (1.7%, 95% one sided upper confidence limit 3.5%) suffered bleeding requiring compression and additional bed rest. Bleeding occurred at ambulation in four patients and after walking for 15 minutes in one. Uncomplicated ambulation was achieved after an additional two hours bed rest in three patients and after overnight bed rest in two. One of these patients had a haematoma $> 5 \times 5$ cm at follow up. Haematomas $> 5 \times 5$ cm were seen in eight additional patients during 48 hour follow up. All complications were treated conservatively without further sequelae. There were no late bleeding or vascular complications such as a false aneurysm or arteriovenous fistula. All but 17 patients were at home at follow up 48 hours after the procedure. Prolonged hospitalisation was related to cardiac rehabilitation.

Discussion

The results of this study show that early ambulation (two hours) after elective coronary angioplasty with 6 F guiding catheters and low dose heparin is safe, with a low incidence of puncture site complications. This study is the first report of such an approach in a selected group of consecutive patients.

The reported incidence of puncture site complications after angioplasty varies from 1.5% to 18%, depending on the definitions and diagnostic protocol applied. Peripheral vascular complications are associated with sheath size, the level of anticoagulation, and sheath dwell time.⁶⁻⁸ We have previously reported that an excess of puncture site complications was not observed (2.3% *v* 2.2%) after four hour ambulation compared with bed rest for at least 12 hours after coronary angioplasty with 6 F catheters and low dose heparin. Repeat bleeding occurred in 1% of patients after four hour ambulation.² In the present study, bleeding after ambulation occurred in five patients (1.7%) and haematomas developed in nine (3.0%). There was no late bleeding. Transfusion and surgical vascular repair were not required. Repeat bleeding was managed by compression and additional bed rest without further sequelae. These results are in accord with those of our previous study² and with those of Baum and Gantt⁴ who reported that the incidence of repeat bleeding after diagnostic coronary angiography was 3% after two hours of bed rest and 2% after four hours of bed rest.⁴

The reported duration of bed rest to maintain femoral artery access site haemostasis after diagnostic and interventional coronary procedures varies between six and 24 hours. Reduction of this time period may add to the patient's comfort, although it is primarily pursued for economic and logistic reasons in many centres confronted with increasing numbers of patients and restricted hospital facilities. Strategies to decrease immobilisation time after cardiac catheterisation include brachial and radial access,⁹⁻¹¹ the use of femoral closure devices,¹² and smaller sized catheters.²⁻⁴

We have used 6 F guiding catheters as standard angioplasty equipment for many years. Consequently, there were no angiographic exclusion criteria in the present study, except for planned directional and rotational atherectomy or the use of specific stents. 6 F guiding catheters are appropriate in complex coronary angioplasty, such as bifurcation lesions and chronic total occlusion, and do not preclude stent implantation.¹³⁻¹⁵

The reported sheath dwell times after angioplasty vary from four to 10 hours in uncomplicated patients and depend on the institutional heparinisation protocol.⁶⁻⁸ Low dose heparin in the present study enabled immediate removal of the sheath with an average compression time of 9.5 minutes, thereby avoiding additional sheath dwell time. In an earlier study in which the results of 1375 patients were examined prospectively, routine use of heparin 5000 IU in elective coronary angioplasty was found to be safe without an increased risk of ischaemic complications (mean (SD) activated clotting times 15, 30, and 60 minutes after bolus injection were 259 (60), 240 (41), and 212 (60) seconds, respectively).¹⁶ Comparable results on the safety of low dose heparin during angioplasty were reported in a randomised study in a relatively small cohort of patients.¹⁷ The incidence of ischaemic complications in eligible patients in the present study is similar to our previously reported results and those reported by others.¹⁶⁻¹⁹ Consequently, a low dose heparin protocol may potentially add to the reduction in hospital admission time.

A transradial approach has been advocated for outpatient coronary angioplasty and stenting.^{12, 18} In a recent randomised study major puncture site complications, defined as bleeding necessitating transfusion or vascular repair, after angioplasty using the radial approach were absent.¹⁹ In contrast, the incidence using the femoral approach was 2%.¹⁹ Transfusion and vascular repair were not necessary in our study, but five patients (1.7%) required additional bed rest after bleeding. Crossover from intentionally radial to femoral angioplasty has been reported as 6% and exclusion of the radial approach due to vascular status as 18%.¹⁹ These limitations are negligible with 6 F guiding catheters by the femoral approach. Late bleeding requiring urgent medical assistance did not occur in our patients, indicating that ambulation after two hours is safe. Therefore, the present protocol potentially constitutes an alternative for outpatient balloon angioplasty or stent implantation by the radial approach.

LIMITATIONS

Our study group can be considered as a selected population. Patients given oral anticoagulants or heparin before or after the procedure probably had a higher risk for puncture site complications but they were not included. Nevertheless, the study group does represent an elective angioplasty population potentially eligible for outpatient PTCA.

Potential late puncture site sequelae may not have been identified because of the brief follow up period, although none was reported. The incidence of such complications ranges from 0.5% to 1.0% and the diagnosis is usually delayed for several days to weeks.²⁰

We recently reported on the safety of four hour ambulation after coronary angioplasty and stenting compared with bed rest for at least 12 hours.² The present study was designed primarily to evaluate the feasibility and safety of a further reduction in immobilisation time after angioplasty. There is a similar outcome after two hour ambulation in a comparable patient population undergoing elective PTCA. This questions the appropriateness of a randomised trial for which a large number of patients are required to detect statistical differences that are clinically relevant. This two hour ambulation protocol has been incorporated into a trial evaluating outpatient angioplasty and stent implantation at our centre.

CLINICAL IMPLICATIONS

Our findings suggest that two hour immobilisation after coronary angioplasty and stenting, using 6 F guiding catheters by the femoral route and low dose heparin, is adequate for haemostasis in most patients, with a low incidence of puncture site complications. Repeat bleeding at ambulation after two hours of bed rest is rare and can generally be managed by compression and an additional two hours of bed rest without further sequelae. The applied protocol may facilitate a short hospital stay and serve as an alternative for outpatient balloon angioplasty or stent implantation by the radial approach.

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